Bosch

Symbol of Quality Pharmaceuticals

Internship Report

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Dedicated To

My Beloved Parent,

Respected Teachers, Supervisor and Chairperson of department of industry

&

All Those Who Devoted Their Yesterday for Our Bright Today.

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

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Introduction

Bosch Pharmaceuticals was established in 1994 and it stands amongst the sixth top most pharmaceutical companies in Pakistan. Bosch has the honor to be the first pharmaceutical plant in Pakistan to have seven separate sterile manufacturing facilities, along with two separate manufacturing plant for oral and parenteral penicillin formulations and separate manufacturing areas for Cephalosporins, quinolones, ophthalmics and aminoglycosides Penicillin.

Bosch is also has the honor to be the first Lyophilized manufacturing unit in Pakistan. Bosch having its partners in quality with world renowned names as Sandoz – Austria, Asahi Kasei-Japan, ACS Dobfar- Italy, Klockner Pentaplast- Germany, VAW-Germany, Saint Gobain- France, Color Con UK , Helvoet Pharma Belgium and Capsulit Italy is proud to be the pioneer and the largest producer of Cephlosporin specialities and amongst the largest producers of penicillins, aminoglycosides and quinolone specialities in Pakistan.

At initial stage it had only 95 employees in 1995 but Currently it has more than 3000 employees. To maintain its GMP and meet the F.D. A. approval requirements through expansion of the current plant which had increased from 50,000 sq ft. in 1994 to 150,000 sq. ft in 2004. To meet the growth requirements upto 2020 , new plants are in plan, one for the basic raw material to be setup at Port Qasim and other to manufacture finished pharmaceutical products at Korangi Industrial Area.

Bosch's vision is to provide its finished goods at an economical price for all classes and grades of people and the same vision is shared by its team of highly qualified, hardworking and dedicated professionals with vast experience in research, production and marketing of quality health care products.

Bosch pharmaceuticals is Pakistan's first Halaal certified firm which follows the true USP standards in every area or department of Industries,

It's well known products are listed below:

- Cebosh
- Calamox
- Qpro
- Cefalor
- Zecef
- Cefrinex
- Beasy
- Dromax and many others…

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Chapter #1
"Ware House"
(First and Last step of Raw, finish and goods)

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Ware house is the first home of raw material and last house for finish good, every raw material comes here first and after manufacturing of finish and goods product stored here in batches until approval from QC, QA and production department. One of the excellent fact about this department is they conduct documentation both digitally and manually through workers so if they system is corrupted they can check manually about the client data and manufacturer's details.

This department works on some rules defines in following steps:

1.1 Receiving:

For receiving there is always a Delivery Challan which is usually called as DC. This provided by manufacturer or any other company working with industry. A worker receives this DC. Then a purchase order no is check in system then the a "Received" stamp is putted on it and then Raw material is allowed to enter in in ware house. Then a worker prepares GRN systematically for this and this GRN is provided to production department and other testing areas such as QC, QA and production as validation that every department is aware of their testing material.

DC should have these things which considers important:

a. Security Stamp
b. Ware House Stamp
c. Control number
d. GRN number
e. Date
f. Gate entry number
g. PO number
h. Suppliers name
i. Description
j. DC number
k. Total Quantity

If these things are mentioned in DC then it is accepted.

1.2 GRN (Good Received Notes):

Good received notes are prepared digitally through system and a copy of it is attached with DC later. The goods received note is an internal document produced after inspecting delivery for proof of order receipt. It's used by stores, procurement, and finance to raise any issues, update your stock records, and to be matched against the original purchase

order and supplier invoice, to allow payment to be made. Manually processing paperwork such as goods receipt and delivery notes can take a large amount of staff time in data entry and distribution to various departments. Paper copies of notes can be mislaid, supplier payments delayed and stock control systems out of date. GRN doesn't only provides all data mentioned in DC but also it provides pack size and no of packs containing loose packages which means packages in remaining.

GRN is first sent to managers first.
This GRN along DC is sent to QC lab with tags or tickets, QC lab mentioned its analytical number or QC number on it after testing.

1.3 Certificate of Analysis:

This is also called CA documents. A Certificate of Analysis is a document issued by Quality Assurance that confirms that a regulated product meets its product specification. They commonly contain the actual results obtained from testing performed as part of quality control of an individual batch of a product. Here batch number, manufacturer number, contractor number, letter of credit and invoice number is added in system. But before CA a packing list is obtained from Vendor. It enables your Vendors to create detailed Packing Lists which provide standardized documentation, communicate actual shipment details to the Logistics Provider and provide you with visibility of all activity and exception.
Selection criteria enable the Vendor to easily select the appropriate Packing List type. Available criteria include shipment mode, destination country and FCL/LCL shipment configuration.
Fully integrated with the underlying database which minimizes the required data entry and ensures data accuracy and consistency.
The Vendor is automatically presented with the appropriate Vendor Bookings for potential inclusion on the Packing List. One or more Vendor Bookings can be included on a given Packing List. Tolerance parameters enable you to impose business rules around the under/over shipping of product quantity by the Vendor. The Vendor can also directly communicate the reason for under/over shipping.
Comprehensive targeted system alerts ensure processes are followed within the prescribed time parameters. All relevant parties are notified of all Packing List activity. Exceptions are communicated directly to the relevant parties for resolution/visibility.
Analysis and reporting tools provide all parties with visibility, communication and resolution capabilities. Dashboard facilities are also available for Vendor performance analyses.

1.4 Role of MNCR in packaging:

MNCR stands for material non-conformance Report, this report is often produced when packaging material needs rework and against MNCR a gate pass can be prepared with material in and out stamps on same paper/report. I have mentioned before in QC packaging lab that we have two cases for checking of material one is major while other is critical. In Critical case we can destroy the packaging material i.e. in case of generic name mistakes or in any printing mistakes in few packets but not all but in major case i.e. if more than 5% packaging material is destroyed or when art work mistake is found in all then material is sent to rejected area where it is stored for almost 15 days if the manufacturer or suppliers can raise their objection but after 15 days they are destroyed by ware house itself by order of director.

1.4.1 PMIR (Packing material issuance requisition):

The main purpose of PMIR is to provide a documented procedure for dispensing of packing material and to provide guidelines on how to issue the required packing material to the production. Following things considered to be important for ware house:

1.4.1.1 Receive the packing material issue requisition and record the serial number, material code and date of receipt. Check for the entries in all the column, Batch Size, Batch No. and signatures for requisite by and authorizes by. If any of these columns is missing, return the requisition to production.

1.4.1.2 Check the materials in “Under Test” status. If the material requisitioned is present in “Under Test” status, inform the Manager – Production and Assistant Manager – QC regarding the same. Hold the issue of the other materials till the material is approved by QC.

1.4.1.3 On received of. packing material issue requisition officer stores shall inform to Q.A. personnel for dispensing activities. Dispensing activities shall be carried out in presence of Q.A. personnel only.

1.4.1.4 Check the packing material requisition to confirm the Name of packing Material, Item, Code of packing material, and Quantity to be dispensed.

1.4.1.5 Open the pack of packing material requisition carefully and dispense one by one packing material in sequence as mentioned in of packing material requisition will be made two copy. one copy will be kept in store department and duplicate copy attach with B.P.R.

1.5 MIR (Material issuance Report):

This is obtained by production department about after 2 years for retest of material and the other thing is color and flavors retesting after 6 months.

In all these we maintain the value of Bin Card from physical and digital system.

1.6 Bin card:

Bin Card also is known as Stock Card or Bin Tag, is the summary of inventory movement and the remaining balance. It is the movement that includes beginning balance, stock receipt, stock issue, and the ending quantity. It is very important for the warehouse to know how much stock remains just by looking at this report.

The stock keepers must write into the Bin Card every time the item move in or out of the warehouse, and it sticks to each material bin for quick access. It contains only the quantity of in and out movement and the balance at a specific point, which reconciles with the physical balance otherwise it is useless.

The internal auditors may perform surprise count on inventory by comparing the actual quantity with a bin card. If there are any differences, it will lead to further investigation to understand the cause, whether it is due to error or fraud.

Bin card has following format:

Company Name
Bin Card

Material Nam:	Maximum Stock level
Material Code:	Minimum Stock Level
Location	Reorder Level

Date	Receipt		Issue		Balance	Name
	GRN #	Qty	Request #	Qty		

1.7 Advantages of Bin card:

1.7.1 Be aware of inventory level:

It will help the stock keeper to keep track of each inventory or material level and propose any purchase if necessary. There is the minimum level of each material on the card bin which will help the staff to alert to their supervision.

1.7.2 Internal Control in warehouse:

It will help the staff to identify the correct material quicker, it will be beneficial when all the items are very similar. The risk of issue wrong items also reduces.

1.7.3 Reduce the chance of miss record:

Every there is a new receipt or issue, the staff will require to update immediately in this report where it keeps next to the item. It will help to reduce the risk of error or forget.

1.7.4 Assist during the inventory count:

During annual count, it will help the auditor and responsible person to identify the material from list to floor and vice versa. Moreover, it also helps the auditor to very inventory quantity during the count as well. [1]

1.8 Disadvantage of Bin Card:

1.8.1 Require more time:

The warehouse officers require to spend time on updating the bin card. Moreover, the staffs are able to check the stock level by checking the report rather than this card.

1.8.2 Duplicate work:

During the inventory receipt and issue, we require to update both in bin card and report (Excel or other control systems). And this report will be used during the counting which is more reliable.

1.8.3 Require warehouse space:

The bin card will take warehouse space which can use for storing other items. The more detail we require; the more space it takes. [2]

Difference between Bin Card and Store ledger

Bin Card	Store Ledger
Record the movement balance include receipt, issue and the remaining balance at any specific time	Store ledger keeps track the movement of inventory includes its value
It is kept by the Stock keeper in the warehouse next to the actual inventory.	This report keeps by the cost accountant.
The stock keeper requires to update the report immediately after the movement.	The responsible person requires to update this report on a monthly basis.
It is only for the control in the warehouse, we cannot use it as the reference for preparing financial reports such as Balance Sheet and Income Statement.	It is the basis for management account for preparing the costing and it will impact the company's financial statement.

1.9 Other Roles of ware house:

Ware House also plays role for:

1.8.2 Market Return Status Report:

It defines the return causes of material from market, these causes might be expiry or breakage but it is always mentioned on this report. The return material is checked physically and always claim department handles the return report.
This MRSR is sent to QA and the material is stored for 6 months here then after quarantine it is sent from production for release.

1.8.3 Dispensing:

Material from storage is sent to dispensing lab where dispensing takes place from material. In this lab there will always a QA officer along lab workers which signs on MIR.

Dispensing includes all of the steps necessary to translate a medication order (prescription) into an individualized medication supply that is both safe and appropriate. Below is a very brief description of what a typical visit to your local pharmacy may look like:

1.8.3.1 The pharmacist will ask if you have visited this pharmacy before. If the answer is 'No', you will be asked to fill out a consent form. This allows the pharmacist to fill your prescription. If the answer is 'Yes', they will ask for an identifier (birthday or home address). This allows for an easy search within the pharmacy's computer system for your prescription records. You will then be asked if you have had this medication before, and what it is being used to treat. This information will allow the pharmacist to personalize your medication counsel when the medication is picked up.

1.8.3.2 A member of the pharmacy team will enter the prescription into your profile, checking the: doctor's information, medication/dose, indications from the prescriber, and quantity of the script. The pharmacy system will check for possible interactions or other potential issues through the Nova Scotia Drug Information System.

1.8.3.3 The medication bottle will be scanned and packaged with the Lot and Expiry. The medication is then counted for the designated quantity, labelled and handed off to the pharmacist to be checked.

1.8.3.4 The pharmacist will perform a clinical check of your medication, which includes an assessment for drug interactions, allergies, as well as reviewing previous medications for the same use and ensuring it is the most appropriate drug, dose and duration for your condition. A pharmacist or pharmacy technician will perform a technical check on the accuracy of the information entered into the pharmacy software system, the label and the contents of the vial or package. They will also print off counselling documents to provide the patient with more information on the medication.

1.8.3.5 The patient will pick up their medication and the pharmacist will provide counseling to the patient on the medication. If it is a refill, this may include an assessment regarding how well the medication is working for you, and whether you are experiencing any side effects.

1.8.3.6 A detailed description of the dispensing process can be viewed below:

- ✓ Input & Initial Check (Do we have all of the information we need?)
- ✓ Therapeutic Check (Is the prescription right for you?)
- ✓ Preparation
- ✓ Technical Check (Is the prescription filled accurately?)

Input & Initial Check (Do we have all of the information we need?)

- ✓ Prescriber details
- ✓ Patient details (age, weight, medical conditions, allergies, etc.)
- ✓ Medical insurance coverage details
- ✓ Confirm medication/items to be dispensed
- ✓ Confirm indication
- ✓ Preference details (safety caps, etc.)
- ✓ Prescription meets legal requirements (date, drug, strength, instructions, signature, etc.)

Therapeutic Check (Is the prescription right for you?)

- ✓ Ensure dosage is both safe and appropriate based on age, weight, etc.

- ✓ Ensure the medication is compatible with current medical conditions and allergies
- ✓ Ensure the medication is compatible with other medications being taken
- ✓ Ensure the prescription is appropriate for the condition being treated

Preparation

- ✓ Select appropriate drug, brand, strength, form, quantity
- ✓ Repackage when necessary
- ✓ Prepare when necessary (reconstitute or compound from raw ingredients)
- ✓ Review expiry, instructions
- ✓ Apply cautionary labels
- ✓ Complete documentation and records
- ✓ Organize counselling aids (e.g. written materials)

Technical Check (Is the prescription filled accurately?)

- ✓ Ensure correct drug, brand, strength, form, quantity
- ✓ Ensure correct formula/methodology has been used for compounded products
- ✓ Confirm successful medical insurance processing

Before dispensing and after dispensing we will weigh the material, in dispensing lab I saw balance of 100 kg and 10 kg but there was an another balance for smaller weight in case if 10 kg balance or 100 kg balance shows error for smaller weights.

In dispensing place, the laminar pressure is of 200 ± 5 Pascal and temperature is below 25°C, the same temperature is for storage room for both raw material and product.

1.9 QR code for every pass/tag:

A QR code simply consists of a black square and dots (yeah). That, essentially, is what a QR code looks like. The pattern on QR codes can be alphanumeric, numeric, binary or Kanji (a form of Japanese character originated from China). QR codes stand for Quick-response codes, which are two-dimensional barcodes containing data that point to a website or application. The idea behind a QR code is to create an image that any mobile device can read (or scan) with a certain QR code scan application and transfer it to something meaningful. [3]

1.11 Storage Conditions in Ware house:

What I have observed in my four days visit of ware house is the storage condition in ware house is at 20°C temperature and 65% humidity, literally at every hour a monitoring person notes all of these parameters in a log book, raw materials and products are placed in different racks present in ware house.

Bosch

Chapter # 2
Production Areas

Production Areas in Bosch Pharmaceuticals are as follows:

1. Oral Solid I
2. Oral Solid II
3. Penicillin Oral solid
4. Cephalosporin Non Sterile area
5. Carbapenem sterile area
6. Cephalosporin sterile area
7. Lyophilization Sterile area
8. Sterile Liquid I
9. Sterile Liquid II

2.1 Oral Solid I, Oral Solid II, Penicillin Oral solid and Cephalosporin Non Sterile area

These departments are actually production department where actually manufacturing/compression of tablets, sealing of capsules, suspension and sachet fillings process takes place.

Here in the first step the dispensed material is arrived from ware house.

2.1.2 Compression for Tablets:

Here mostly dry method is used if there is wet method using then there would be use of ribbon mixer.

Step: 1

The dispensed material is taken to production house where it is blended first and we make sure there is no lump formulation and also we can use some kind of binders here which increase the adhesion between active and non-active particles of drugs but also increases cohesion between the die while compression so the tablet made in desired shape, if there is any cracking then binders are added again while blending or granulation(slagging) is done. Before blending the material, we make sure that we have taken weight, in case of consumption production house can inform ware house the range of weight is 98 to 105 %. Before Blending a sample is taken for QC lab for testing.

While blending we used some kind of sample rod which has three holes and it collects material of blender from three position of blender and these three samples are sent to QC lab too for determining if there is any variation in composition or chemical property.

Instrument we are using for blending is called cone blender which is rotated at specific RPM. The conical shape at both ends enables uniform mixing and easy discharge. The cone is statically balanced which protects the gear box and motor from any excessive load. Powder is loaded into the cone through a wide opening and discharged through a butterfly or a Slide valve. During is process it is necessary that no one is in room inside.

There are three cone blenders in Penicillin Production one is off 200 kg, 400 kg and 600 kg,

- 200 kg is used for tablets and capsules.
- 400 kg is used for tablets, capsules and suspension.
- 600 kg is used for suspension only.

Step: 2

This is called compression step where tablets are formed finally.

This is called tablet compression or punch machine which has upper and lower punches which defines hardness of tablets and also it has dies which defines geometry of tablets. After compression these tablets are also sent to QC department for testing.

Step: 3

In this step compressed tablets are dried in fixed bed dryer and then they are subjected to coating process and it is performed in high coater or pan coated both required preparation of solution first then this solution is sprayed from gun in pan or in high coated. System inside coated always rotated to keep coating uniform. The color solution is always verified from FDA.

High coater system.

Pan coating system.

Coating is done at different temperature and RPM from which the pan moves.

This is arguably one of the most common types of coating pans that you'll always come across in the market. It is at times known as conventional tablet coating pan and consists of a circular metallic pan with a diameter of between 6-80 inches. You can always tilt this metallic pan on a bench top stand and also rotate it using an electric motor. When dealing with a standard coating pan, you'll need to load a batch of tablets into it and set it to rotate. It is this rotating motion that makes the tablets to tumble within the pan. The mounting of this coating pan is often at 40°, and it rotates on its horizontal axis by a powerful motor. During the coating process, the heated air inside the pan is supplied by inlet air supply, and it exhausts using ducts. The coating solution in a conventional tablet coating is applied to tablets either by lading or spraying.

Moreover, this type of coating machine uses the atomizing system to produce an equal distribution of coating solutions or suspension.

When using the standard coating pan, you can always achieve drying efficiency in several ways:

- **An immersion sword:**
  This is where the distribution of drying air takes place through a perforated metal sword immersed in the bed.

- **Baffled pan and diffuser:**
  This one enables the distribution of drying air evenly over the surface of the tablets.

- **Immersion tube system:**
  This involves immersing a tube in the bed where the tube produces heated air via the spray nozzle.

After coating tablets are sent to QC department for testing.

Step: 4

This is called blistering step.

But before blistering tablets are sieved by 30 to 60 mesh size to remove excess powder. Blister packaging is made using several types of rugged polymers, including:

- Polyethylene terephthalate (PET)
- Polyvinyl chloride (PVC)
- Polyvinylidene chloride (PVDC)
- Polychlorotrifluoroethylene (PCTFE)
- Cyclic olefin polymers (COP)

Blister packaging is manufactured from a plastic sheet that is thermoformed to create cups or blisters that hold a product in place. The packaging typically has a paperboard backing or a lidding seal of aluminum foil or plastic film. Blister packs provide a safe, secure way to ship medicines and small consumer items, offering additional protection when goods are transported inside custom cardboard boxes. Each type of material used to create blister packaging offers something different.

PVC is the most popular material used for creating blister packaging—mainly because it is inexpensive. These blister packs are made using 0.25mm or 0.3mm PVC sheets.

PVDC is often combined with PVC sheets to create blister packs with an extra layer of protection, for better sealing of items from oxygen and moisture.

PCTFE is a type of laminate blister packaging used to form a moisture barrier around the product. Compared to other polymers used to create blister packs, PCTFE has less water vapor permeability.

Blistered tablets are sent to QC department.

The Benefits of Blister Packaging:

- **Wide variety:**
  Blister packaging comes in a wide variety of shapes, sizes and strengths. The different variations mean you can choose the packaging solution that best protects your products based on how you intend to transport them.

- **Keeps items fresh:**
  For long-haul shipping, blister packaging can protect perishables from air and moisture exposure, minimizing deterioration. Foods and medications are protected from environmental factor-induced spoilage when packaged in blister packs. Blister packaging is usually water-resistant, and it protects against ultraviolet (UV) light and any impacts so your products remain fresh and undamaged throughout the duration of the journey.

- **Security:**
  Shipping medications raises concerns that the product could be tampered with. Blister packaging makes it difficult for a non-intended recipient to access the product, and it's easy to tell when blister packs have already been opened, making them safe vehicles for transporting medications.

- **Cost-effective:**
  Blister packaging can reduce shipping costs because it reduces the need for additional packaging. Plus, they can be customized in a variety of ways to fit any product, which makes items easier to store in cardboard boxes for bulk shipping.

- **Eco-friendly packaging:**
  Most blister packs are made for reuse and, in some cases, can be recycled, making them eco-friendly packaging solutions.

- **FDA approved:**
  Blister packs can be easily customized to meet FDA considerations for container labels for shipping medications. The SUPPORT Act allowed the FDA to require special packaging, such as blister packs, to ship opioids and other types of medication that pose a risk of abuse or overdose.

At the end these blistered tablets are packed in packages and sent to ware house for storage where these are stored at 20 to 25℃ to avoid degradation of product.

2.1.3 Sealing and filling of Capsules:

Step:1

In initiation first of all capsules shell (Hard or soft) are sent to QC packaging department which defines if the shell is able to withstand in critical situation and of desired shape with proper color and embossed logo.

The medicinal agent is sent to QC lab for further testing in form of powders before filling sealing. After QC verified both steps then sealing and filling is proceeded.

Step: 2

This is called Ambica filling machine which doesn't only fill the capsule shell automatically with medicinal agents but also sealed it then blistering is performed in same way as for tablets.

Step: 3

Brushing is done and blistering is Done in same way as for tablets.

Step: 4

Packaging is done in same way as for tablets.

In the end the sample from this batch is sent to QC lab.

Tablets and capsules produced in per run are in 300,000 in amounts.

2.1.4 Powder filling in glass or plastic bottles:

Step: 1

Bulk is send to QC Lab after dispensing or blending for testing.

Bottles and Vials are send to QC packaging labs for testing.

Step: 2

After that this powder to introduced to double hopper system.

To remember: For double Hopper system there is always BMR (Batch Manufacturing Report). This BMR has product name, BMI Code, Batch size and Batch no importantly.

This double hopper system fills powder in bottles then purging with Nitrogen gas is done to avoid presence of oxygen in remaining cavity of bottle then these bottles are capped. If there are used plastic bottles, then sealing is necessary from top but for glass sealing is done from around bottle. One labor always tests this sealing in the end then they are packed. These bottles are also send to QC lab for testing.

Step: 3

This is packaging step.

Amount of samples send to QC labs at a time:

S.no	Tablets	Capsules	Powder
1	Before dispensing (Raw material)	Shell	Bulk
2	After Dispensing	Medicinal Agent	Vial or bottle
3	Blended	Filled Capsules	Filled
4	From Sample Rod	Blistered	Packed
5	Slagging (if necessary)	Packed	-
6	Compressed (Core)	-	-
7	Coated	-	-
8	Blistered and Blistered material	-	-
9	Packed	-	-

It shows that there are many batches produces in the process.

Three batches for dispensing material, three for after dispensing, three for blended from sample rod and one from after blend, Three for slagging, Three for core, three coated, Three blistered and blistered material and finally a batch for packed. We do this because if any problem occurs during the process then we can stop manufacturing before proceeding further which means that with each and every step proceeded test is checked by QA, QC manager and then sent to Ware house.

QC lab prepares a report for all these tests and prints four tag for each bulk, filling, processing (include in-process) and finally packaging, those are attached, defining the material is approved or not. QC lab always keeps a copy of file and send this original file to QA and Ware house. Which means that one tags for each is always taken by QC as record of proceeded test.

Cephalosporin products of Bosch Pharmaceuticals:

- Cebosh (suspension, capsules, tablets)
- Cefalor (suspension, capsules)
- Cefrinex (Capsules, Suspension)
- Dromax (Capsules, Suspension, tables.)
- Prelox (Tablets, suspension)

Penicillin Products of Bosch Pharmaceuticals:

These are back bone of the industry.

- Calamox (Tablets, suspensions)
- Supramox (suspension, capsules)

OSD I & II Products of Bosch Pharmaceuticals:

- Gemixa (Tablets)
- iZilon (Tablets)
- Norocin (Tablets)
- Quinoflox (Tablet)
- Qumic (Tablets)
- Macalin (suspension, Tablets)
- Olinc (Capsules)
- Zezot (tablets)

2.2 Carbapenem, Cephalosporin and Lyophilization Sterile area

In this area carbapenem sterile products are made and stores or in simple way we can say that here sterilization of injectable are performed. In this department we have a washing area first where washing of vials, caps and different ampules are taken place. Usually we have 1 cc to 6 cc of ampules. Washing of vials and ampules are take place by a solvent name Teepol.

- **Teepol:**
  Teepol Heavy Duty Bio Laundry Detergent is specially formulated to give extra stain removal performance, even at low temperatures and is versatile enough to be suitable for hand and machine washing. Teepol Non Bio Laundry Detergent is equally effective for hand and machine use and is kinder for sensitive skins. This is superior cleaning without the enzymes.

After washing these vials and ampules and sterilized by mean of solvents Phenol, Puret, Tescosit-N and Vanoquat.

- **Phenol:**
  Phenol is the specific name for carbolic acid, which is the simplest member of the family of organic hydroxyl compounds known as phenols, or phenolics. Phenol is derived from benzene and propylene, which are used to produce cumene, which is then oxidized to become cumene hydroperoxide, before being split into phenol and its co-product, acetone.

- **Puret:**
  It is a floor Cleaning solution that is equipped to handle a greasy and muddy floors. It also has a disinfectant to kill microorganisms and bacteria around the house, giving you a clean and healthy environment.

- **Descosit-N:**
  Have same properties as Puret but different nature of reaction for cleaning.

- **Vanoquat:**
  Vanoquat disinfectant is a quaternary ammonium disinfectant and can be used on a variety of surfaces and is recommended for disinfecting game larders, processing rooms, kennels

along with any areas where food needs to be prepared. Effective against a wide range of pathogenic and spoilage organisms. Passes EN 1276 at recommended dilution rate & contact time. For use in all water conditions**.** DEFRA approved for Aquaculture**.** Suitable for single or two stage clean and disinfect programs.

But we don't use each disinfectant at a time but we can use one disinfectant for a week or few days because microorganisms will be able to heal and with stand for same use of disinfectant again and again. Disinfectant is introduced in vials and ampules washing machine.

In washing are they received 5 to 6 bags of vials in first half and each bag contains 65 vials. While stoppers are 2500 and seals are 10,000.

They have a sterilized area here where they have an autoclave of 160 boxes, contains 4 columns and 40 rows to sterilized the product at 180°C.

This area has usually 30°C of temperature with 30% humidity which gives excellent performance for resistance for microbial growth.

After this medicinal agent are filled in vials and ampoules and sent to QC lab for further testing and then goes to packaging.

To Keep remember is:

- Vial filling machine has filter of 0.5 micron and filling is done at 40 to 60°C
- Rubber stoppers are washed for 25 minutes in distilled water
- Vials are autoclave for two hours while stoppers are autoclaved for five hours.
- For rubber stoppers washing we used filters of 8 microns and 0.5 micron
- Each sterilizer has load of 167 vials
- After whole process wash the equipment with 70% IPA solution.

Prior to this process MIR and BMR is produced by ERP (Enterprise Resource Planning).

Lyophilization and Cephalosporin has same method but which differs it from Carbapenem department is their products.

Mostly ampules are filled with this equipment in sterilized area.

2.3 Sterile Liquid I and Sterile Liquid II Department

Here the first step starts from Dispensing area, the dispensed material is sent to here from warehouse Dispensing lab, first of all the dispensed material is weighted here and then it is introduced in chamber/batch then WFI is transferred into this batch through 2 micron filters and then mixing is take place. After that a sample is taken and pH is checked after this the batch is ready to fill in ampules, that's short description of here and now we focus on how ampules are filled and most importantly what equipment are using here.

There are two types of ampule filling machines are using in Sterile Liquid I (Rota and Safa) while in Sterile Liquid II equipment used is automatic that it doesn't only do brilliant washing by distilled and recycled water but also wash it with water for injection. It has a dryer equipped and a cooler too. Both of them has same principles.

2.3.1 Principle of Ampule filling machine:

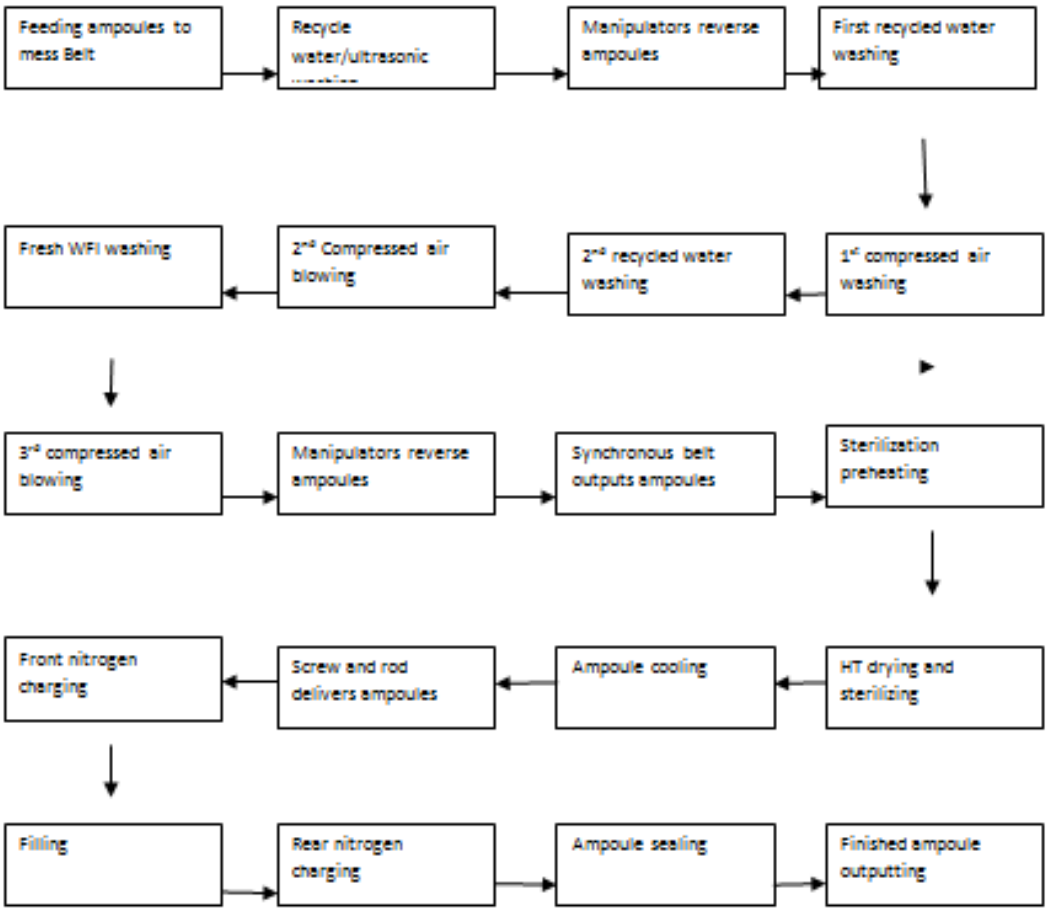
The infeed conveyor receives the ampoules from the sterilizing tunnel. Later the ampoules are loaded into the conveyor belt into a screw conveyor in the upright position. What happens again is that the screw conveyor then transports the ampoules to the segment wheel to be carried to a conveyor cradle. It is worth noting that the conveyor cradle carries 8, 6 or 4 ampoules in a group through various stations. Pre-gassing, before filling, filling, post-gassing after filling, pre-heating, heating which is done in vertical positions.

The machine performs the following operations:

Ampoule transportation by the infeed conveyor, in-feed scroll, and the ampoule transfer into the transportation rack. Normally 8 ampoules are advanced per machine stroke. Centering the neck of the ampoule during the gas flushing and liquid filling. Rotations of the ampoules in the pre-heating and heating stations. Removal of burned-off ampoule tips by the Clippers and ejection into a different container. Discharge of the filled ampoules into a tray.

Liquid filling- The Core:

The filling manifold is the first process. Eight AISI 316 L dosing syringes and another eight stainless steel discharge needles. A selection of electro-mechanical tube also knows as the rotary piston. Micro-fine dosing adjustment volume for the filling of the ampoules Also, an ampoule neck centering normally done during filling and the principle of no ampoule – no filling without machine stopping. The ampoule sealing in the pre-heating with the adjustable flames and flow-meter for oxygen and combustible gasses.
The sealing station is also having oxygen and other combustible gases. Ampoule rotation during pre-heating and the sealing cycles Clippers which then remove the ampoule tips into the waste bin. Safety valves and pressure reducers which is on the oxygen and the combustible gas circuit. The to a stainless hood whose main function is to channel fumes out during the heating process. Then the automatic ampoule discharge into the twin tray.



Let me point out that compressed air is necessary to use for absolute removal of water from ampules.

2.3.1.1 Parts of an Ampoule Filling and Sealing Machine

Ampoule filling machine is an assembly of many parts and components. Some of the main sections include:

2.3.1.1.1 Filling source:

This is where the liquid is fed. It acts as the reservoir tank for the whole filling process and can be refilled when the liquid is depleted

2.3.1.1.2 Conveyor belt:

This conveys the ampoule bottles from the filling station to the receiving station.

2.3.1.1.3 **Rotary pumps:** To ensure that the right pressure is within the ampoule bottle

2.3.1.1.4 **Stainless steel belt:**
This is the part where loading of the ampoules takes place and receives the sealed ampoules.

2.3.1.1.5 **Volume adjustable wheel:**
It is used to adjust the volume of the liquid that is fed into the ampoule bottles.

2.3.1.1.6 **Sensor of volume:**
Responds to the changes in the volume as adjusted by the adjustable volume wheel.

2.3.1.1.7 **Pedal switch:**
Adjustable for auto mode operation of the machine depending on the user preference.

2.3.1.1.8 **Plunger:**
Used to squeeze or push the liquid into the ampoule bottle.

2.3.1.1.9 **Needle bevel:**
To allow passage of the liquid into the ampoule bottle.

2.3.1.1.10 **Exhaust fume excavator:**
To channel out the fumes produced during the ampoule sealing process.
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2.3.1.2 Benefits of Ampoule Filling and Sealing Machine

- ✓ Easy integration with modern manufacturing technologies
- ✓ Increases production capacity (For instance, automatic eight head ampoule filling & sealing machine provides output up to 12000 ampoules per hour.)
- ✓ Ability to monitor how the ampoules are being produced
- ✓ Ensures accuracy of contents
- ✓ Easy to operate
- ✓ Ample cooling system

Some of the most common types of ampoules filling and sealing machines are:

- ✓ 8 head ampoule filling and sealing machine:
  - Same as 6 to 16.

- ✓ 4 head ampoule filling and sealing machine:
  - Has production output of around 90 to 100 ampoules per minute
  - Has got ampoule neck centering and the filling functions.
  - Can fill 1ml to 10ml ampoules
  - Has the capability of nitrogen flushing prior to and after filling.
  - Has got the capability of filling a single dose at a range of 0.5ml to 25ml.
  - Can fill either type B or type C open mouth ampoules.
  - The overall dimension of 1200 mm L * 1070 mm W * 965mm H

- ✓ 2 head ampoule filling and sealing machine:
  - Mono block equipment that is designed with filler and sealer on a single platform
  - One motor which synchronizes with all the drives of the unit
  - Has a provision for nitrogen injection prior and after the liquid filling
  - The capability of filling a single dose at a range of 0.5ml to 25ml
  - Can fill either type B or type C open mouth ampoules.
  - Has provision for the collection of ampoules in an upright position in the dead tray
  - Has where the waste tips of ampoules are collected
  - Power voltage is 230 Volts, Single Phase, 50 Hertz, 4 Wire System
  - Overall dimension is 915mm (L) x 760mm (W) x 965mm (H) approx.

- ✓ 6-16 head ampoule filling and sealing machine:
  - Drives have got a single motor unit.
  - Has the prior and after nitrogen flushing
  - Provision for collection of ampoule tips
  - Easy regulation of the oxygen as well as LPG and the nitrogen flow
  - No ampoule no filling feature to avoid wastage.
  - Has provision for attachment of PLC system
  - Production is around 90 to 150 ampoules per minute.
  - Overall dimension is 2380mm (L) X 1200mm (W) X 1000mm (H)
  - Power requirement is 1 H.P., 380 Volts, 3 Phase, 50 Hz (4 Wire Systems)

- ✓ For 16,
  - Provision for collection of ampoule tips
  - Ampoule capacity of 16,000 to 36,000 ampoules per hour
  - Works with ampoule size of 1ml to 10 ml ampoules
  - Works under the principle of no ampoule no filling function.
  - Provision for PLC system.
  - The power supply of 380 Volts and 50Hz [4]

Chapter # 3
"Quality Control Lab"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

3.1 Quality Control Department

In very first day I learned that the very first thing to enter in QC lab is you always have to wear show cover prior to going into any lab due to avoidance of outside contamination below the shoe sole while lab coat is necessary. If you are testing any sample, doesn't matter if its product or raw material or any other substance just don't look into sample handling and holding medium from top because that may cause fall of you4r hair strands sometimes in sample and to avoid that you should wear your hat to avoid this. Day starts with calibration of equipment which are:

- ✓ Potentiometer
- ✓ Conductometer

Calibration of such equipment are necessary first because prior to any other substance or samples water samples are tested first which are provided from production department during process or provided after sterilization.

3.1.1 Calibration of Potentiometer:

For this we have to maintain room temperature at 25 °C and then calibration is done by standard buffer at 12 pH, 9 pH, 7 pH and 4 pH. These buffers are called certifies standard buffers.

- ✓ Preparation of Buffer of pH 4:
  This is also called potassium phthalate buffer of 0.05 M prepared by dissolving 10.12 gm of $KHC_8H_4O_4$ in 1000 ml water after drying at 110°C for one hour.

- ✓ Preparation of Buffer of pH 7:
  This is 0.05 equimolol phosphate buffer and is prepared by dissolving 3.53 gm of Na_2HPO_4 and 3.4 gm KH_2PO_4 in 1000 ml water after drying at 120°C for 2 hours.

- ✓ Preparation of Buffer of pH 9:
  This is also called sodium Tetra borate buffer. It is prepared by dissolving $Na_2B_4O_7$. 10 H_2O in 1000 ml water but make sure you are protecting the solution from CO_2 absorption.

- ✓ Preparation of Buffer of pH 12:
  This is prepared by dissolving saturated solution of calcium hydro oxide by dissolving in 1000 ml water and used after continuous shaking and descent

at 25°C but same here, we have to protect this solution from CO2 absorption. [5]

Now pH of these buffers are checked from pH meter, pH of buffers 12 and 9 should be within + 0.07 variation while the pH of buffer 7 and 4 should be within + 0.02. These buffers can be used for three months and calibration is required for every day. Calibration is always done in presence of department manager or any other Technical assistant.

3.1.2 Calibration of Conductometer:

The first step is to check that the conductometer is in correct measurement mode. Wash the electrode with distilled or deionized water and then dry it. Perform the calibration with buffer of 1413 µS and record the detail. Rinse the electrode with buffer solution and then dipped it inside the buffer solution that the probe must be immersed completely. Press CAL/MEAS to enter in calibration mode and then press ENTER/HOLD to confirm calibration to the current buffer. Rinse the electrode with deionized water and then dry it.

3.1.3 Tests for Water:

After this sterilized and non-sterilized water samples are arrived. I saw these water samples in lab.

- ✓ WFI
- ✓ OSD
- ✓ LOOP WATER
- ✓ STERLIZED WATER FOR INJECTION
- ✓ BACTEROSTATIC WATER

Following tests are performed for all these water samples.

Water samples are cooled first to room temperature.

✓ **Impurities test:**

- ✓ Chloride test:
  Done by adding $AgNO_3$ and HNO_3 in water sample. After few mins turbidity is observe if appears.

- ✓ Sulfate test:

It is done by adding $BaCl_2$ in water sample After few mins turbidity is observe if appears.

- ✓ Ammonia test:
  For this we add Nessler's reagent ($K_2[HgI_4]$) in water sample. After few mins turbidity is observe if appears.

- ✓ Calcium test:
  For this we add ammonium oxalate in water sample. After few mins turbidity is observe if appears.

- ✓ Carbon test:
  For this we add Calcium hydroxide in water sample. After few mins turbidity is observe if appears.

- ✓ Oxidizing agent test:
  For this we add potassium permanganate in water sample and after we mins we observe if the solution turns white or not.

These all tests are performed in six test tubes and 5 ml of sample is taken in each tube from provided sample vial.

- ✓ **Potentiometric test:**
  After this pH of water sample is checked, the computed value is compared with the value of water sample in Log book present in department.

  - ✓ WFI (5.0 to 7.0).
  - ✓ OSD (mentioned in log book)
  - ✓ LOOP WATER (7.0).
  - ✓ STERLIZED WATER FOR INJECTION (5.0 to 7.0).
  - ✓ BACTEROSTATIC WATER (5.0 to 7.0).

- ✓ **Conductivity test:**
  After this conductivity test is performed. Conductivity for every water sample should be less then or approx. 1.3 µS/m.

✓ **Particles count test:**

This test is performed in instrument named LS-20

The following configuration can be seen above.

Environmental Conditions:

- Operating: 50°F to 104°F (10°C to 40°C) / 20% to 95% non-condensing

Storage:

- 14°F to 122°F (-10°C to 50°C) / up to 98% non-condensing

Minimum System Requirement:

- Windows 7TM or Windows 10TM compatible computer.

Included:

- LS20 instrument
- USB to RJ45 cable
- power supply
- 500 ml beaker with edge guard
- 10 feet of tubing
- flow cell cleaning solution
- nut and ferrule kit
- 2x magnetic stir bars
- Operators Manual
- LS Software on USB key

Optional:

- Printed operating manual
- IQ/OQ Validation Documents
- 10ml syringe
- 5-piece beaker set (50, 100, 250, 600, 1000 ml beakers)
- certificate of origin

Requirement of results obtained from water samples:

We always check the particles of 10-micron size shouldn't be greater than 6000 and particles of 25-micron size shouldn't be greater than 600.

In the end we make sure that final report is printed out for all samples.

Sample Required:

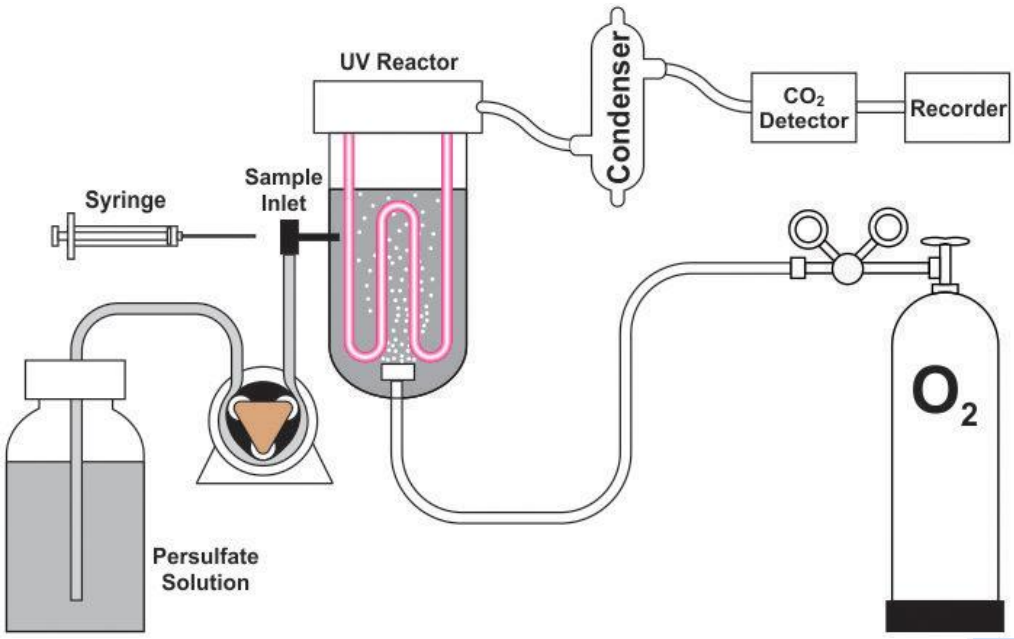
25 ml in vial and 10 ml for suck = 35 ml

- ✓ **Total organic compound test:**
  Sample has always two types of carbons:
  - ✓ Organic
  - ✓ Inorganic

  The apparatus we are using here can eliminate inorganic carbon but also removed organic Carbon from the sample or in simplest way we can say that through this instrument we calculate the number of organic and inorganic carbon in sample.

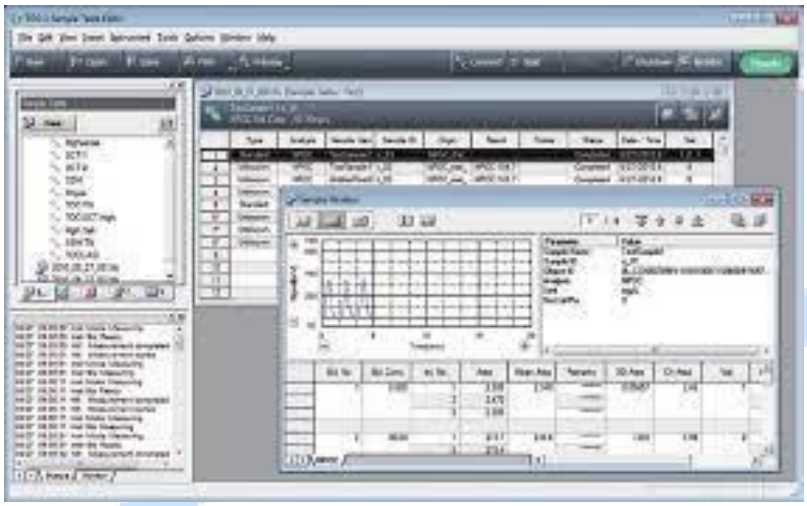
3.1.3..1 Principle:

This instrument has a generator which contributes to separate oxygen from air then this air is transferred to combustion which it encounters to organic carbon which causes combustion and this amount of combustion represented the total number of organic carbon presented in sample. Combustion always take place in presence of platinum catalyst, moreover this instrument includes some solvents which are water, per chloric acid and HCl. This combustion takes place at 680°C which means that coolant is also employed here. Oxygen gas also used to serve as carrier gas to remove inorganic carbon. Approx. 15 to 30 minutes are taken to complete all process but period vary for different samples and it can be seen from log book. The solvent in this used to sparging of inorganic carbon which has pH less than 3 and both of these are detected by NDIR detector.



Picture of instrument:

Result displayed:



3.1.4 Endotoxin, Pyrogens and Bacterial tests:

These tests are performed by microbiological lab which is also a part of QC lab. For this method we employed is called LAL method (Limulus amebocyte lysate). This LAL reagent should be certified by FDA. LAL is a reagent made from the blood of the horseshoe crab. In the presence of bacterial endotoxins, the lysate reacts to form a clot or cause a color change depending on the technique. After introduction of reagent into material in Petri dish we performed incubation to see micro bacterial growth. Micro bacteria always create colonies in medium which can be seen. There are two types of bacteria which might present in sample. The gram-positive bacteria retain the crystal violet color and stains purple whereas the gram-negative bacteria lose crystal violet and stain red. Thus, the two types of bacteria are distinguished by gram staining. Gram-negative bacteria are more resistant against antibodies because their cell wall is impenetrable. Same tests are performed for anti-biotic. If there is no growth of bacteria, then the sample is suspected to filtration and the bacteria is removed but this sample is then sent for sterilization in double autoclave which employees wet steam method for sterilization. One of the most important thing is petri dish should be covered with another petri dish or aluminum foil and other thing is HEPA filters in room or better is fumigation to provide pure air in lab. Methylene Di Oxide and Potassium Permanganate is used for fumigation while HEPA filters might employed horizontally or vertically to provide pure air in lab.

After sterilization reports are sent to QC lab and a report is prepared which must contain resulting prints about all tests.
Incubation Time is 7 days. For sterilization 14 days is necessary.

TAMC:

Samples are prepared and dilutions made. The samples are then plated on media and incubated based on method specifications. After incubation plates are read and results generated based on countable range.

TYMC:

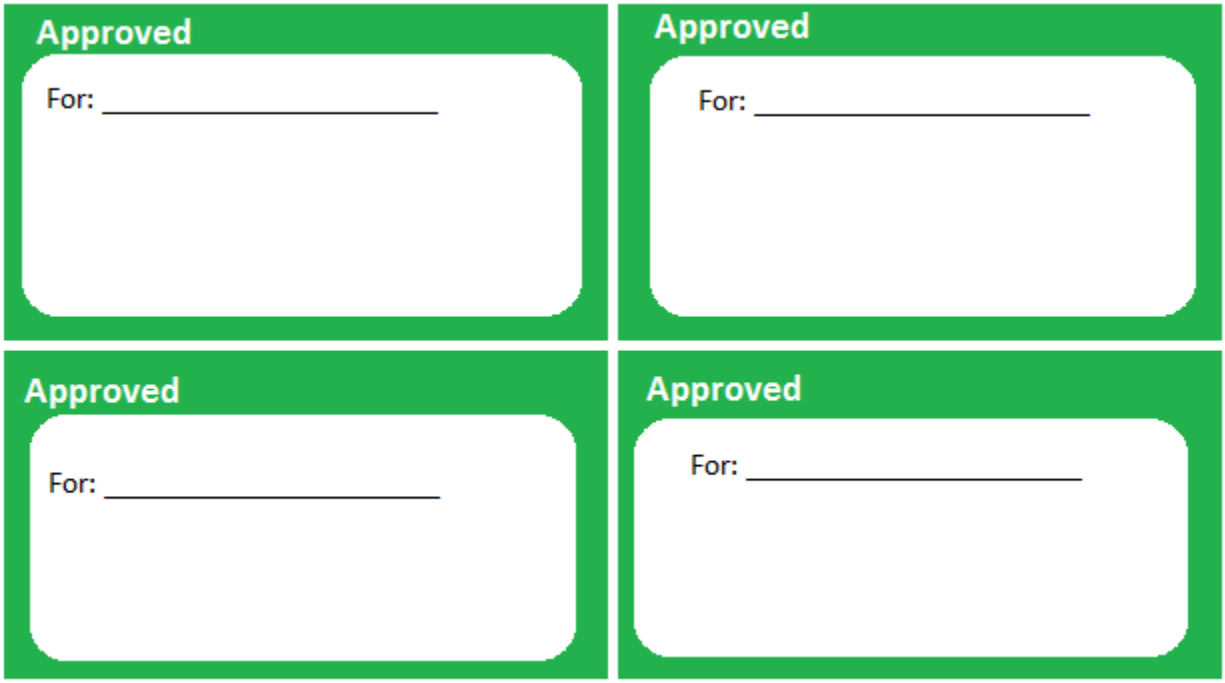
The Total Yeast & Mold Count to Assess the Microbiological Safety of Products
The total yeast and mold count (TYMC) is a test to detect mesophilic fungi in pharmaceutical ingredients that range from raw materials and water to the finished products. It is part of the qualitative phase of bioburden testing (including microbial limit testing) to determine the presence or absence of specific microorganisms. For pharmaceutical and cosmetics manufacturers it is very important from a safety perspective to ensure that their products are free from hazardous microbes such as yeasts and molds.

3.1.5 Tests for other pharmaceutical products (Tablets, Capsules and suspension products) and raw material:

For this we always consider that there is always use of different tags for every product.

- ✓ Processing (Indicates that sample was used to be tested during the process; send by production department, it should be blend or in powder form.)
- ✓ Filling (Indicates that sample is about to get filled in capsule shell or in vial or in bottle)
- ✓ Bulk (Indicates that sample is in powder form and it is provided for testing by production department)
- ✓ Coating (Indicated that tablets are coated and requires tests)
- ✓ Packaging (This is done by packaging department in QC)

For every sample tag must be look like:



This tag should contain:

- Date of Manufacturing
- Date of Testing
- Quantity
- Batch number
- Intimation number (Provided by production department)
- Remarks
- Sign of Department manager and the executive if passed or failed.

In case of sample failed, the whole batch is rejected.

3.1.5.1 Tests for Tablets:

Tablets are solid dose pharmaceutical preparation containing drug substances usually prepared with the aid of suitable pharmaceutical excipients. They may vary in size, shape, weight, hardness, thickness, disintegration, and dissolution characteristics and in other aspects, depending on their intended use and method of manufacture. It has been estimated that solid-dosage forms constitute approximately 90% of all dosage forms clinically used to provide systemic administration of therapeutic agents. The widespread use of tablets has been achieved as a result of their convenience and also the diversity of tablet types.

These tests are performed for tablets:

3.1.5.1.1 Weight Variation:

For this we select 10 to 20 tablets from batch and weight them individually then find the average and compare that individual weight with average one, the batch passed the test if not more than two tablets come out of that average percentage limit otherwise the whole batch is rejected.

3.1.5.1.2 Friability Test:

For this we used Roche friability instrument which rotates a disk containing tablets from 25 rpm and tablets are allowed to fall from six inches' distance in friabilator. Weight of tablets are measured before and after before this and the range of weight loss should be 0.5 to 1.0 % otherwise the whole batch is rejected.

3.1.5.1.3 Hardness test:

By hardness test we don't only test hardness but we also measure the thickness of randomly selected tablets. Normally hardness should be 4 to 10kg for both coated and uncoated tablets.

3.1.5.1.4 Dissolution Test:

For dissolution test we used dissolution apparatus contains seven vessels and temperature is about 37±0.5 and the tablets are about to dissolve in those vessels.
First of all, we wait for temperature to reach then paddles are started to stirrer in those vessels at 50 to 60 rpm then tablets are introduced which contains liquid medium containing some vessels of buffer 2 and 7 pH. The dissolution time is approx. 30 minutes.
2 pH buffer is produced by dissolving KCl and HCl both of 2M into 1000 ml water while 7 pH buffer is produced by dissolving H_2PO_4 and NaOH in 1000 ml water.

Important note:

- ✓ Only for product QBAL and BOSHCAM dissolution and all other tests are performed in dark because they are light sensitive.
- ✓ Introduce 1000 ml buffer solution in each vessel.
- ✓ Both baskets and paddles are used depends upon the tablet is coated or not but for coated tablet dissolution tests aren't performed but HPLC test is necessary to perform.

3.1.5.1.5 Disintegration Test:

For disintegration test same apparatus is used but the vessels are two here with same buffers in different vessels whereas instead of stirring the basket containing 6 test tubes moved to and fro vertically and disintegration is checked after 15 to 30 minutes.

Tubes are moved with frequency of 28 to 38 cpm and with distance of 5 to 6 cm.

For coated tablets: Disintegration time is 1 to 2 hours

For uncoated tablets: Disintegration time is 15 to 30 minutes.

3.1.5.1.6 HPLC test:

HPLC test is necessary to prepare assay of medicines which doesn't only show resolution of active ingredients but also non active ingredients such as diluents, lubricants and binders etc.

There are three software using here.

- Lab Solution
- Empower
- Control Panel

Instrument used here are of waters, Shimadzu and Agilent.

For HPLC testing we must remember that HPLC water requires 3 runs, standard always requires 5 runs from column while sample requires two runs from column. Sample is injected itself and detected by the detector.

Important points:

- Mobile phase should be less viscous
- Injected volume should not be too high
- Column shouldn't be overloaded
- Channels should not be formed in column
- Column should be inclined
- Less diameter of column
- Air bubbles shouldn't be present in sample or solvent.
- Column shouldn't drain

The formula used here for assay is:

(Sample abs. x weight of standard x 1 x 100 x 50 x potency x 1000 x 3)

Standard abs. x 100 x 50 x 2 x 1 x 100

Mg/3 ml x 100

75

(in waters)

When you want to check the potency of drug you take its assay.

An assay is an investigative (analytic) procedure for qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of a target entity (the analyte).

To prepare standard always use HPLC water and HPLC graded solvents.

Waters:

(Preferred software: Empower)

Agilant:


(Preferred Software: Control panel)

Shimadzu:


(preferred software: Lab solution)

3.1.5.1.7 Spectroscopy:

Spectroscopy is performed to detect impurities. For this we often used double beam spectrophotometer and single beam spectrophotometer which is also called FT-IR.

Principle of FTIR:

In FTIR analyses, Infrared light from the light source passes through a Michelson interferometer along the optical path. The Michelson interferometer comprises a beam splitter, moving mirror, and fixed mirror. The light beam split into two by the beam splitter is reflected from the moving mirror and fixed mirror, before being recombined by the beam splitter. As the moving mirror makes reciprocating movements, the optical path difference to the fixed mirror changes, such that the phase difference changes with time. The light beams are recombined in the Michelson interferometer to produce interference light. The intensity of the interference light is recorded in an interferogram, with the optical path difference recorded along the horizontal axis.

Principle of double beam:
Spectrophotometer is based on the photometric technique which states that When a beam of incident light of intensity I_0 passes through a solution, a part of the incident light is reflected (I_r), a part is absorbed (I_a) and rest of the light is transmitted (I_t)

Thus,

$I_0 = I_r + I_a + I_t$
In photometers (colorimeter & spectrophotometer), (I_r) is eliminated because the measurement of (I_0) and It is sufficient to determine the (I_a). For this purpose, the amount of light reflected (I_r) is kept constant by using cells that have identical properties. (I_0) & (I_t) is then measured. The mathematical relationship between the amount of light absorbed and the concentration of the substance can be shown by the two fundamental laws of photometry on which the Spectrophotometer is based i.e. Beer's law and Lambert's law.

$$A = \epsilon cl$$

Double beam spectrophotometer operates between 185 nm to 1000 nm wavelength. It has two photocells. This instrument splits the light from the Monochromator into two beams. One beam is used for reference and the other for sample reading. It eliminates the error which occurs due to fluctuations in the light output and the sensitivity of the detector. [6]

3.1.5.2 Capsule tests:

Capsule are solid dosage forms in which the active medicament is enclosed in either a hard or soft soluble container or shell of a suitable form of gelatin.

OR

Capsules are solid dosage forms in which drug and/or inert substances are enclosed in a gelatin shell. The gelatin shell may be hard or soft depending on their composition.

For capsule tests we randomly selected 20 capsules from batch and first we weight the filled capsule then empty it and weight the empty capsules, printed out the results and the subtraction shows the weight of medicinal agent inside capsule shell.
Like tablets we take average weight here but the range of weight variation should be 90 to 110 %,

3.1.5.2.1 Determination of moisture content:

Moisture content to medicinal agent is find out by Karl Fischer reagent.
(Take 0.1 gm always)

Principle:

The principle of Karl Fischer titration is based on the oxidation reaction between iodine and sulphur dioxide. Water reacts with iodine and sulphur dioxide to form sulphur trioxide and hydrogen iodide. An endpoint is reached when all the water is consumed. The chemical equation for the reaction between sulphur dioxide, iodine, and water (which is employed during Karl Fischer titration) is provided below.

$I_2 + SO_2 + H_2O \rightarrow 2HI + SO_3$

Karl Fischer Titration Equipment

Drying tube, sample injection cap, electrode analysis, Drain cook, a cathode chamber, detection electrode, rotor, anode chamber, KF reagent.

Ingredients of KF reagent:

Iodine, Buffer (Imidazole), sulphur dioxide, solvent (methanol).

3.1.5.2.2 Dissolution Test

Performed in same way as tablet.

3.1.5.2.3 Disintegration Test

Performed in same way as tablet.

3.1.5.3 Testing for powder (suspension product, granules or raw material):

For powder material or granules, we first find out moisture content in sample by Karl Fisher.

3.1.5.3.1 Loss on Drying:

Main difference between LOD and Karl fisher is LOD describes the amount volatile compounds in sample while Karl fisher defines the amount of moisture in sample.
For sugar the LOD temperature is 60°C for 10 minutes while for granules temperature is 80°C for 13 minutes. Results are printed out. After this we can do spectroscopy tests and HPLC tests and do assay etc.

3.1.5.4 Vials Testing:

For vials we take weight of filled vials then empty vials then in same way moisture content is find out.

Standard Ranges of dissolution tests, disintegration tests, LOD, TOC, Friability and hardness or any other test can be note from Log Book in lab for various varieties of product.

3.2 QC packaging lab

Packaging material such as boxes and cartons are delivered to QC lab from ware house with tickets which confirms the amount of packets inside it, GRN (Good received notes) are also attached which shows how many packets are loose in it in format a x b, c x d.
Here c and d defines loose packets.

This lab checks these things:

3.2.1 Physical test:

To check hardness of packets, color and most importantly generic name and industry logo and name, they also can tear packets to check strength between sides.

3.2.2 Art Work:

Art work is also checked and every detail should be matched from standard.

3.2.3 Color shade:

Color shade is also checked from standard file; it should be not too dark or not too light.

3.2.4 EGC is also checked.

Beside checking packets, they also check ampules size i.e. diameter, height, neck diameter critical side and everything else we need by electronic micrometer.

Sometimes for vials we do glass grain test and Surface glass test but most important among them is called Hydraulic resistance test.

This is test is performed by crushing glass in to fine material and then it is treated with acetone and titrated to with any acid under condition of CO_2 free water with indicator methyl red soln. which actually defines the amount of alkali release from glass.

Usually Type III of glass required this test.

For glass grain test we used spectrophotometer with photodiode detector and photomultiplier tube with range of 290 nm to 450 nm.

In both cases we should be careful that solution will prepared in CO_2 free water.

After passing all test a GIR is sent digitally.

GIR (Good Inwards report).

While destroying packets make sure that packets destroyed must be less than 5% in care of more than 5% material can be returned to MNCR. This is called Major case. While in Critical case the destroyed packages are dumped. But if there is any printing mistake in packages then they are stored in Rejected material room in ware house for fifteen days so the seller can't raise objections and after 15 days they are destroyed too.

Another term we used here is BMR (Batch manufacturing report). It must contain:

1. Date analyzed
2. Date supplies
3. Quantity
4. Status
5. Remarks

Package checking is the last step of QC lab after that the batch is sent to QA department and then to packaging department for further verification and then to ware house for storage.

Make sure that with even a minor mistake whole batch is rejected.

Product I see in my five days experience in QC:

s.no.	State	Name
1	Capsules	Abapen Cap 300 mg
2	Capsules	Abapen Cap 400 mg
3	Vial	Amplus Inj 0.25gm
4	Vial	Bactamox Plus Inj 0.75g
5	Tablets	Boshcam-B 20 mg
6	Capsules	Btrol 500 mg
7	Vials	Calamox
8	Suspension	Calamox DS
9	Vial	Cebac Inj
10	suspension	Cebosh DS
11	Capsules	Cefalor 250 mg
12	Tablets	Cebosh 400 mg
13	Capsules	Cefalor 500 mg
14	Vials	Ceprazone Inj 0.25gm
15	Vials	Fortazim Inj 0.25 g
16	Tablets	Qbal 500 mg
17	Vials	Supramox Inj 1gm
18	Tablets	Prelox 100 mg
19	Tablets	Maclacin 500 mg
20	Tablets	Zecef 125 mg
21	Tablets	Zentro 20 mg
22	Vial	Cefotax Inj 1gm

Chapter # 4
"Quality Assurance Department"

Prepared by Altamash Asif Ghori
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4.1 Quality Assurance Department

In the pharmaceutical industry, quality assurance (QA) is essential for ensuring that pharmaceutical products are manufactured to a safe and consistent standard. QA is a very broad field that refers to any aspect that may affect a drug's quality during its research, development, manufacturing, and sales phases. QA professionals are responsible for instituting a range of practices that help guarantee a drug's quality.

Since QA is such a broad field, it can be helpful to look at specific ways that it is implemented in practice. Here's a look at a few concrete examples of how QA works in real life so you can get a better idea of why it is so important in the pharmaceutical industry.

A drug that doesn't work as intended or that is defective in some way can present a threat to public health. Ensuring that pharmaceutical products are safe and effective is the primary goal of any pharmaceutical company's QA department. There are a number of methods and procedures QA departments use to achieve this goal.

Due to their impact on public health, pharmaceutical products and pharmaceutical QA are highly regulated. There are many laws and rules that pharmaceutical companies must comply with before they can sell and market a pharmaceutical product. Part of a QA professional's job is to assist companies with regulatory compliance, which can be achieved in a number of ways.

For instance, as part of their quality assurance training, students learn about good manufacturing practices (GMP). GMP is a series of measures that drug manufacturers must comply with to ensure their drugs are produced to a consistent and reliable standard. A QA professional implements various measures at manufacturing facilities, such as calibrating equipment, maintaining documentation, and conducting quality tests, that are covered by GMP and that can help a facility pass its inspection.

The public wants assurances that the pharmaceutical drugs they take are safe and useful. If a pharmaceutical manufacturer is found not to be in compliance with QA regulations, or if they have created a pharmaceutical product that is either unsafe or doesn't work as intended, the public may lose faith in the quality of that company's products. By ensuring that measures are in place to guarantee product quality, a QA professional plays a significant role in reassuring the public that a certain drug—and, by extension, that drug's manufacturer—can be trusted. In turn, this helps pharmaceutical companies maintain their public reputations, which is essential for business success. [7]

4.1.2 Quality Assurance Department Functions in Pharmaceuticals

Quality Assurance Department shall function for assuring the quality of all the Products manufactured, at every stage of manufacturing / processing of Drug Products. This shall be achieved by performing the functions of monitoring as per the laid systems for the following areas which is not limited to this:

4.1.2.1 Ensuring proper warehousing practices:

4.1.2.1.1 For Incoming components (Active Pharmaceuticals Ingredients)

- API
- Excipients
- Packaging Materials
- containers and closures

4.1.2.1.2 labels with proper storage conditions which is required for drug stability etc.

QA department is responsible for the proper storage of API and other excipients and segregation of the material in the warehouse.

4.1.2.2 Manufacturing process and critical process checks:

This is one of the most critical activity performed by the QA department.

4.1.2.2.1 For this Activity special team is assigned named as IPQA (In Process Quality Assurance). Which keep an eye on all our activities related to the Storage of RM to the final product dispatch

4.1.2.2.2 Before starting any manufacturing process, the IPQA person ensure the paperwork and physical condition of the area where the product is going manufactured during the manufacturing of the product several samples are collected by IPQA for testing to ensure the quality of the product during the manufacturing process.

4.1.2.3 Process monitoring and Process controls:

4.1.2.3.1 During the manufacturing of the product the whole process is monitored by the QA department and

4.1.2.3.2 ensure that all the steps followed for the manufacturing of the product are validated and as per SOP.

4.1.2.3.3 If the QA person is found any alteration in the method of manufacturing of the product, then the appropriate action is taken to ensure the quality of the product.

4.1.2.4 Batch Record Review:

4.1.2.4.1 All the data which is generated during the manufacturing of the Pharmaceutical product is recorded in a file (soft copy / Hardcopy).

4.1.2.4.2 Which tell us about the all essential data related to product manufacturing (e.g.- Timing of process, ingredients, environmental conditions, person involve etc.), in the end of the manufacturing process.

4.1.2.4.3 QA person review the batch record to ensure the data enter in the batch record is legible if QA person found any kind of data integrity issues then the appropriate action is taken as per the SOP.

4.1.2.5 Final release of Drug Products for distribution and sale:

When the Pharmaceutical product is manufactured and Packed then the role of QA comes to

- ensure that the product is safe for market or not
- all the QC test reports are attached with batch record
- all the calculation related to that batch are correct
- several other parameters are checked and after ensuring the product safety then the QA person allow to distribute the product in the market.

4.1.2.6 Stability testing and evaluation of shelf-life of products:

QA department is responsible for the stability testing of the pharmaceutical product manufactured in their labs and ensure that the shelf life of the product is same as per the study and mention on the product to avoid the market complains.

4.1.2.7 Ensuring proper warehousing of finished products:

Storage condition plays an important role in the stability of the Pharmaceutical products so the QA person ensures all the parameters which are required to prevent the product decontamination during the storage.

4.1.2.8 Complaints and product recalls:

In case of any market complain come to the manufacturing Factory then it's a responsibility of a QA department to act on that and the appropriate action is taken

- or in case product recall is required from the market then the QA department initiate the recall process and ensure all the products related to the complaint batch is recalled.
- All this decision is performed through the SOP.

4.1.2.9 Handling of Change Control Systems:

Any other than validated step/ activity required to x in any document and process is taken through the change control system

- it's a documented process to apply change in the Pharmaceutical industries. Change control system finally review by the QA department for approval.

4.1.2.10 Out of specification investigations:

In any case during the testing of any pharmaceutical product the outcome is not per the expected outcome

- and the final result come is different from the standard specification then the QA department come in role and perform an investigation to find the root cause through the specific SOP.

4.1.2.11 Event Investigation:

In case of any unexpected event happened during the

- Manufacturing
- Testing

- documentation of a pharmaceutical product then the QA department is responsible for the investigation of the event find the root cause and take appropriate action to prevent such kind of events in future.

4.1.2.10 Returned products (salvage and disposal):

When the product is returned in the manufacturing factory due to any reason then the QA department is responsible to take action on the product

- whether QA perform same addition process on the product to prevent or in case the product is not salvage the product is destroyed on the order of the QA department.

4.1.2.11 Internal Quality Audits and Quality Review:

4.1.2.11.1 The Quality review and Internal audit and comes in the major responsibilities of the QA department

4.1.2.11.2 Internal Audit is performed by QA department frequently (surprisingly or scheduled)

4.1.2.11.3 To ensure that all other department in the Company is performing their activities as per SOP.

4.1.2.11.4 Quality Review is organized by the QA department to enhance the quality of the output of the company in all aspects like

- product quality
- employee facility
- infrastructure
- machinery
- company policies etc.

4.1.2.12 Reprocessing of non-conforming products:

I. QA department allow reprocessing the product in case the manufactured product don'ts meet the expected quality parameter in the final quality testing
II. the QA department monitors all the reprocessing activities closely.

4.1.2.13 Other Quality Assurance functions:

To achieve the objectives of Quality Assurance, below functions of the department has been classified but are not limited to this.

- Plan and manage all the activities of Quality Assurance Dept. to assure the quality of all products manufactured by the Company.
- Co-ordinate with manufacturing department in controlling their process and products at every stage of manufacturing to meet the established specifications through testing, auditing and reporting.
- Review the adequacy and relevance of specifications & analytical procedures in co-ordination with Quality Control Dept. and R& D.
- Co-ordinate technical audits of the Quality Control Laboratory to determine the analytical Quality Systems are yielding the highest quality information and to ensure that the analytical instrumentation is functioning properly and calibration and servicing is as per schedule.
- Monitor the production environment and services to the production operation.
- Products are stored, handled and distributed in a way to maintained product quality throughout their shelf life.
- Maintenance of Quality Control records of manufacturing procedures for each batch manufactured.
- Maintenance Records of
  - Release
  - Quarantine or rejection of components and finished products
  - Containers, closures and labels based on Quality Control test results.
- Routine "Good Manufacturing Practices Auditing" of manufacturing process, control and related areas.
- Suggest and organize training programmers for development of technical and administration skills of all the employees to meet with cGMP

regulations on continuous basis, co-coordinating with Plant and Quality Head.

- Establish guidelines and procedures on cGMP and Standard Operating Procedures of overall Quality Assurance activities. To review protocols related to
  - Method
  - Process
  - Cleaning
  - Analytical Method Validation etc.
  - Document Management System

- Overall reviews of:
  - non-conformance
  - failure investigations
  - analyzing the Quality trends
  - investigations of market complaints
  - batch failure investigations
  - deviations
  - verification of change control procedures
  - updating the specifications
  - test procedures
  - manufacturing processes etc.

- The Quality Assurance system is regularly audited by self-inspection for effectiveness and applicability.
- To follow reporting system to the Corporate Quality Head on weekly / monthly basis as per the standard procedure.

4.2 Documentation Department (QA)

In Bosch Pharmaceuticals PVT LTD, Quality assurance documentation department, officers check two types of documents File reports,

- BAR (Batch Analytical Report)
- BMR and BPR (Batch Manufacturing Report and Batch Packaging Report)

BAR is provided from QC lab after analyzing raw material, in process and product, they complied every report in a file.

It contains reports of:

- Physical Test
- Weight Variation
- Dissolution Test
- Disintegration Test
- Hardness Test
- Friability Test
- Karl Fisher Moisture content test
- UV Spectrum and absorbance test
- Particle count (If sample is of water)
- Endotoxin and other microbiological tests
- HPLC test (Assay)
- Packaging Test

For all these tests make sure we have intimations first. I have written about all of these previously on my QC lab section.

The other report to be checked is BMR and BPR (Batch Manufacturing Report and Batch Packaging Report)

This must contain these reports:

- ✓ Packaging report (Provided from packaging Area in production house or white house)
- ✓ Material Issue Requisition
- ✓ Weight/Volume Record
- ✓ Line Clearance Report (Given by QA officer)
- ✓ In Process control sheet
- ✓ Batch Intimations Report
- ✓ BMR (a paper)
- ✓ Packaging requisition

- ✓ Packaging instruction and report
- ✓ Coding Instruction and Yield accountability
- ✓ Printing Control Format
- ✓ Line clearance sheet for packaging
- ✓ Printed paid weight/volume report
- ✓ Packaging material reconciliation sheet
- ✓ Destruction certificate

This BMR is provided by Production house.

- ✓ **Packaging report:**
  Packaging quality control is the inspection of finished product packaging done to determine whether it passes quality standards before it is approved for the next step in the supply chain. Packaging department managers, quality control officers, and procurement personnel perform packaging quality control inspections upon receiving raw materials, after production, during storage, before transport, and upon distribution to prevent contamination and maintain product quality.

- ✓ **Material Issue Requisition:**
  A material requisition, also known as a materials requisition form, or a material request, is a document used by the production department to request materials they need to complete a manufacturing process. It is used to authorize and keep a record of the components used so that an appropriate inventory can be stocked to keep production moving. Information on the requisition is used to update the stores record card, also known as the bin card, and the stores ledger. It's also used to determine the direct materials used on various jobs or products, along with the indirect materials used by various cost centers. The bin card is a paper or computer record used to keep track of inventory for each stock item held in storage. The card details the amount of stock received and issued, the amount of stock reserved to meet current production orders, and any residual balance free for future use. The production manager generally fills out the materials requisition form and delivers it to either the materials or storage department where all the raw materials are located. Then, the materials manager approves the request and has the raw materials moved from the storage area to the production floor. The person who is requesting the materials will keep a copy of the form, as will the warehouse staff. An additional copy goes along with the picked goods to their eventual destination. If any items listed on the form are not in stock, another copy may go to the purchasing department so they can create a purchase requisition and purchase order to obtain the necessary materials.

- ✓ **Weight/Volume Record:**
  It only justifies weight and volume of manufactured goods.

- ✓ **Line Clearance Report:**
  Line clearance is a process which provides a high degree of confidence or assurance that the said line or area is free from any unwanted residue or left over of previous processing's before proceeding for next process. Quality assurance has to provide Line clearance before the start of any activity whether it is batch to batch change over and Product to product change over. Change over from one batch to another batch of same product and same Strength or increasing in strength provided the excipients is same. Cleaning between batches of same product but in ascending or increasing strength.

- ✓ **In Process control sheet:**
  As already mentioned many operations are involved during the manufacturing of a finished product and it is understood that quality is the responsibility of all the persons involved in the manufacturing and also Quality cannot be tested into products; it should be built-in (i.e. by design) and verified during the process to the extent possible rather than depend alone on end product testing. Hence it is necessary to check and control the critical points of the product during the manufacturing and up to the final packing of the product. Thus the main purposes of In-Process Quality Control checks (IPQC) are to monitor control and improve effectively the whole applied operations at every stage of the finished pharmaceutical products. In-Process control includes inspection of raw material, equipment, environment, process, testing with respect to specification, packing and so on. The In-Process control is performed at regular intervals of either one hour or half an hour later. The Good Manufacturing Practices follow to eliminate the risks at every stage of manufacturing process Good Documentation Practices and Good Review Practices should be follow during the In-process checks6 to maintain the record. The quality assurance (QA) dept. plays an important role at the different stages of manufacturing of finished pharmaceutical product. One of them is IPQC checks of critical points. Critical Process controls changes in the process step and methods. The changes are not permitted within pre-established limits; it must be approved by the QA dept. All tests and results should be fully documented as part of the batch record. In-process controls and their acceptance criteria should be defined on the information obtained during the development stage or previous records. The acceptance criteria, type and extent of testing can depend on the nature of the process step being conducted,
  finished product being manufactured, and the degree to which the process introduces variability in the product's quality.

- ✓ **Batch Intimations Report:**
  (Have defined this in ware house section)

- ✓ **BMR:**
  (Have defined this in production section)

- ✓ **Packaging requisition:**

Same as material requisition but now for packaging.

- ✓ **Packaging instruction and report:**
  This function enables the system to find a packing instruction by specific characteristics. The condition technique is applied for this. You define a packing instruction/reference packing instruction that refers to specific characteristics, such as material/reference material and ship-to party. If you now want to pack this specific material for this specific ship-to party, the system can find the pre-defined packing instruction and use it to create one or more HU proposals that exactly fit the requirements of the customer. Packing instruction determination thus automates the packing process.

- ✓ **Coding Instruction and Yield accountability:**
  QR codes on pharmaceutical packaging, prescription, and labels have been used to enhance and advance printed medical drugs and communicate better to buyers in the form of using the QR code technology.
  Yield is return (on investment) or output in production terms. Maintenance planning and documentation increases production output. Accountability is the duty of management, be it commercial or political to properly report on its activities and results.

- ✓ **Printing Control Format:**
  Tablets must comply with finished product specifications and any appropriate compendia requirements, and that can be ensured. Variation in viscosity causes significant change in both solvent and water-based ink properties affecting printability, fade resistance and drying. Viscosity control can help alleviate the frequency of miscues – sticking and picking, print weak (thin line), print broad (fuzzy and washed out), print missing (incomplete) and smudged (spotty marked printed product). Color consistency and color density are highly critical to the right print quality. Controlling ink viscosity is the key to color consistency because that is the factor subjected to the highest variability. The percent solids of fluid are the characteristic of the ink that gives it color. Ink viscosity is an indicator to the percent solids of the fluid. Printing with incorrect viscosity harms more than just quality. Poor viscosity management drives up usage of pigments and solvents, affecting the profit margins. Materials rejected due to poor quality can be reduced with proper viscosity management. Eliminating manual viscosity control frees operators' time and enables them to focus on other tasks. Lowering the use of pigment and solvent is good for the environment. On-dose identification helps in product differentiation and enhances product safety. Perhaps to a greater degree than other industries, pharmaceutical printing demands the highest quality printing. Legibility and contrast are non-negotiable when it comes to regulatory and traceability codes.

- ✓ **Line clearance sheet for packaging:**
  (Same as line clearance sheet but this time for packaging)

- ✓ **Printed paid weight/volume report:**
  (Same as weight volume report but after print)

- ✓ **Packaging material reconciliation sheet:**
  The purpose of reconciliation is to ensure that all materials have been accounted for and no mix-up occurred. Reconciliation is carried out on printed and/or coded components and the finished product. The limits outlined in this procedure should help detect errors at the time of manufacture and avoid release of a non-conforming product. Reconciliation should be performed at the end of each stage, especially if the goods are moved from one location to another. Final reconciliation should cover the whole process. The reconciliation calculation should be based on real figures. Estimate is allowed in relation to materials that can be lost during the process.

- ✓ **Destruction certificate:**
  A certificate of destruction is a formal document containing detailed information about the destruction of your papers that ensures the shredding process complied with all relevant security laws. These certificates help protect your company in case of legal action or an audit. A thorough certificate of destruction will contain these items:
  - A unique, serialized transaction number that you can use in an audit trail
  - Transfer of custody that establishes the client's turning over of materials for destruction at a specific location and date
  - A reference to the terms and conditions, or the policies and procedures of the client and company for the processing of materials
  - Acceptance of fiduciary responsibility whereby the company's agent accepts responsibility and agrees that all materials accepted are considered confidential and are to be treated as such (can refer to the terms and conditions of a service agreement)
  - The date the information was collected and the date the information ceased to exist
  - The location of the destruction of the documents
  - The name of a witness to the destruction process

  Before you agree to have a shredding company destroy your documents, be sure to ask if they provide a certificate of destruction. Have them detail what's included on their certificate to ensure you have all the necessary requirements by law or for your industry.

You can expect to receive your certificate anywhere within a week of when the shredding was performed, but many offer them same day.

4.3 QA Lab or Stability Lab

In Stability Lab, Stability testing is utilized to determine if the quality of a drug substance or drug product is altered over time by various environmental factors, such as light, temperature, and humidity. A drug "substance," often referred to as an Active Pharmaceutical Ingredient (API), is defined as the unformulated material that may subsequently be formulated with excipients to produce a dosage form. A drug "product" is the formulated mixture of the drug substance and excipients comprising the final marketed dosage form.

For a drug substance, stability testing determines the "re-test period," the timeframe during which the drug substance is expected to remain within its specification, and therefore can be used in the manufacture of a given drug product. After the established re-test period has elapsed, a drug substance can only be used if additional specification testing is performed, the material passes inspection, and the substance is distributed soon after meeting acceptance criteria.

For a drug product, stability testing determines the shelf-life of the product by establishing the duration for which the product is safe to use and retains therapeutic value according to the level of the active ingredient(s).

During a stability study, materials are stored at various temperature and humidity conditions and samples are pulled at predetermined time points and subjected to a battery of tests that may include: an identification test, assay, physical tests, microbiological limits, and preservative effectiveness testing, using appropriately validated methods and/or recognized compendia methods. Acceptance criteria are stipulated before initialization of the study, and if a product fails to meet specifications at any time point, the stability study may be halted and restarted after reformulation or other modifications have occurred.

The first step here is collection of samples and store them. For each new product collection of the sample shall be done for first three consecutive batches for Stability study under Accelerated temperature and humidity conditions. For all products at least one batch per year shall be kept under Long term stability testing. Quality Assurance Supervisor shall collect the sample as per instructions from Manager Quality Assurance as per stability study schedule. Samples are collected as an intact-marketed pack. The quantity of sample collected shall be in sufficient number depending upon the product and its stability indicating tests. Samples are kept at Controlled temperature (25 ± 2°C) and Relative humidity (60 ± 5%) conditions for Long term stability testing. Samples are kept at temperature (40 ± 2°C) and Relative humidity (75 ± 5%) for Accelerated stability testing.

Periodicity of analysis for stability samples shall be as follow:

1. Accelerated Stability Testing Conditions (45°C ±2°C / 75%±5%) = 0,1,2,3 and 6 months.
2. Long Term Stability Testing Conditions (25°C ± 2°C/ 60% ± 5%) = 0,3,6,9,12,18,24 36,48,60 months.
3. Long-term stability study shall be carried out up to the expiry period of the product.

Long-term stability analysis shall be performed within ±7 working days of the due date. Accelerated stability samples shall be analyzed within ± 5 working days of the due date. The sample for stability studies shall be taken within one month from the date of approval of the batch. An annual schedule of the

batches to be studied for stability and the date of analysis shall be made every December for the following year. Entry in stability register shall be made accordingly.

In QC lab following tests are performed.

1. Weight Variation
2. Karl Fisher Moisture Content
3. Disintegration test
4. Dissolution Test
5. Spectroscopy
6. HPLC or ASSAY

1. Weight Variation:

- Weight variation test for hard gelatin capsules, ten hard gelatin capsules are usually weighed individually and the contents are removed. The emptied shells are individually weighed and the net weight of the contents is calculated by subtracting the weight of the shell from the respective gross weight. The content of active ingredient in each capsule may be determined by calculation based on the per cent drug content in the formulation

- For soft gelatin capsules, the gross weight of 10 gelatin capsules is determined individually. Then each capsule is cut open with a suitable clean, dry cutting instrument (e.g., scissors or a sharp open blade), and the contents are removed by washing with a suitable solvent (that dissolves the fill but not the shell). The solvent is allowed to evaporate at room temperature over a period of about 30 minutes, followed by weighing of the individual washed shells. The net contents are calculated by subtraction and the content of active ingredient in each of the capsules can be determined by calculation based on the per cent drug content in the formulation.

- The test for uniformity of weight is performed by weighing individually 20 tablets randomly selected from a tablet batch and determining their individual weights. The individual weights are compared with the average weight.
  The sample complies with USP standard if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

I have defined about further tests in QC section of this report but now here I will point out some little details asked to us in lab.

Disintegration test ensures that tablets mass is broken down in to smaller fragments which can pass through easily through the mesh size at the standardized conditions as specified in the relevant pharmacopoeia. Therefore, it is a physical phenomenon.

On the other hand, Dissolution test ensures that the active moiety (API) is dissolved in the medium at given PH, at the standardized conditions as specified in the relevant pharmacopoeia.

Dissolution ensures active moiety (API) is released and dissolved in the Dissolution media and forms a solution from the tablets mass and only then it can get into the systemic circulation in our body. Thus making it bioavailable. Therefore, Dissolution test is directly related to bioavailability of the drug. Dissolution test is called as In- vitro test, while conducting bioavailability test on human volunteers is called In-vivo test. There is a correlation between In-vivo and In-vitro test. It is called as IV-IV Correlation.

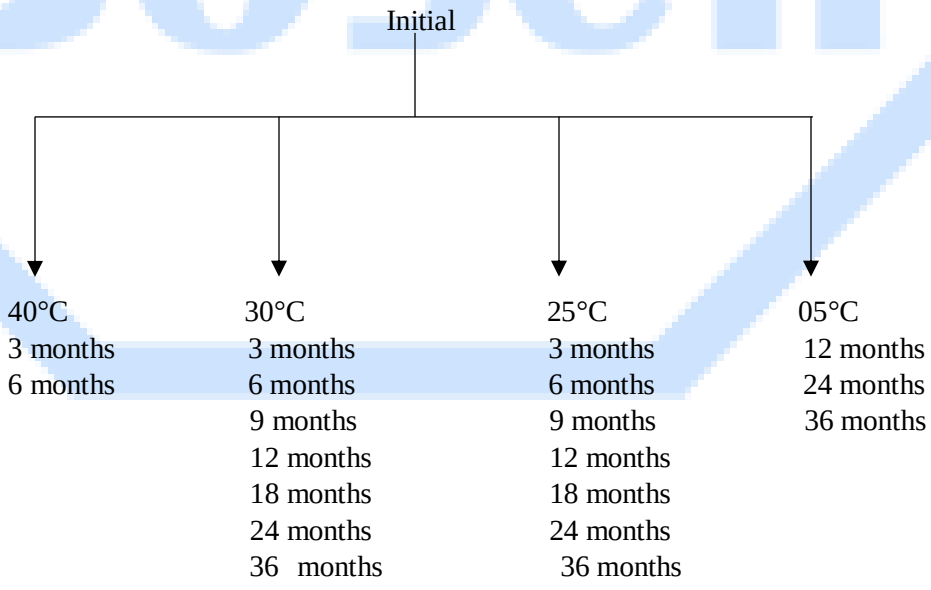
For satisfactory bioavailability of a drug in pharmaceutical dosage forms, the Dissolution test, and the Disintegration test should be satisfactory as these are interested related.

20 ml sample is always injected from dissolution vessel to perform HPLC and Spectrometry. This 20 ml sample is stored in test tubes and we make sure that every sample/chemical we take must be covered with aluminum foil from mouth and name should be return on carrying medium.

Dissolution is performed in buffer medium or in distilled water depends upon the specs. Every worker should carry the specs during testing. I usually have seen potassium phosphate mono basic buffer with pH maintained by NaOH using for capsules. Samples for spectroscopy and HPLC is always prepared in this medium.

Agilant instruments are using here for HPLC with control panel software.

Stability lab checks physical appearance of every sample too which also justifies its stability. If the sample reaches its expiry it is demolished after some documentation.



4.3.1 Stability Chamber

Stability Chambers provide a controlled temperature and humidity environment. They are perfect for stability tests, e.g. in Pharma or packaging. Other applications include environmental testing or controlled storage. In the pharmaceutical industry, stability testing helps provide evidence as to how the quality of a drug will vary with time under a variety of environmental conditions including temperature, humidity, and light exposure. This testing must be completed before a drug enters the market.

To test the quality of the drug under specific temperatures and humidities, a batch of the drug of interest is placed in a stability chamber that has controlled temperature and humidity for a specified amount of time. Samples are checked periodically for quality analysis. Because stability testing takes place over time spans ranging from one week, to six months, to one year or more, the stability chambers used need to be reliable and consistent.

Another type of stability test is focused on photo stability, or how the drug is affected when exposed to a certain amount of light and UV over time. For this type of test, stability chambers are needed that meet specific guidelines and are able to emit the required light and UV over time.

The temperature also needs to be uniform throughout the unit. Stability chambers that use traditional non-directed airflow systems use a fan mounted at the top of the unit to push air down through wire shelves. When the shelves are filled with samples, this air movement will be blocked, leading to varying temperature conditions throughout the chamber. This inconsistency could compromise the stability conditions and the stability testing overall. In contrast, stability chambers that use a horizontal laminar airflow system include a positive pressure feed plenum on one side of the chamber and a negative pressure return plenum on the other to create horizontal airflow directed across the surface of each shelf. Using this method means that, even when the shelves are filled with samples, they will receive a consistent flow of conditioned air allowing for optimum temperature uniformity throughout the chamber and across all samples. Horizontal laminar airflow systems also increase the capacity of the stability chambers by ensuring temperature uniformity even when the shelves are full, allowing for testing of larger sample batches. Samples can be tested in a stability chamber for anywhere from one week, to six months, to one year or more depending on the type of testing being conducted. If a chamber breaks down, the pharmaceutical lab has potentially lost months of work and will be set back in their timeline, prolonging the time it takes for the drug to get to market. Stability chambers used for stability testing in the pharmaceutical industry must be durable and their long-term performance should be rigorously tested.

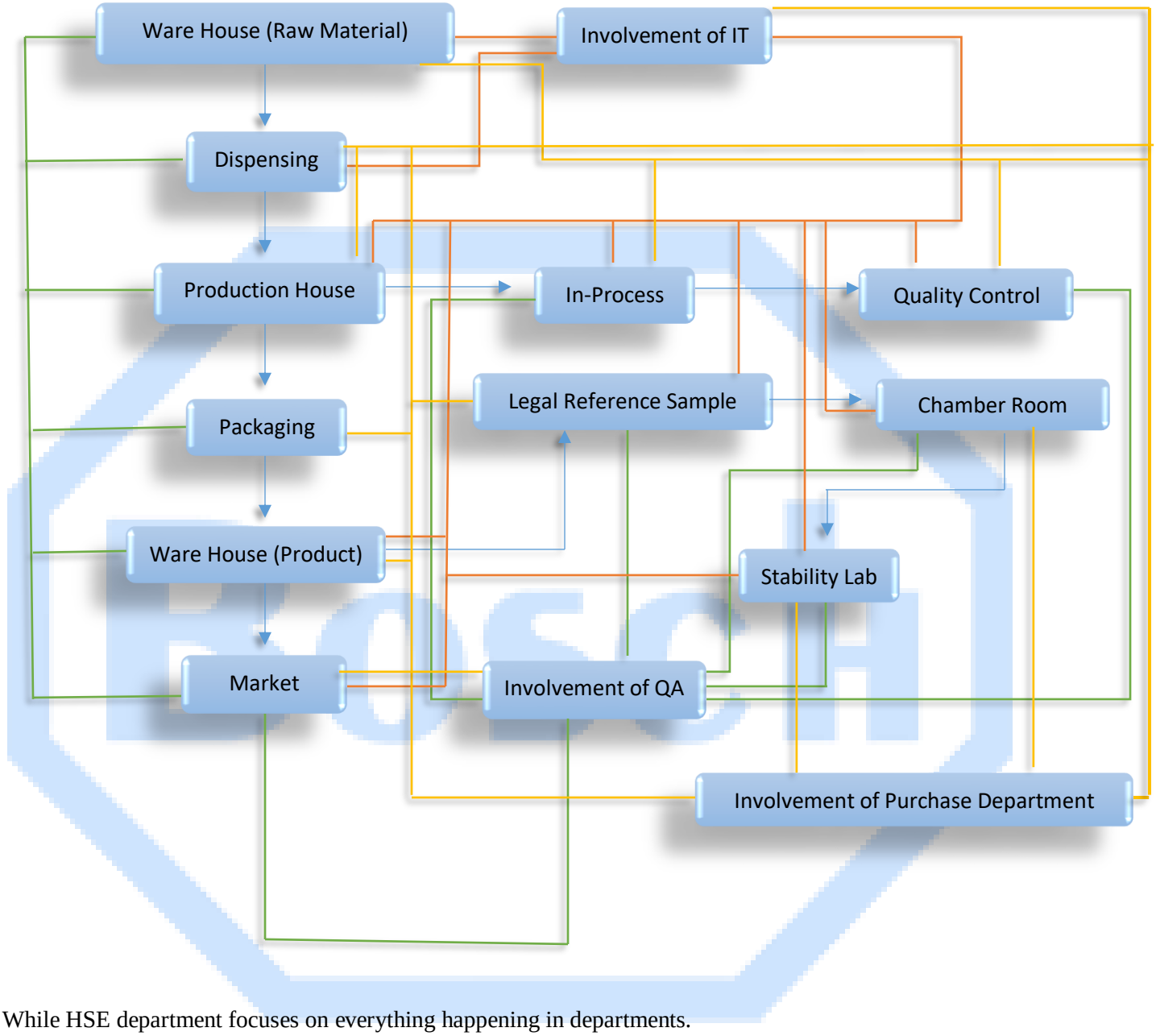
Additional features can help pharmaceutical labs feel safe when using a stability chamber. For example, high and low temperature alarms can warn users as to when the temperature is deviating. Even better, remote monitoring systems allow users to track the conditions inside the chamber even when they are not in the lab. Photo stability testing evaluates whether unacceptable changes happen to a drug product when it is exposed to a

combination of white light and ultra-violet (UV) light. Stability chambers used for this type of testing need to provide ideal light emissions to meet the ICH requirements of guideline Q1B—they must be able to maintain light exposure of more than 1.2 million lux hours and emit more than 200 watts of UV energy to samples. Unlike stability testing for temperature and humidity, photo stability testing can be completed in as little as one week and specific units can be programmed so that the light shuts off when the required exposure has been reached.

One concern when performing photo stability testing is safety. Exposure to UV light can be damaging to an individual's eyes and should be avoided. Chambers where the light switches off automatically when the door is opened will help prevent exposure to UV light and keep your workers safe. Stability testing for the pharmaceutical industry requires a major time investment and choosing the right instrument should not be taken lightly. Stability chambers used to test drugs for stability under varying temperature, humidity, and light exposure need to be reliable, stable, and adhere to ICH guidelines. Stability chambers from Thermo Fisher Scientific fulfill these needs as they maintain consistent temperature over time and throughout the chamber using horizontal laminar air flow and adhere to ICH guidelines and to your needs.[8]


thermoscientific
3900 Series

The whole chain from raw material to product looks like as below:



While HSE department focuses on everything happening in departments.

Administration department controls all department activities and all cleaning and employee activities.

Chapter # 5
"Optical Section"

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This department doesn't only fill ampules but check it manually throughout workers in light and in dark, this department also performs every test which justifies its strength and reliability of product. They don't only check ampules but also check vials by taking weight and volume and looking out for cracks. Glass ampoules have been widely used in packaging injection drugs. Glass has important characteristics that allow it to be widely used in fabrication of recipients for drugs and other sterile substances. However, contamination of solutions with glass micro particles on breaking open glass ampoules, the presence of metals, percutaneous injury, and biological contamination justify the need of educational materials to orient the manipulation of ampoules. Glass micro particles generated in the snap-opening of ampoules, as well as metals that contaminate their contents can be aspirated and injected through several routes. Exogenous contaminations by glass and metals can reach several sites in the organism. They trigger organic reactions that may give rise to injuries. Opening ampoules can expose professionals to the risk of percutaneous injuries. These lesions increase the biological risk as they are the gateway for viruses and bacteria. Ampoules opening systems (VIBRAC and OPC) have been developed to reduce the incidence of such accidents. Alternative materials to glass may represent an interesting strategy to increase safety. The use of prefilled syringes may represent an evolution regarding safety.

They check ampules of 1cc to 10cc.

Although they were checking ampules and vials manually but there should be instrumental checking too but it is performed in QC, but make sure that instead of QC this department comes under QA so if production has any fault so instead of hiding it QA will take notice of it.

Chapter # 6
"Legal Reference Sample"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

We can say that this is the last step of whole chain process when the cartons of product are delivered for marketing, a batch is selected from it which is then stored for some specific days in some specific conditions under required temperature and humidity. Those batches are stored here and later when stability lab asks for testing from any of these batches legal reference sampling department provide it.

But it provides for two conditions:

1. Return
2. Non return

1. **Return:**
   It means that batch is providing for just checking inserts, leaflets and printing or QR Code, in this case taken batch is always return.

2. **Non Return:**
   It means that the batch is providing for non-return purpose, which means that it is for testing where is actually consumes.

A sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analyzed should the need arise during the shelf life of the batch concerned. Where stability permits, reference samples from critical intermediate stages (e.g. those requiring analytical testing and release) or intermediates, that are transported outside of the manufacturer's control, should be kept. The batch is stored for 1 year plus expiry after that it is discarded. Stability lab always ask for batches for shelf life testing. This department also comes in under of QA.

A sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labelling, patient information leaflet, batch number, expiry date should the need arise during the shelf life of the batch concerned.

For finished products, in many instances the reference and retention samples will be presented identically, i.e. as fully packaged units. In such circumstances, reference and retention samples may be regarded as interchangeable.

It is necessary for the manufacturer, importer or site of batch release, to keep reference and/or retention samples from each batch of finished product and, for the manufacturer to keep a reference sample from a batch of starting material and/or intermediate product. Each packaging site should keep reference samples of each batch of primary and printed packaging materials. Records of traceability of samples should be maintained and be available for review by competent authorities. Reference and retention samples from each batch of finished product should be retained for at least one year after the expiry date. The reference sample should be of sufficient size to permit the carrying out, on, at least, two occasions, of the full analytical controls on the batch in accordance with the Marketing Authorization File which has been assessed and approved by the relevant Competent Authority / Authorities. Storage of reference samples of finished products and active substances should be in accordance with the labelling requirements and should be in accordance with the marketing authorization.

Chapter # 7
"Engineering Department"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

The engineering department mainly focuses on the production of distilled water, loop water and WFI. It has HVAC systems in two different rooms.

HVAC stands for heating, ventilation, and air conditioning. This system provides heating and cooling to residential and commercial buildings. They used gas filled sealer (2) and air cooler sealer (3) to provide required temperature. Beside that they use air handling units (AHU) for required temperature and humidity during process and also munters humidifier for required humidity, a compressor is also needed and a boiler too.

7.1 Working of HVAC system:

The three main functions of an HVAC system are interrelated, especially when providing acceptable indoor air quality and thermal comfort. Your heating and air conditioning system is often one of the most complicated and extensive systems in your home, but when it stops working you'll know soon enough! There are nine parts to your HVAC system that you should be familiar with the air return, filter, exhaust outlets, ducts, electrical elements, outdoor unit, compressor, coils and blower.

- **Air Return:**
  Your air return is the part of your system that marks the starting point of the ventilation cycle. This return sucks in air, draws it through a filter, and then passes it into the main system. Pro tip: Make sure to dust your returns frequently as debris and dust can easily build up on your filters.

- **Filter:**
  Your filter is the second part of the air return in which the air is drawn through. Pro tip: Make sure to change your filters regularly to keep your system in tip-top shape.

- **Exhaust Outlets:**
  Another part of your system is the exhaust outlets where the exhaust created by the heating system is expelled. Pro tip: Check your chimney flue or vent stack annually and tune it up if necessary.

- **Ducts:**
  Your ducts are the channels in which the heated or cooled air passes through. Pro tip: Get your ducts cleaned every 2 to 5 years in order to keep everything in working condition.

- **Electrical Elements:**
  This part of your system can be a bit trickier, but often problems originate here first. Pro tip: If something isn't working right check for a tripped breaker or dead batteries in your thermostat.

- **Outdoor Unit:**
  This is likely the part of your system you think of when someone mentions an HVAC system. The outdoor unit houses the fan which provides air flow. Pro tip: Keep your unit clear of debris and vegetation as it can cause serious problems if plants are sucked into your fan.

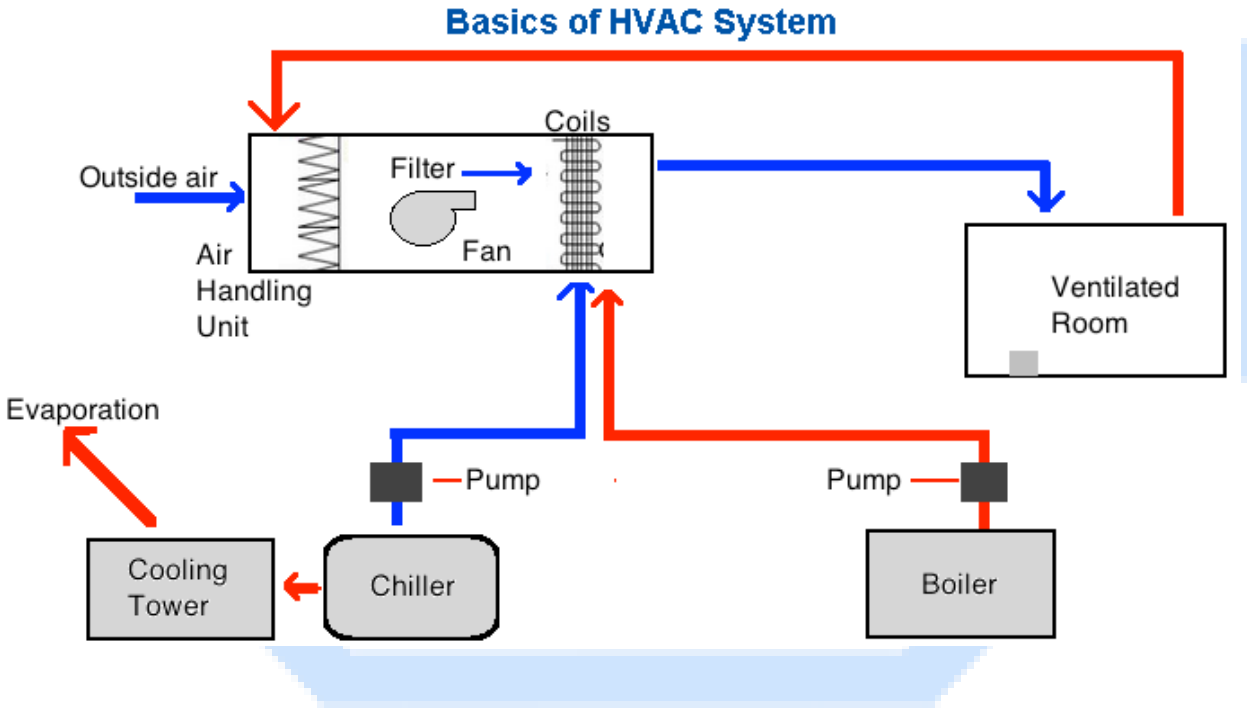
- **Compressor:**
  As a part of the outdoor unit, the compressor is responsible for converting refrigerant from a gas to liquid and sends it to the coils. Pro tip: If something isn't working quite right, check your compressor. It is often the cause of many system failures.

- **Coils:**
  Usually another part of the outdoor unit, coils cool the air as it passes through with a little help from the refrigerant. Pro tip: Check your coils annually. If they freeze up, you may want to check your filter and/or refrigerant levels.

- **Blower:**
  The blower draws in warm air through the main section of the unit. Pro tip: The more efficiently this air moves through, the more durable your system will be.

What Is the Difference Between HVAC and Air Conditioning?

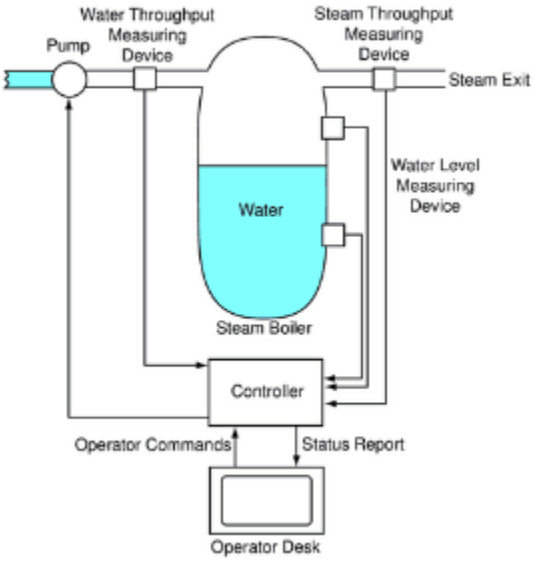
The difference between HVAC and air conditioning, air conditioning is actually the last portion of what HVAC stands for, but they are often used interchangeably in reference to any type of heating or cooling device in a home. Think about HVAC as the overarching term and air conditioning as one piece of the puzzle. [9]



7.2 Boiler:

The basic working principle of boiler is very simple and easy to understand. The boiler is essentially a closed vessel inside which water is stored. Fuel (generally coal) is burnt in a furnace and hot gasses are produced. These hot gasses come in contact with water vessel where the heat of these hot gases transfer to the water and consequently steam is produced in the boiler.

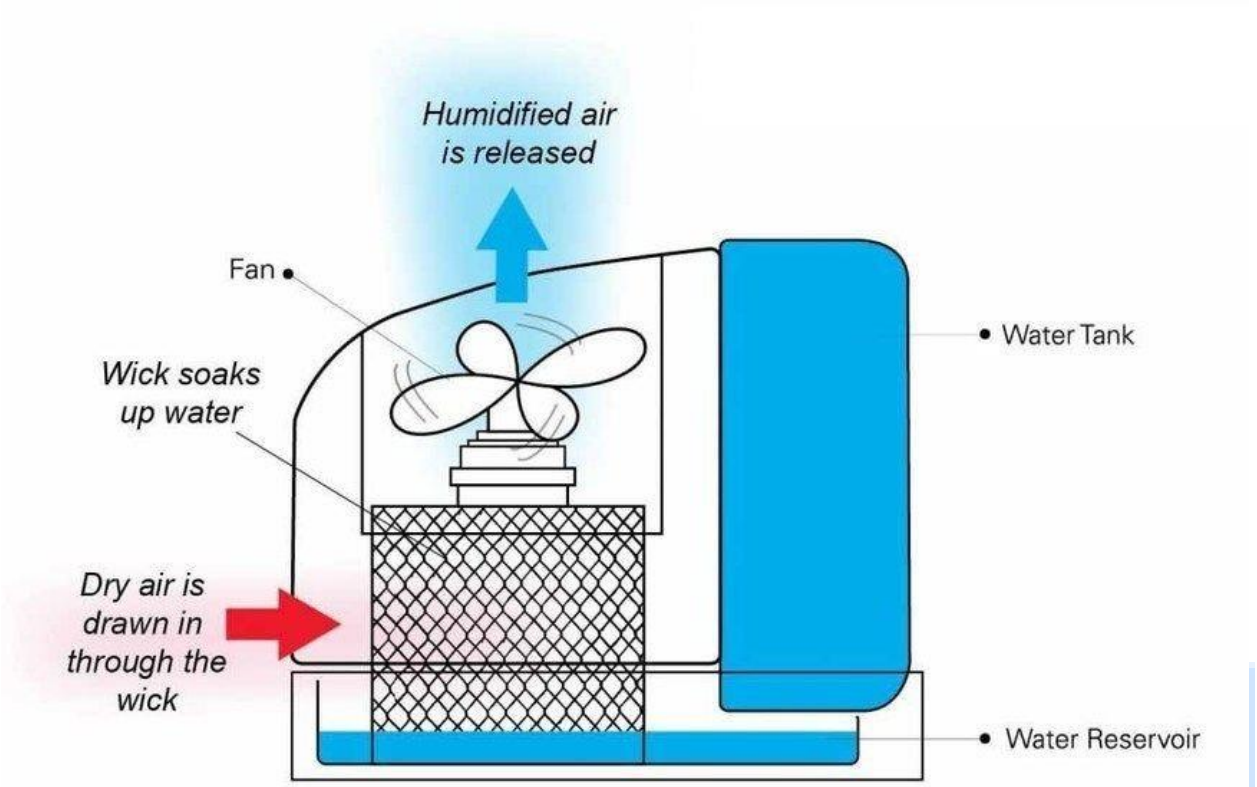
Then this steam is piped to the turbine of thermal power plant. There are many different types of boiler utilized for different purposes like running a production unit, sanitizing some area, sterilizing equipment, to warm up the surroundings etc.



7.3 Humidifier:

Humidity is defined as the amount of moisture in the air. If you are standing in the bathroom after a hot shower and can see the steam hanging in the air, or if you are outside after a heavy rain, then you are in an area of high humidity. If you are standing in the middle of a desert that has not seen rainfall for two months, or if you are breathing air out of a SCUBA tank, then you are experiencing low humidity. Air contains a certain amount of water vapor. The amount of water vapor any mass of air can contain depends on the temperature of that air: The warmer the air is; the more water it can hold. A low relative humidity means that the air is dry and could hold a lot more moisture at that temperature. The most common type of humidifier is called an evaporative humidifier. This type of humidifier is actually quite simple and, for the most part, self-regulating. A reservoir holds cold water and dispenses it into a basin. A wicking filter absorbs the water from the basin. A fan then blows air through the moistened filter. As the air passes through the filter, it evaporates some of the water there. The higher the relative humidity, the harder it is to evaporate water from the filter, which is why a humidifier is self-regulating -- as humidity increases, the humidifier's water-vapor output naturally decreases.

Sometimes an evaporative humidifier will be hooked up to the heating and cooling system of a house or building. These systems work in a similar way: A metal mesh or screen is located in the duct coming from the furnace and/or air conditioner; water from the building's pipes flows down the screen; as air coming from the duct blows across the screen, it picks up moisture.



7.4 Production of WFI:

This process involves a shell and tube heat exchangers (columns) where heat transfer is done by falling film evaporation. Very high temperatures are reached for every drop of water produced, thus ensuring sterility levels demanded for WFI. Separation of the Pyrogenic load is achieved through centrifugal forces generated during the upward movement of the steam. During the process, the feed and distilled water within the plant is in constant motion and hence there is no stagnancy. Impurities, along with the Pyrogenic load, are continuously purged from the last column. At start-up during pre-heating and self-sanitizing the residual accumulated water will also drain off before WFI is produced. Our plant is designed to be crevice-free as crevices promote stagnation and stimulate bacterial growth. All columns are designed to ASME specifications and are approved by CE for PED regulations as per European Union requirements. All parts in the plant coming into contact with WFI and Pure Steam are electro polished, pipe joints are orbitally welded, gaskets are made from pure Teflon or pharmaceutical-grade silicon and the first column is a double tube sheet designed to prevent pure steam mixing with plant steam, should there be a weld joint failure in the tube sheet. This state-of-the-art system delivers WFI of a quality standard for storage and distribution that is, much higher than what is desired by pharmacopoeias throughout the world. [10]

7.5 Production of Distilled water:

The principle for operation of a distiller is simple. Water is heated to boiling in an enclosed container. As the water evaporates, inorganic chemicals, large non-volatile organic chemicals, and microorganisms are left behind or killed off in the boiling chamber. The steam then enters condensing coils or a chamber where the steam is cooled by air or water and condenses back to a liquid. Also called stills, distillation units generally consist of a boiling chamber (where the water enters, is heated, and vaporized), condensing coils or chamber (where the water is cooled and converted back to liquid), and a storage tank for treated water. Distillation units are usually installed as point-of-use (POU) systems that are placed near the kitchen faucet and used to purify water for drinking and cooking only. Home stills can be located on the counter or floor, or attached to the wall, depending on size. Models can be manual, partially automated, or fully automated. Distillers vary from small, round units that distill less than one quart of water per hour to rectangular carts that distill about one-half gallon of water per hour. As with all home water treatment systems, distillation units require some level of regular maintenance to keep the unit operating properly. Contaminants left in the boiling chamber need to be regularly flushed out. Even with regular removal of the brackish (saline) residues, calcium and magnesium scale will quickly collect at the bottom of the boiling chamber. Over time, this scale reduces heat transfer and should regularly be removed either by hand scrubbing or by soaking with acetic acid. Vinegar is commonly used to clean home distillers. Although minerals that can cause corrosion and scaling are removed during distillation, distilled (and RO) water is very corrosive (aggressive). It should not be stored or transferred in metal pipes. [11]

Chapter # 8

"Packaging Area or White House"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

The pharmaceutical industry requires safe and secure packaging to maintain the identification and stability of the drugs. The packaging must provide proper protection and reduce the risk of contamination. The drugs should not react chemically and physically with the contents, or it could increase the possibility of toxicity. The packaging of pharmaceutical products means protection, information, and ease. The containers, cartons, closures, and boxes are a form of typical packaging. The glass, metal, plastic, metal materials are used for closures. There are various testing instruments to keep the integrity, quality, and compatibility of packaging materials. The type of pharmaceutical materials helps to decide the requirements and specification of quality testing.

The containers are tested for chemical resistance, water resistance; the closure is tested for transparency tester, seal ability, etc. A good packaging maintains the therapeutic effectiveness of the medicines till the time they are consumed. A good packaging is an art which includes storage, transportation and article preparation.

8.1 What is an Ideal Packaging?

An ideal packaging keeps the product safe without spoiling or leaking the actual products. Protection from environmental conditions is vital such as moisture, air, and light at the time of storage. Gas permeability is another critical factor. For tolerating the shocks of transportation, packages require good strength resistance.

8.2 What is an ideal packaging container?

Ensure to select containers with a comprehensive care after considering the nature or type of the articles. A container must be chosen after considering the effects of storage and transportation. The design of container must allow proper removal of the materials and must provide high safety to prevent loss of constituents. The container must not have any chemical and physical impact with the contents. Any contamination of the drugs is an invitation of toxicity. Prefer airtight container that is resistant to liquids, gases, and solids during handling, shipment, and storage. If the container needs to be opened for more than one time, remember to check the airtight feature when closed again. The container must be resistant to air or any other gases. Water absorption and moisture resistance protect the contents from being spoiled. The crushing, bursting, and compression resistance adds more protections against damage to contents packed inside. The testing equipment is intended to provide secure and safe transportation of sensitive goods like medicines, and food items to prevent the risk of contamination as well as toxicity. The pharmaceutical industry using advanced testing machines for providing the excellent protection to the drugs, so consumers do not face any health hazard.

In Bosch Pharmaceuticals PVT LTD packaging is done both manually and through mechanical system.

8.3 Types of Packaging:

Different kinds of packaging are:

- Primary
- Secondary
- Tertiary

Product packaging involves various layers of materials, classified as follows:

8.3.1 Primary, sales, or consumption-unit packaging:

Primary packaging contains, stores, and protects a product. It is in direct contact with the item and serves to maintain it in optimal conditions. This packaging designates the smallest consumption unit, facilitating the unit sale of the merchandise. It takes on very diverse forms: cans, jars, sacks, bottles, bags, etc. Primary packaging carries out the following functions:

- Identify the product in line with current regulations and display the instructions for use, as well as other essential data such as the expiration date.
- Identify the brand and increase consumer appeal (depending on the product).
- Ensure the merchandise remains in a stable position in its sale location in the store (make sure it doesn't fall).
- Guarantee that the contents are isolated.
- Protect the goods using the minimum possible material.

8.3.2 Secondary or grouped packaging:

Secondary packaging consists of the grouping together of primary packaging. It adds more protection and facilitates the marketing of the product on a larger scale. This packaging mostly comprises cardboard boxes, although they can also be plastic. For example, in the case of milk, an individual carton would be primary packaging, while the cardboard box containing the pack of cartons would account for secondary packaging. Secondary packaging is tasked with the following:

- Be resistant to stacking (in the warehouse and at points of sale) and to handling during transportation so as to protect the product from damage.
- Contain a specific amount of product.
- Attract customers' attention, especially for secondary packaging intended to be sold directly to the general public.

8.3.3 Tertiary packaging:

Tertiary packaging includes primary and secondary packaging to, thus, create larger unit loads, the most common forms of which are pallets, containers, and the modular cardboard boxes that they contain. The functions and characteristics of tertiary packaging comprise the following:

- Remain stable and enable loads to be stored compactly.
- Leverage the storage capacity of the installations and industrial vehicles.
- Be authorized for use and made of resistant materials.
- On occasion, tertiary packaging can also perform a significant role in relation to the brand's image. This is especially true for e-commerce logistics, where the box or packaging employed in transportation is tertiary and can include visual brand elements. An example of this is Amazon's easily recognizable parcels.

8.4 Blistering

For Blistering of Capsules and Tablets the most common equipment we used here is called High-speed Card Packaging machine.

Beside this I will also discuss how many types of blistering machines are available. Based on their operation process, the blister packaging machine is divided into three distinct categories.

These are:

- Roller type blister packaging machine
- Roller plate blister packaging machine
- Flat plate blister packaging machine (we are using this)

8.4.1 Roller type blister machine:

The working rule of the roller blister packing machines is quite simple. The forming film is heated and softened by the heating device. The blister is then sucked by the negative vacuum pressure on the roller forming molding roller, and therefore the filling device fills the packaged object into the blister, then passes through the roller type. The heat sealing device seals the single-sided adhesive-coated cover film on the surface of the blister material at an appropriate temperature and pressure and seals the packaged object within the blister.

8.4.2 Roller plate blister sealing machine:

The roller plate type blister packaging machine is developed with the foundation of a roller type and flat type blister packaging machine. That is, a flat type molding device is employed for blow molding (positive pressure forming), and a roll type sealing device is sealed, and its blister packaging machine working principle is essentially the same.

8.4.3 Flat blister sealing machine:

The working rule of the flat forming blister machine: The formed film is heated and softened by the flat heating device. The softened film is blown into a blister by using compressed gas within the flat forming device, and therefore the filling device fills the package into the blister. Then, it's sent to the flat sealing device, and therefore the cover film is sealed with the formed film under suitable temperature and pressure, then the batch number is printed, and thus the broken line is pressed by the typing imprinting device. Finally, the punching device is punched into a predetermined size product section. On here we used Temperature of 155°C to 170°C with relative humidity in room 46%

8.5 Blister Machine Working Principle:

Regardless of the type, the blister packaging machine process is almost the same. In the above process, among machines, the most important difference is predicated on a blister forming device and the heat-sealing device. The blister forming is split into drum type and flat-plate type. Flat-plate type of blister forming device generally performs better than the drum type. Heat-sealing is additionally divided into drum type and a flat-plate type. Regarding the heat-sealing effect, the flat-plate type is better than the drum type, while the drum type has advantages in speed and reliability. The above blister packaging process is often completed by

manual operation, semi-automatic operation, or automatic operation. For large scale production volume of blister packaging, relatively fixed variety, and therefore the demand for safe and sanitary, it's advisable to use an automatic packaging line for production. Additionally, automatic blister packaging machines are often connected with automatic printer, manual inserting machine, boxing machine. for an automated blister packaging line, to save lots of labor and time.

8.5.1 Advantages:

If you are in food, drugs, or chemical industries, chances are you may not be sure whether to buy a blister packaging machine or not. To make things crystal clear, here are the top benefits of using a blister packaging machine:

8.5.1.1 Guarantees product integrity:

At this point, you can tell that this blister packing is used for very sensitive applications. They include food and drug industries. Blister packs provide an air-tight seal to the products. They won't be exposed to moisture nor air. In doing so, the end product will retain its quality.

8.5.1.2 Tamper proof:

Lister packages cannot be interfered with by any external physical forces. This also goes a long way in preserving the integrity of the pills and capsules.

8.5.1.3 Cost-effective:

Blister packaging can save you a significant amount of money, especially when you want to cut down on the cost of packing capsules and pills. It is cheaper than plastic packaging.

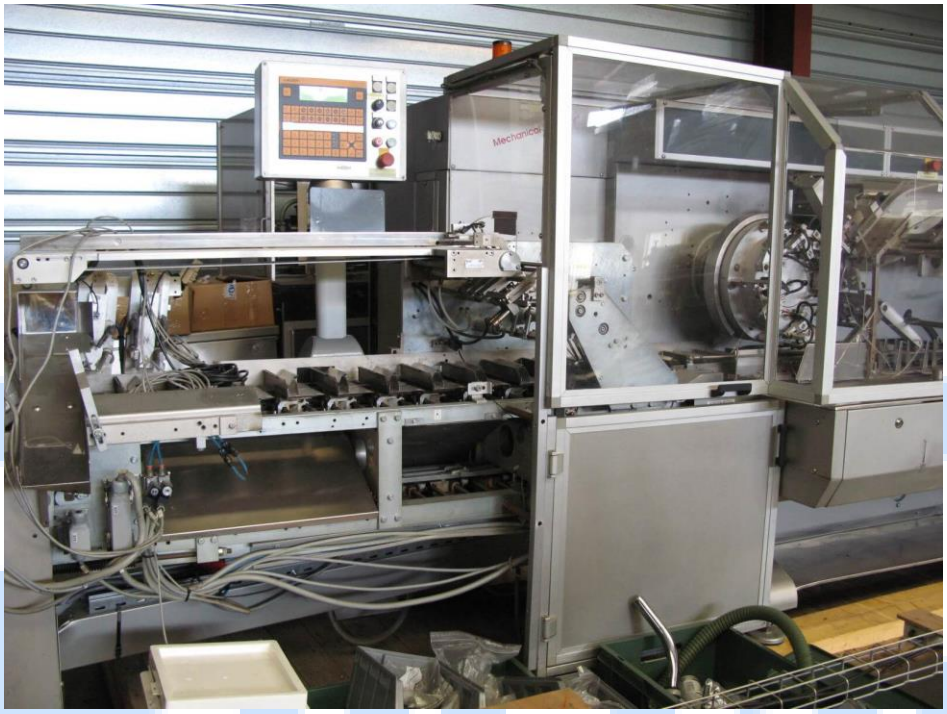
8.5.1.4 Accurate dosage: Since the pills and tablets are in their designated packages, maintaining the accuracy of the dosage won't be a challenge in any way. It will be easy for one to keep track of the drug dosage.

8.5.1.5 Improves identification:

As we have stated, labeling is one of the activities that are highlighted by the blister packing machine process. It ensures that the products are easily identified by their names among other information.

8.6 Cartoning:

In cartoning process we used Cam Carton instrument.



This instrument completely works on sensors. It senses cartons and then filled those blistered tablets or capsules in it.

8.6.1 Working:

Here Carton erection, carried-out by means of an articulated twin blade inserted into the carton ensuring positive pre-breaking, allows low grammage board to be used even when handling square-section formats or carton with glueing and creasing imperfections. Perfect product introduction (even for products with irregular shape/dimensions) is guaranteed by the insertion of the moveable mouthpiece inside the carton, avoiding any uncontrolled passage of product from bucket to carton. Products are also prevented from straying out of the carton by the action of the spring loaded guides which automatically close during the return stroke of the pusher. The use of closed profile cams with surface hardening treatment, guarantees the reliability of all positive driven movements during the course of time.

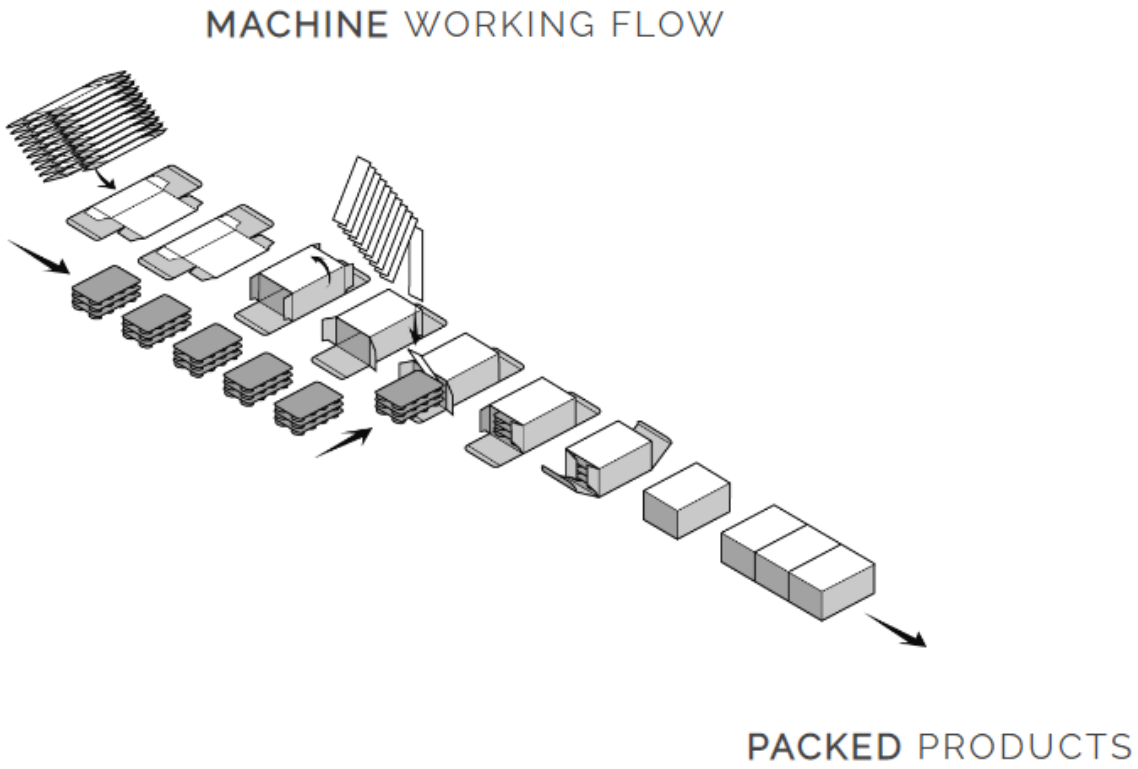
Particular attention has been given to machine cleaning below the carton transport area, where possible product or packaging material residue is conveyed to easily accessible collection areas. The cartoner can be equipped with a complete range of product feeding systems and additional

units, such as: coders, leaflet and booklet feeders, detection and reject devices, etc. As on all CAM machinery, the PMM is also equipped with the Mechanical Memory® system, transforming complete size change-over into a series of rapid and pre-set operations, which can be carried-out by unskilled personnel allowing production to be resumed immediately without the need for fine-tuning adjustments. This also insert the insert paper in cartoning.

TECHNICAL DATA

Mechanical speed	**STROKES/1'**	25÷140
Motors	**KW**	0.92
Power absorption	**KW**	1.55 (Hot-melt + 3.9)
Air consumption	**Nl/1'**	16.9
Air pressure	**bar**	5÷6
Gross weight	**kg**	~1400
Net weight	**kg**	~1050

Size range	**min.**	**max.**
A	15	90
B	12	70
C	50	200
A + B	-	140



With every turn 10 cartons are checked which should be weight 120 gm then they are moved to storage in another big carton which is moved to ware house. In packaging department rpm used is 70.

8.7 Pouching:

Pouching is done for light sensitive products such as QBAL, BOSHCAM and RABOSH. In this ampules and tablets are first packed in pouch to protect them from light then they are subjected to cartoning process.

8.7 Vials and Bottles cartoning machine:

This equipment was used in packaging department for cartoning of vials and bottles, both manual and automatic cartoning is done here and passes are sticks on batch.

Approximately 4000 vials, 2000 to 3000 injectable and 3000 of capsules and tablets is output of each packaging sub section in whole White house packaging section.

Chapter # 9
"Purchase Department"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

All businesses need specific goods, materials and equipment to manufacture products, offer goods for sale to customers, or perform the services they are selling. Someone has to ensure that these goods are bought into the company, in the right volume and at the right time, to meet the company's requirements. That role falls to the purchasing, or purchase, department.

The role itself is a broad one, covering such areas as market analysis, negotiations with suppliers and producers, transport, storage options, procurement technologies and order times to ensure that goods are bought as economically and time-efficiently as possible. Specific functions include:

- Identifying requirements for goods, materials and services.
- Identifying reliable suppliers.
- Price negotiations.
- Comparison of delivery terms.
- Establishing order quantities.
- Writing requests for bids and awarding supply contracts.
- Coordinating delivery with the warehouse against storage capacities.
- Product testing and quality control.
- Managing budgets and payments.

Purchase department in Bosch pharma works on these basic principle:

1. Find out price (chemicals, equipment or any other necessary thing to run business)
2. Provide pricing papers to director for approval
3. Confirmation of papers from Director Ware house, QA and QC
4. Storage in Ware House

   This is short procedure.

Purchasing departments handle all of the paperwork involved with purchasing and delivery of supplies and materials. Purchasing ensures timely delivery of materials from vendors, generates and tracks purchase orders and works alongside the receiving department and the accounts payable department to ensure that promised deliveries were received in full and are being paid for on time. In a small business, this means working closely with the accounting department to ensure that there is sufficient capital to buy the items purchased and that cash is flowing smoothly and all payments are made on time.

The purchasing department also must ensure that it is complying with all company policies. For example, in a small business, individual staff members may communicate with the purchasing department about purchasing needs for things such as office supplies or computers. Before making a purchase, the purchasing department must ensure that it heeds the proper protocols for purchase and budget approval and must ensure that any items are purchased in accordance with the overall purchasing policy of the organization.

Purchasing is responsible for the procurement process. This means it ensures the supply of goods, production materials and equipment so that a smooth production and sales process can take place.

For this, goods must be procured at the right time, in the right quantity, and of the right quantity. If the purchasing process falls down, there's a risk that the business will not be able to manufacture products or keep the shelves stocked with sufficient volume to meet customer demand.

8.1 Strategic Vs. Operational Role of the Purchase Department

Since the role of the purchase department is so varied, we tend to divide it up into two sub-functions: strategic purchasing and operational purchasing.

Strategic purchasing is responsible for planning all the high-level tasks and decisions that go hand in hand with procurement. In this role, the purchase department will set the overall direction of procurement based on the company's needs and goals, evaluate suppliers and develop long-term relationships across the supply chain. The objective is to source goods as economically as possible whilst ensuring the lowest possible risk to the business. This might include decisions about whether the products or components are manufactured in-house or purchased from external suppliers.

Operational purchasing, also known as tactical purchasing, takes care of the administrative aspects of purchasing. It's a short-term, transactional role which focuses on repeat ordering, receiving inventory and invoice payments as well as the handling of returns and complaints. With its operational hat on, the purchasing department will be more concerned with keeping the production line running than with understanding supplier capabilities or supporting the company's long-term needs.

Now that you know what the purchase department is, let's look at some of its key roles and functions.

8.1.1 Needs and Supplier Analysis:

The starting point for strategic purchasing is to benchmark how the business is currently performing, how resources are being used, and what the purchasing costs are per department, team or job function. The purchase department will then look at the company's growth trajectory and come up with a plan to help the business perform better and/ or save costs.

At the same time, the purchasing department will analyze the supplier's market to see if the company is using the right supplier, at the right price point, to meet its business

needs. The team might compare multiple suppliers, including those based in other countries, to prepare a shortlist of possible suppliers.

8.1.2 Award Supplier Contracts:

Each business will have its own requirements but generally, the team will be looking at each supplier's cost, quality, reputation, reliability, production capacity and delivery schedules before awarding a supplier contract. Technological capability may be a consideration in some industries. A supplier's inability to meet any of these requirements could result in significant losses for the company so it's important to get these decisions right. In large companies, the department might also be making decisions about whether to make the products in-house.

Finding the right goods at the right price can be complex and time-consuming, and the purchasing department may use a competitive tender (bidding) process to choose a supplier. This normally involves the issue of a "Request for Proposal" which invites interested suppliers to submit a quote or bid and explain how they meet the selection criteria.

The team might also call for financial statements, references and credit reports so they can assess the health of the bidding company. Price negotiations may follow as the purchasing department tries to achieve the best possible unit price. This might include negotiating discounts based on volume, tiered or graduated pricing depending on the company's needs.

8.1.3 Supplier Selection and Relationships:

It's not unusual for larger companies to have multiple suppliers on their books, and an essential role of the purchase department is to manage and maintain these relationships. Close cooperation with key suppliers means you can share knowledge about market shifts, new products and technologies or other factors that could help you stay ahead of the competition.

A retail business, for example, should be sharing feedback from customers about existing products and using this knowledge to innovate new and improved product offerings.

8.1.4 Ordering and Inventory Control:

At the operational level, it's essential to have the right quantities of raw materials in the warehouse or the right quantities of products on the shelf at exactly the time when the customer walks through the door. Running out of products means you lose sales and your customers may turn to competitors to get the products they need.

Overstocking means you potentially will have to pay more in storage costs and you run the risk of the product becoming obsolete before you have the opportunity to use

or sell it. Generally, the purchasing department will have systems in place which trigger a stock order whenever a certain quantity of inventory is reached. For those that use a merchandise management system, the minimum stock and the order quantity are generally predefined and are automatically ordered by the software. This means a well-stocked warehouse is guaranteed, and the purchase department can focus on checking items and invoices for accuracy, and coordinating delivery dates with the warehouse team.

8.1.5 Compliance and Quality Control:

Quality control is an essential part of the procurement process. The purchase department needs to continually inspect the quality, performance and reliability of the supplier to ensure they do not lapse into complacency. For suppliers in other countries, this might include monitoring workers' right, compensation and working conditions. It's important to be clear where accountability lies. It's often said that "what gets measured gets done." One essential role of the purchasing department is to analyze and measure performance data to ensure that suppliers are achieving the desired outcomes, in accordance with the company's procurement strategy. For example, the department might measure:

8.1.5.1 The percentage of products delivered on time.
8.1.5.2 The number of suppliers used and how much product they supply.
8.1.5.3 Supplier availability.
8.1.5.4 Lead times.
8.1.5.5 Product defect rates.

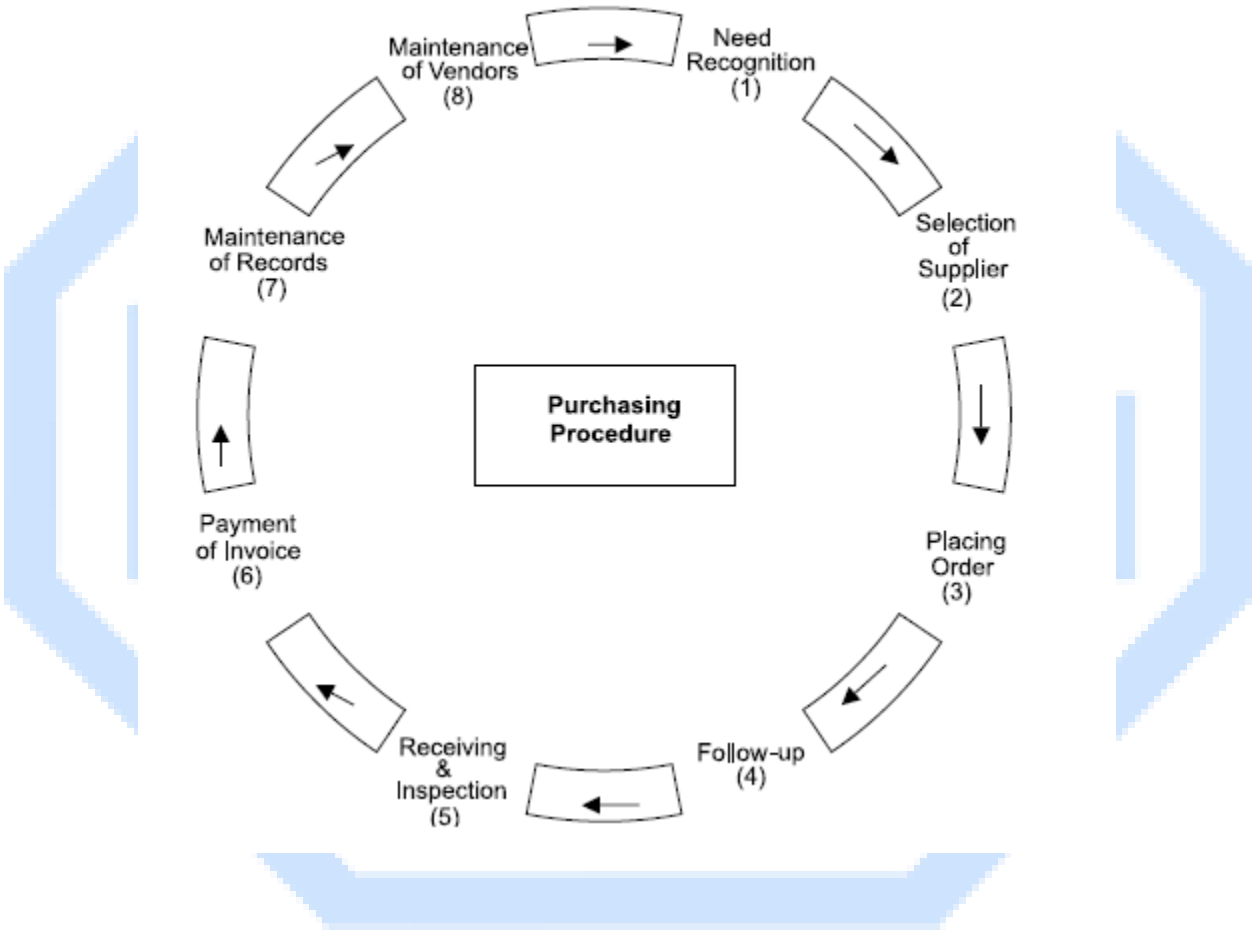
These metrics enable the purchase department to assess how well suppliers are fulfilling the company's requirements, how well they respond to urgent demand, and whether to company is over-relying on just one or two key suppliers which could leave the company vulnerable if the supplier goes bust. Armed with this data, the purchasing department can then revisit the strategic plan and make adjustments as necessary.

8.2 Purchasing Department Staff

At the top of the purchasing department, there is a purchasing manager who supervises the department staff and works closely with the organization executive do plan and oversee the budget. The purchasing manager has to maintain close communications with department heads to better understand their needs and the role their purchases play in the

company. For instance, a purchasing manager for an online retailer needs to have a working knowledge of the way network servers play the company's operational workflow. Purchasing officers, purchasing agents, and buyers all work under the supervision of the purchasing manager. Their duties and responsibilities may vary depending on an organization's size and priorities. A purchasing agent for a pharmaceutical company may focus on purchasing the chemicals used in manufacturing specific drugs. A purchasing agent for a mortgage broker may handle for curing goods and services that range from necessary office supplies to vehicle rentals.

Purchasing procedure



Follow up procedure:

- ✓ Follow-up procedure should be employed wherever the costs and risks resulting from the delayed deliveries of materials are greater than the cost of follow-up procedure, the follow-up procedure tries to see that the purchase order is confirmed by the supplier and the delivery is promised. It is also necessary to review the outstanding orders at regular intervals and to communicate with the supplier in case of need. Generally, a routine urge

is made to the supplier by sending a printed post card or a circular letter asking him to confirm that the delivery is on the way or will be made as per agreement. In absence of any reply or unsatisfactory reply, the supplier may be contact through personal letter, phone, telegram and/or even personal visit.

8.2.1 Receiving and Inspection of material:

The receiving department receives the materials supplied by the vendor. The quantity is verified and tallied with the purchase order. The receipt of the materials is recorded on the specially designed receiving slips or forms which also specify the name of the vendor and the purchase order number. It also records any discrepancy, damaged condition of the consignment or inferiority of the materials. The purchase department is informed immediately about the receipt of the materials. Usually a copy of the receiving slip is sent to the purchase department.

8.2.2 Payment of Invoice:

When the goods are received in satisfactory condition, the invoice is checked before it is approved for the payment. The invoice is checked to see that the goods were duly authorized to purchase, they were properly ordered, they are priced as per the agreed terms, the quantity and quality confirm to the order, the calculations are arithmetically correct etc.

8.2.3 Maintenance of Record:

Maintenance of the records is an important part and parcel of the efficient purchase function. In the industrial firms, most of the purchases are repeat orders and hence the past records serve as a good guide for the future action. They are very useful for deciding the timings of the purchases and in selecting the best source of the supply.

8.2.4 Maintenance of Vendo relationship:

The quantum and frequency of the transactions with the same key suppliers provide a platform for the purchase department to establish and maintain good relations with them. Good relations develop mutual trust and confidence in the course of the time which is beneficial to both the parties. The efficiency of the purchase department can be measured by the amount of the goodwill it has with its suppliers.

8.2.5 Selection of Suppliers:

Selection of the right supplier is the responsibility of the purchase department. It can contribute substantially to the fundamental objectives of the business enterprise. Different strategies are required for acquiring different types of materials. The selection of supplier for standardized products will differ from non-standardized products. Following factors are considered for the selection of suppliers:

8.2.6 Sources of suppliers:

The best buying is possible only when the decision maker is familiar with all possible sources of supply and their respective terms and conditions. The purchase department should try to locate the appropriate sources of the supplier of various types of materials. This is known as 'survey stage'. A survey of the following will help in developing the possible sources of supply:

- Specialized trade directories.
- Assistance of professional bodies or consultants.
- The buyer's guide or purchase handbook.
- The manufacturer's or distributor's catalogue.
- Advertisements in dailies.
- Advertisement in specialized trade journals.
- Trade fair exhibitions.

8.2.7 Development of Approved list of suppliers:

The survey stage highlights the existence of the source. A business inquiry is made with the appropriate supplier. It is known as 'Inquiry Stage'. Here a short listing is made out of the given sources of suppliers in terms of production facilities and capacity, financial standing, product quality, possibility of timely supply, technical competence, manufacturing efficiency, general business policies followed, standing in the industry, competitive attitude, and interest in buying orders etc.

8.2.8 Evaluation and Selection of suppliers:

The purchase policy and procedure differ according to the type of items to be purchased. Hence, evolution and selection of the supplier differ accordingly. In the 'purchasing handbook' edited by Aljian, it has been described that the following variables to be considered while evaluating the quotations of the suppliers:

8.2.8.1 **Cost Factors:** Price, transportation cost, installation cost if any, tooling and other operations cost, incidence of sales tax and excise duty, terms of payment and cash discount are considered in cost factor.

8.2.8.2 **Delivery:** Routing and F.O.B. terms are important in determining the point at which the title to the goods passes from vendor to the buyer and the responsibility for the payment of the payment charges.

8.2.8.3 **Design and Specification Factors:** Specification compliance, specification deviations, specification advantages, important dimensions and weights are considered in line with the demonstration of sample, experience of other users, after sale services etc.

8.2.8.4 **Legal Factors:** Legal factors include warranty, cancellation provision, patent protection, public liability, federal laws and reputation compliance.

8.2.8.5 **Vendor Rating:** The evaluation of supplier or vendor rating provides valuable information which help in improving the quality of the decision. In the vendor rating three basic aspects are considered namely quality, service and price. How much weight should be given to each of these factors is a matter of judgment and is decided according to the specific need of the organization. Quality would be the main consideration in the manufacturing of the electrical equipment while price would be the prime consideration in the product having a tense competitive market and for a company procuring its requirements under the blanket contract with agreed price, the supplier rating would be done on the basis of two variables namely quality and delivery.

8.3 Purchasing Department Duties

8.3.1 **Competitive Duties:**

Many times, state, local, or federal laws require government agencies to make certain purchases with a competitive bidding process. Some private companies use the same practice and require their purchasing department to solicit and evaluate bids before selecting the best business to supply whatever is needed. For example, a county government purchasing department may seek bids from automobile dealers to replace their police cars. And growing tech company may send a request for proposals (RFPs) to furniture companies to furnish a new department, and a distribution company may ask for bids from local contractors for the construction of a new warehouse complex. In the competitive bidding process, the procurement department opens the purchasing process to any eligible vendors and generally selects the bid based on the lowest cost. However, at times, an organization will restrict the bidding pool in a non-competitive bidding process. A television station may open and non-competitive building process purchase new cameras and include only vendors who sell only a particular brand of

equipment. Purchasing departments handle both competitive and non-competitive bidding processes. They have to collect information from company stakeholders regarding the types of goods and services required then contact vendors who could be interested in bidding and purchase advertisements to announce the bidding process. When it comes to a non-competitive bidding process, the procurement department may also have the task of choosing the qualified vendors.

8.3.2 Non-competitive Duties:

Purchasing departments often buy certain types of goods and services directly from the vendor. This type of sole-source or non-competitive purchasing requires purchasing agents to carefully research and evaluate vendors and products before making their purchase. Buyers have to assess the quality of goods or services, prices, and the vendor's ability to deliver those goods or services on time. In the case of large organizations, purchasing agents generally have to conduct extensive research on a vendor by evaluating references or financial reports to determine its ability to perform in a long-term contract. In these situations, finding the right supplier may involve visiting the vendors manufacturing plants are distribution centers to understand their fulfillment capabilities and their products. Purchasing staff may attend trade shows to stay current with the new products and vendors or go to industry conferences to learn more about the goods and services that are critical to supporting their operation. Sometimes, the purchasing department has to negotiate a contract for service to a single or multiple locations. For instance, the procurement department for a nationwide bank may negotiate a deal with a national beverage vendor to deliver soft drinks every week to all of its office locations across the country. These contracts generally include location-specific quantities and delivery times. The job's not over after the contract is negotiated. After deals are in place, the purchasing department monitors the vendor's performance to ensure they are complying with the established terms and conditions. It's also possible that purchasing agents will handle the return of any defective Goods in the processing of refund or replacement request. In some organizations, purchasing staff may manage critical operating inventories or year-end inventory reporting of property, including office furniture, company vehicles, and computer hardware.

In short Some necessary functions of Purchase Department:

1. Receiving indents
2. Assessment of demand or description of need
3. Selection of sources of supply
4. Receiving of quotation

5. Placing order
6. Making delivery at the proper time by following up the orders.
7. Verification of invoices
8. Inspection of incoming materials
9. Meeting transport requirements of incoming and outgoing materials
10. Maintaining purchasing records and files
11. Reporting to top management
12. Developing coordination among other departments
13. Creating goodwill of the organization in the eyes of the suppliers.[12]

Chapter # 10
"IT Department"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

Almost all companies, large or small, have an Information Technology -- or IT -- department that handles all the technological issues that arise. Generally, they may be viewed as the guys and gals who reboot the system or come to your station to reinstall new software. Although they perform these tasks from time to time, they're actually much more vital to the success of a business; they complete many more tasks behind the scenes than people are aware of. Here's what the IT department does.

10.1 IT Department Overview of Responsibilities:

In an overall sense, the IT Department is responsible for providing the infrastructure for automation. It implements the governance for the use of network and operating systems, and it assists the operational units by providing them the functionality they need. It's important to note that although the IT department implements and facilitates the flow of information, it doesn't create the policy that defines which information is correct or accessible to others.

10.2 The Three Major IT Functions:

- Governance refers to the implementation of operational parameters for working units and individuals' use of IT systems, architecture, and networks. The governance of the master data is based on workflow processes that integrate business rules and subject matter domain expertise. This is part of the conventional IT security as well as the data assurance for which the IT department is also responsible.

- Infrastructure refers to the hardware components, the network, the circuitry, and all other equipment necessary to make an IT system function according to the established needs and system "size" of the company.

- Functionality is perhaps the most apparent task performed by the IT department. It refers to creating and maintaining operational applications; developing, securing, and storing electronic data that belongs to the organization; and assisting in the use of software and data management to all functional areas of the organization.

10.3 IT Network Responsibilities:

The IT department oversees the installation and maintenance of computer network systems within a company. This may only require a single IT employee, or in the case of larger organizations, a team. Its primary function is to ensure that the network runs smoothly.

The IT department must evaluate and install the proper hardware and software necessary to keep the network functioning properly. This includes working within a budget that allocates the amount of money the company can afford on network devices and software. The IT department must make sure that the equipment it invests in both optimally serves the needs of the company without going over budget.

Networks can be simple or extremely complex depending upon their size and composition. In addition to staying current on trends within business technology, employees may require college degrees in a computer field to adequately handle the issues that arise in maintaining such a network.

10.3.1 Network Contingencies:

Should a network system go down, the repercussions can be costly, not just to the company and its operations, but outside entities that require products or services from the company. These outside entities could be affected and lose faith in the company's ability to provide them with what they need. The IT department must put a crisis plan in place that can be implemented should the system go down. It must be designed to put the network back up quickly or allow it to switch over to an alternate system until the necessary repairs are completed. Through the maintenance and planning of a network system, the IT department must forge professional relationships with outside vendors and industry experts. This helps the department employees perform their duties more efficiently as well as stay current on the latest technology that might be beneficial to the company for which they work.

10.3.2 Application Development:

Quite often, companies see the main role of the IT department as creating the applications that serve its core business needs. The right applications allow a business to be innovative, more productive, efficient, and to move ahead of its competitors. In many ways, this makes the IT department crucial to the success of a business. The expertise necessary to create the applications that can set a business apart from the others requires an IT department with programmers,

analysts, interface designers, database administrators, testers, and other professionals. These employees become quite knowledgeable about the operations of the business itself. As a result, they become valuable to other departments outside IT.

10.3.3 Telephony:

Most people are aware that the IT department focuses on the success of computer operations and other information technologies needs within a business. However, with many new forms of electronic communication replacing older technology, communication is being redefined and is now referred to as "telephony." This includes point to point phone calls as well as conference calls. Video and web conference also fall under this category and include other forms of technology necessary to facilitate communication: network drives, electronic mail (email), and secure servers. The IT department must fully understand how these systems work and interact with each other. The department must also ensure that these systems remain operational at all times.

10.3.4 Company Website:

The IT department is responsible for creating and maintaining the company's website. It designs the layout, creates the code, and tests the site for usability. Depending upon the needs of the company, the IT department can design the site for information only, or create a completely interactive commercial site that can sell products directly to consumers.

10.3.5 Technical Support:

Employees are familiar with having to contact the IT department for computer support. The IT department provides this service for all the users who need access to the company's computer systems. This might entail installing new software or hardware, repairing hardware that has become faulty, training employees in the use of new software, and troubleshooting problems with the system or with an individual's computer.

It's apparent that not all the IT department does is apparent - it creates and maintains so many systems that go unseen or unrecognized by employees. These services, however, are integral to the success of a business. Though they may not

be appreciated when business is running smoothly, their importance is greatly recognized when something goes wrong.

10.4 The Function of Data Management

This is another one of the IT department functions that make it indispensable. With the increasing complexity of the world of business comes an increasing amount of data that businesses have to deal with. This data also comes in multiple dimensions. A business will see traffic in many different kinds of data, including text data, audio data, and video data, among others. In order to control this data, a business will need an IT department to run something called a database. The database will allow the business to do three things:

10.4.1 Store Data:

By putting the data in a storable format, a database allows you to store vast amounts of data in a small space. Long gone are the days when data had to be stored on paper and other bulky mediums. In an age where information is power, it helps to be able to hold a lot of it conveniently.

10.4.2 Manage Data:

Data isn't very useful in its original form, known as raw data. It needs to be sorted into a meaningful form that can be meaningfully deciphered and used to make decisions in the business. The IT department provides the tools with which this data can be managed, including analyzing it and drawing conclusions from it.

10.4.3 Access Data:

No matter what kind of data your business needs to store, that data is valuable and needs to be controlled so that only the right people can have access to it. The IT department provides the security measures that will safeguard that data and prevent unauthorized access to it.

10.5 The Function of Marketing

Marketing has been a core aspect of business for as long as businesses have been around. With the rise of computers and the internet, marketing campaigns are becoming increasingly digital. The IT department can help with the marketing functions of a business in numerous ways:

10.5.1 Content Creation:

You can create advertising and sales copy on a computer using word processing software. You can also create beautiful graphical ads using powerful computers with graphics capabilities.

10.5.2 Online Advertising:

Social media is becoming increasingly important to advertising and, since it lives on the internet, what better department to help you with your efforts than the IT department? By launching social media marketing campaigns, the IT department can improve sales and increase revenue. It can also launch marketing campaigns for the business on other platforms, such as Google AdWords.

10.5.3 Ecommerce:

With more and more businesses going online, the use of computers has become invaluable to how you conduct your business and sell your products and services. The IT department would be instrumental in the processing of orders made on your online store.

10.5.4 Marketing Research:

With the rise of search engines, it is now possible to conduct research online about consumer trends and the most profitable opportunities. The IT department can also be instrumental in this. [13]

10.6 The Function of Process Improvement

It can prove to be quite important in the improvement of processes and efficiency in order to save the company money. A small business could save on printing and copying costs by relying purely on paperless communication. Collaboration software and video conferencing would save on logistics expenses which would have been incurred every time different teams needed to meet and work together. It would also save on time as not much time would be wasted on transit.

The Human Resources department can become more efficient because of the IT department since training sessions can be done online and communication with

employees can be done without the need for paper. The result is massive savings on both time and cost.

10.7 The Function of Enterprise Resource Planning

Enterprise resource planning is all about linking the different functions of an organization, such as accounting, human resources, manufacturing, and sales, using software systems. These systems can help in operations as well as strategic decision making. For a small business, the reduced complexity means these systems can be installed one module at a time and can be scaled, as the need arises.

Chapter # 11
"Health, Safety and Environment Department"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

Health, safety and environment (HSE) management from ensure the health and safety of your workers and compliance with HSE construction requirements.

In industry or any construction site, your employees – both staff and sub-contractor personnel – must work together using various materials and equipment. Accidents may have disastrous consequences for employees, bystanders and your organization. Our health, safety and environment management provides coordination and monitoring to ensure the health and safety of your workers and compliance with HSE construction requirements.

Successful businesses protect the environment, their employees, communities and other members of the public. Failure to minimize the impact of your businesses activities will result in censure by employees, regulatory authorities and customers. Increasingly, stakeholders are also looking for evidence to prove you are adhering to best practice.

Your business will undoubtedly already have policies and procedures in place concerning health and safety and protecting the environment. Are you sure they adhere to best practice? Are you certain you are complying with local, national and international regulations? If you are sure, can you prove it?

For over many years occupational accidents have been given respect in many countries around the world. This is mainly done due to the cost associated with occupational accidents and injuries and high number of worksite accidents occurred in those countries. Legislation for the prevention of occupational accidents and work related diseases have been introduced in those nations and things started to get improved.

In developing countries, the work related ailments are an increasing problem. Work related diseases seem to be miscalculated, therefore incidence rates are normally considered for the comparison between the industries. Most of the construction companies in Pakistan follow responsive strategy
instead of pre-emptive strategy. This means that the construction companies take mitigation steps after the occurrence of accidents on their worksites. Pakistan has the defective occupational health and safety (OHS) legislation, certain sectors have not been included neither in the Labor Policy nor in the OHS legislation. The national enforcement outfits lack interest in the field. Pakistan, having the literacy rate of just 57.7 percent and due to the absence of strong legislation, is considered as a country that lacks safety culture. Additionally, high occupational casualties justify that the Pakistan has been ineffective in reducing the occupational accidents and injuries. Most of the construction companies, see this topic as liability or an obstacle for them in attaining their professional commitments and goals. Similarly, laborers associate OHS with limitation to their

efficiency, wherever personal protective equipment (PPE) has been provided to them, they have initially refused to use it because they don't feel comfortable to work with.

Since 2003 till 2009, 2,836 fatal incident cases have been reported in Pakistan. This is just 0.005 percent representation of 55 million labor, the total labor force of Pakistan. Construction sector is just 6 percent of the total labor force; this means that 3.3 million laborers are associated with the construction sector. If supposed 6 percent of 2,836 incident cases had been reported by construction sector, then this means only 170 cases have been reported by the sector of 3.3 million laborers during the years 2003-2009. This reflects that the reporting of fatal and injury incident cases is extremely low in Pakistan. This could be because of incompetency of government officers or may be construction companies are not willing to share the complete information about the cases with government officials. The fatality incidence rate per 100,000 workers of Pakistan is 20.7 which is much higher than many affluent nations. In contrast, fatal accident rate of United Kingdom is 0.55 per 100,000 workers. In Pakistan, there is no concept of using the pre-fabricated materials. Even today, majority of building components are produced at work sites. All this will eventually increase cost and time. Arrangements for complete in-site facilities require the uninterrupted water and energy supply. The construction industry is one of the major consumers of world's water resources; water is the primary ingredient of concrete. Sometime ice is also required for bringing down concrete's temperature. The construction industry is also linked with high carbon dioxide emissions as most construction sites have diesel generators and the vehicles that are used in construction industry are diesel powered. All phases of construction; design, materials and product manufacture, distribution, on-site operations, in use emissions and refurbish/demolish contribute significantly in the carbon dioxide emissions. Floorings and carpets often contain volatile organic compounds (V.O.C) which deteriorate the indoor air quality. Most of the building projects lack alternative energy option like solar or wind and incase of power shutdown, activities in these buildings. [16]

11.1 Health & Safety Laws in Pakistan:

Prior to World War I, the common notion was that the workers were replaceable but after the World War, labor shortages have been felt. Workers' rights have been spotted during that time, but no attention was made towards improvement of working settings. The most significant incident leading to the regulation of occupational safety was Triangle Shirtwaist's fire. It was occurred in New York City on March 25, 1911. 146 garment workers died mainly due to the suffocation, smoke inhalation, fire, or falling to their deaths. Similarly, in 1930 when the construction of the Hawks Nest tunnel was in progressed near Gauley Bridge, West Virginia, workers exposed to the silica dust. Atleast 476 mine workers killed and 1500 disabled by silicosis. This was

probably American worst industrial disaster. In 1986, Chernobyl disaster had affected 500,000 workers. Health & safety law is a frame of regulations that connects specified fragments of the population such as working class and health, safety and welfare of community. Felon law, regulatory power and inspectorate normally ensure implementation of health and safety law in most of the countries. Individuals, business or cartels are accounted or compensated for individual's injury or loss of life by means of the regulatory framework for occupational health and safety and civil law mechanism Normally OHS law and the civil law function together. OHS law normally has the provisions related to laxity and occupier's liability. These provisions are made into force and are referenced whenever relevant cases are brought up before the labor courts. These provisions provide special rights to enforcement agencies to investigate the suspect and penalize the guilty. As mentioned above; authorization, supervision and enforcement are the core values of any regulation. United States had framed Occupational Safety & Health (OSH) Act 1970 which provides detailed framework about health & safety, while Occupational Safety and Health Administration ensures act's enforcement by providing assistance, education and trainings and by reviewing the statute and standards. Occupational Safety & Health Review Commission facilitates administrative hearing and appellate review. OSH Act is a code-based legislation as it provides detail methods on how to get things done. United Kingdom had formulated Health & Safety at Work Act 1974 that defines core structure and authority for the encouragement, directive and implementation of work-station health, safety and well-being. Health and Safety Executive plays the same role in United Kingdom as Occupational Safety and Health Administration plays in United States. In Australia, Occupational Safety & Health Act 1984 provides fundamental charter related to health and safety at work spots, while Safe Work Australia provides relevant assistance, edification and trainings. Commonwealth Rehabilitation Service (CRS) assists the disabled and handicapped persons regarding their job related matters and their reintegration in society. The Safety, Rehabilitation and Compensation Commission (SRCC) facilitate judicial trials. Unlike American's OSH Act 1974, Australian act is an outcome-based legislation which means that the law is flexible, need-based, and focuses on demand and performance requirement. Although 20 percent of global world force is from South Asia but effective legislation on health & safety still lacks in the region that's why South Asian countries have had high fatality incidence rate e.g. fatality incidence rates of Afghanistan, Bangladesh, India, Nepal, Pakistan and Sri Lanka are 19.9, 26.4, 11.5, 29.9, 20.7 and 18.3 respectively. The legislation in Gulf Countries is disintegrated and is at the preliminary phase of development. As contrast to health and safety legislation, explicit legislation is not promptly accessible and exists only in the shape of Labor Law in most of the cases. There is an existing legislation in UAE, however, it differs from one emirate to another and is not centralized.

Role of HSE Department:

Work-associated health, safety and environment (HSE) comprise the communal, cerebral and corporal comfort of laborers, their dependents and the society. In order to achieve this collaboration and contribution among government, workers, trade unions and other bodies is required. Less consideration has been given to work-related health, safety and environment concerns, but it would cost immensely if ignored. Understanding and ability to protect ourselves, our loved ones, community and the surrounding that we so much rely upon for existence is the key thing to have. Lives of laborers and their relatives, community, proprietors and state might get affected seriously
by work-related accidents and diseases. Table below illustrates effects of work-related accidents on individuals, community and government.

Affecter	Effects
Workers and his family	➢ The grief and suffering of the injury or sickness ➢ The loss of salary ➢ The conceivable loss of a job ➢ Treatment costs
Community	➢ Seeing an adored and praised-worthy individual suffering from an injury or ailment ➢ anxiety and tension ➢ Time and effort to look after for the person ➢ Financial damages and hardship ➢ Loss of life
Employer	➢ Payment for task not done treatment and compensation expenditures ➢ Repair or replacement of damaged machinery and equipment ➢ Decrease or a provisional halt in production ➢ High training expenditures and administration costs ➢ Potential decline in the quality of work ➢ Negative impact on morale of other worker
Government	➢ Decrease in Gross National Product (G.N.P)

These days, many companies have HSE departments as a part of their organizational structure or administrative wings. The chief objective of HSE departments in any organizations are to reduce work-associated health, safety and environmental accidents and diseases. Some responsibilities of HSE departments are mentioned in table below. These responsibilities are assigned to curtail environmental, occupational health and

safety, community health and safety, construction and decommissioning, and sustainable development issues at work site. [14]

Areas of Interest	Responsibilities
Environmental	➢ Water Conservation ➢ Hazardous Materials Management ➢ Waste Management ➢ Noise Control ➢ Contaminated Land ➢ Remediation ➢ Air Emissions ➢ Ambient ➢ Air Quality ➢ Energy Conservation ➢ Wastewater ➢ Ambient Water Quality
Occupational Health & Safety	➢ Personal Protective Equipment (PPE) ➢ Special Hazard Environments ➢ Monitoring, General Facility Design and Operation ➢ Communication and Training ➢ Physical Hazards Protection ➢ Chemical Hazards Protection ➢ Biological Hazards Protection ➢ Radiological Hazards Protection
Community Health & Safety	➢ Traffic Safety ➢ Transport & handling of Hazardous Materials ➢ Disease Prevention ➢ Emergency Preparedness and Response ➢ Water Quality and Availability ➢ Structural Safety of Project Infrastructure Life and Fire Safety (L&FS)
Construction & Decommissioning	➢ Environment ➢ Occupational Health and Safety ➢ Community Health and Safety
Sustainable Development	➢ Reduction in Carbon footprint ➢ Reduction in Energy footprint ➢ Reduction in Water footprint ➢ Conducting Lifecycle assessment ➢ Industrial symbiosis

11.2 Assembly Point:

In simple language you can define an assembly point is a location where workmen/staff/people and visitors can gather in the event of fire/leak/explosion and other emergency to ensure everyone is in a designated safe area. It helps you make sure that people will know where to gather following an emergency evacuation. Logically assembly point should not be very near to the process equipment and very far off for a person to go to the assembly point. The idea is to gather all the people in a safe place. This is the priority. The route to assembly point should be safe. The second one is to extend any help at the time of emergency. No such requirements in mentioned in HSE acts and rules. practically it is not possible! For high hazard industries like petroleum, petrochemical, nuclear power plant etc., Large no of tanks with tons of capacity installed in kilometers. oil & gas companies spread in 100 to 1000 acres. In such plants Hazardous area spread around at least 1km to 10km area. for small to medium scale Industries plant spread in 5 to 50 acres. If government prescribes any fixed distance, it will not give effective results. In practical assembly points are created at four ends of plant. based on the wind direction and entry/exit route, during emergency employees will evacuate from safe gates.

These are some point we should kept in mind while designing assembly point.

11.2.1 Size:

It seems an obvious requirement, but the fire assembly point must be big enough to accommodate all the people into that particular area/building. If your workplace is especially large, you may need more than one primary assembly point, especially if your premises has multiple exit points. The main thing to remember is that the location of your assembly point will differ depending on the size and layout of your premises/buildings, and where the escape route ends.

11.2.2 Access:

For fire assembly points to serve their purpose they must be easily accessible and have an unobstructed pathway leading to them. The path leading to then should always be kept unobstructed and should be marked properly, indicating EMERGRNCY EXIT. You must also try and consider any workmen with mobility issues and assess how far they should be expected to travel, and try to make the journey as quick and convenient for them as possible.

11.2.3 Backup:

If your assembly point is unable to be used on the day a fire strikes, it is vital that there are backup options available. This is to ensure that the fire safety procedures can still go ahead with minimal confusion. To encounter this issue minimum 2 assembly point should be designed. Is should be located opposite to plant/building.

11.2.4 Location:

Large, wide and open areas are preferred for fire assembly points, but they should not be located where they may hinder the arrival of the emergency services e.g. driveways or ambulance. So that people can be evacuated from that place easily. Ensure that the assembly point is well-lit, well-signposted and with no dead ends. If your working area is enclosed/fenced, then assembly point must be located near to entry/exit of that area.

11.2.5 Distance:

The assembly point should be a suitable safe distance away from the unit/building, far enough away to be clear of any possible smoke or heat being generated from the unit/building. Too close to the unit/building could mean your people being affected by heat, smoke and falling debris, they could also be in the collapse zone should the building fall down.

11.2.6 Other dangers:

Don't automatically assume you are clear of danger once you have left the afflicted building. Check for any hazards outside of the premises, such as vehicular movements and any other foreseeable risks, and make sure your people are aware of these potential hazards.

11.2.7 Inform and advise:

To ensure that evacuation can run smoothly during both fire drills and actual fires, your employees need to be fully aware of the fire evacuation procedures, and also the locations of the assembly point and backup assembly points (Master Assembly Point). Ensure that any new staff have been informed of the procedures and assembly points when they begin their job. Once the fire assembly points have been decided, employees and others such as contractors and visitors must be provided with adequate information, instruction and training on the action to take in the event of a fire alert, including assembly points.

Bosch Pharmaceuticals has its own assembly point at the front of Plant II and it has emergency call code 3011.

Chapter # 12 "Research and Development Department"

Prepared by Altamash Asif Ghori
From Department of Applied Chemistry, UOK.

When it comes to product innovation and development, or process refinement and improvement, the role of the R and D department is critical. Other departments, such as sales and marketing, might be more outwardly facing, but while Research & Development is separate from these, it has functions that are closely related. R & D is the means for companies to achieve future growth and maintain their relevance in their chosen market. It involves spending resources on investigation and testing to develop new products or new ways of doing things. It also supports the enhancement of existing products or processes. The name, research and development, may suggest high-tech, or the pharmaceutical sector, but in fact R&D is applicable to a wide range of industries. For example, many consumer appliances will go through rigorous R & D processes, either to develop new versions of products or improve current designs. Underpinning this kind of activity are various key functions which together define the role of the R&D department.

It is unwise to bring a new product to market without first coming up with solid data to support it. This research typically involves conducting a careful, detailed study to support the project – whether there is a need for it, and how to ensure it is something customers will want to use. The research study must also determine the specifications of the product, the projected costs of its production, and the time it will take to produce. The research function prepares the way for new product development. New product development is based on the concepts and requirements coming out of the research phase of a project. This often involves prototyping, to see how a working model of the product performs before going into full production. A crucial part of the development phase is ensuring a new product will meet guidelines and any statutory requirements. Within the scope of Research and Development is the evaluation of existing products to ensure they will still function effectively in the marketplace. The R&D department may consider the potential for product upgrades or changes. There may be problems arising with current products which the R&D department is then tasked to solve. This might involve changes to the manufacturing process. Another aspect of this role of the R and D department is quality control. Here the research and development team may perform regular quality checks on products, based on the department's depth of knowledge around products' specifications and requirements. This may happen in collaboration with a quality assurance department. R&D is not confined to product development. Its various functions may also apply to processes, such as industrial and manufacturing processes. This means the focus on innovation and improvement is not so much on the end but the means. A practical example of this is in developing thermal management solutions to improve safety and performance in various continuous process and manufacturing industries. Again, there can be a similar set of phases, including initial research and identification of issues and feasibilities, followed by development and prototyping. Within these R&D functions, there are different types of research and development, and decision-making associated with them.

12.1 Types of Research and Development:

R and D can involve basic research or applied research. Basic research aims to a comprehensive understanding of a subject, and to build a body of knowledge relating to it. As such it may not

have an immediate practical or commercial application, but it still can be of interest to a business or organization. It is the sort of research that might then initiate further concepts and lead to applied research. Applied research is much more specific with a set of objectives related to a particular customer or industry need or requirement. Under applied research, any investigations will focus on commercial objectives to do with processes or products. This latter form of research will most likely lead to development, with the production of materials, systems and methods. Development itself involves different stages and functions. One is prototyping and designing for production; the other is engineering or manufacturing to produce commercial products, based on the designs and prototypes from the earlier stage.

12.2 The Importance of Innovation:

The main role of the R and D department is to help a company or organization to maintain its competitiveness. This means keeping an eye on developing trends, and on what the competition is doing. R&D is therefore also about analysis and a sound understanding of current conditions within a specific sector or market. The Research & Development department can help direct the future of a business because it provides essential information and ideas that support strategic decision-making. By investing in R&D, a company is investing in technology and future capabilities, transforming these into new processes, products and services. The influx of knowledge that R&D brings can be hugely valuable in developing product lines or enhancing processes. At a basic level, R&D is a tool, but it has the potential to be an enormously effective one.

Bosch Pharmaceuticals PVT LTD works on both pharmacopoeia and non-pharmacopoeia methods but in case of non-pharmacopoeia, the method must be registered first by manager [15]

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12.3 Production house:

R and D department also has a small production house where small scale of production take place according to new research and development.

It has following items:

- ✓ Blender
- ✓ Ribbon Mixer
- ✓ Compressor
- ✓ Coater

The same equipment we saw in production department.

Beside that we have all QC equipment here except TOC, Particle count and FTIR.

Chapter # 13 "Regulatory Department"

Prepared by Altamash Asif Ghori
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Regulatory Department, within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. Regulatory Affairs plays a crucial role in the pharmaceutical industry and is involved in all stages of drug development and also after drug approval and marketing. The drug development process is a lengthy, complex and extremely costly albeit necessary process. Pharmaceutical companies use all the data accumulated during discovery and development stages in order to register the drug and thus market the drug. Throughout the development stages, pharmaceutical companies have to abide by an array of strict rules and guidelines in order to ensure safety and efficacy of the drug in humans. In this highly regulated environment, regulatory affairs play a critical role not only as the interface with health agencies and as a link between different departments in the company but also as the leading department to provide strategic advice on extremely difficult decisions through the life of a drug. Regulatory professionals keep working with the authorities and different departments within the company in order to meet regulatory commitments with the health authorities. Regulatory Affairs also ensures the maintenance of the marketing license and leads life cycle extension activities such as broadening the indication of the drug, change of formulation, changes in the dosage etc. Regulatory Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work, are comfortable with multi-tasking and are eager to expand their knowledge in the wide realms of the Pharmaceutical world. Regulatory Affairs is a rewarding, intellectually stimulating and highly regarded profession within pharmaceutical companies. Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. The companies manufacture and marketing these products must ensure that they supply Quality products to public for their health and welfare. Now most of the companies have specialist departments of Regulatory Affairs professionals. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be noticed. The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. The Regulatory Affairs (RA) departments must be aware of the regulatory requirements in all the company's export markets.

CHALLENGE TO REGULATORY AFFAIRS PROFEESION

Regulatory affairs include complete dynamics:

- Multi –dimensional
- Knowledge in science and technology
- Prolific communication skill
- Deal with people with diverse background, skills, culture, and personalities
- Deal with convicting loyalties, motivations, social and ethical, responsibilities

- Case in point: submission of a dossier
- During submission of a dossier a regulatory affair would be Guided by various regulatory guidance
- Receiving input from various department within the firm about process capabilities and product attribute speciation
- Receiving advice from peers about easy way to get approvals
- Receiving motivation from the management through incentives for achieving speedy approvals

Chapter # 14
"Administration"

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Administration department is backbone of an organization. An effective administrator is an asset to an organization. An effective administrator should have the ability:

- To understand general concepts of Administration
- To enhance the office staff's ability to manage and organize office effectively and professionally
- File in the proper way and filing standard
- Develop an appropriate office management strategy
- Develop an appropriate assets management strategy
- Able to develop administrative procedures
- Able to plan and control administrative budget

The duty of an administrator depends on the company that the administrator works for. The main job responsibility of an administrator is to ensure the efficient performance of all departments in an organization. They act as a connecting link between the senior management and the employees. They provide motivation to the work force and make them realize the goals of the organization.

Office administration is one of the key elements associated with a high level of workplace productivity and efficiency. It is very difficult to run an organization without a good administration faculty. It is administrator, who makes the rules & regulations and applies these rules in an organization.

Sometimes, it is thought that the role of an administrator is not important in the company and neglects their presence. But without presence of an administrator an organization can never work in a sound way. All the tasks & all the departments are relating to the administration.

Administrative and human resources assistants support the work of office departments and, in some cases, specific managers or executives. Sometimes called secretaries, assistants perform clerical duties, such as facilitating communications, keeping records and setting appointments, although responsibilities of an administrative assistant can vary significantly depending on the industry in which he works. Human resources assistants are often more standardized, but there is still plenty of room for leeway, depending on the department's priorities and resources.

If you are hiring an Administrator, the job description can feature:

- Answering incoming calls; taking messages and re-directing calls as required
- Dealing with email enquiries
- Taking minutes
- Diary management and arranging appointments, booking meeting rooms and conference facilities
- Data entry (sales figures, property listings etc.)
- General office management such as ordering stationary
- Organizing travel and accommodation for staff and customers
- Arranging both internal and external events
- Possibly maintaining the company social media accounts
- Providing administration support to Sales Reps, Property Managers and Senior Management

14.1 The Roles of an Administrator

Few of the most important roles of an administrator are:

14.1.1 Planning and Organizing:

Planning is the most vital task of an administrator. It is a responsibility for him/her to plan long-term objectives that can help the organization to reach its ultimate goal. Moreover, to execute these plans and get success is again a big responsibility. The professionals in the admin department in any company need to analyze that how, when, where, and with whom the plan should be made and executed accordingly. Organizing is again equally important, which lets the administrator coordinate the efforts of a business to reach heights of success.

14.1.2 Directing:

So, after planning and organizing are done, the administrator begins direction, which is to be followed by all in the company. Leading the employees within the company to attain the main objective of the organization needs the amalgamation of resources and an effective support system. An interpersonal skill, which is the most commonly found talent among the administrators, is essential as he/she needs to interact and deal with people with different personalities. Moreover, an efficient administrator will use the potential of the workforce to make the plan work as a set. It includes the entrustment of authority, accountability, and control to other administrative teams.

14.1.3 Staffing:

Staffing is another important role of an administrator. For this, complete knowledge about the company and to understand what it requires is very necessary. The administrator must interact and coordinate with other departments of the organization, including the human resource department. Not only the HR department but the admin department, too, actively take part in the recruitment and screening process. After the hiring process is done, the admin team should keenly appraise the progress of the new member of the company.

14.1.4 Liaison:

An efficient administrator is a liaison between employees and management. The admin team understands the need for the employees as well as the management and hence plans things accordingly to meet their demands. It helps to maintain a balance in the organization and also to keep a positive environment free from conflicts. It is the sole responsibility of an administrator to take care of the expectations and performances of each individual.

The administration department is the backbone of the company. A skilled and efficient administrator is an asset to the organization. He/she is a link between the employees and the management of the company. Without an excellent team of an admin department, an organization cannot run smoothly.

Things I have noticed about Administration department in Bosch Pharma PVT LTD.

- It controls Industry transport very well
- It is responsible for cleaning in every department
- It is restricted upon excessive leaves
- It provides card to every employee for attendance and QR code on it.
- It is also responsible for salaries of employees working in here.
- If any employee wants to switch on other department it must provide approval from manager.
- Admin also holds every control on every camera in industry, [17]

14.2 Some Responsibilities of Administration Department:

14.2.1 Facilitating Corporate Communications:

Both types of assistants often play an essential role in a department's communications. An assistant may draft and send out emails on behalf of department management, manage correspondence sent to a departmental email address, and act as a liaison between a department head and other employees, clients or prospects. Assistants are often responsible for opening, reading, and directing postal mail that arrives at the office and is not addressed to a specific person.

An assistant may also be asked to write and update a departmental or company blog that is either shared internally or is made available to the public. HR assistants, in particular, may be responsible for monitoring and updating internal company documents, such as employee handbooks and vacation day notices, or posting health and safety information on an employee bulletin board.

14.2.2 Creating and Maintaining Records:

Administrative and HR assistants often play a significant role in creating and maintaining office records. HR assistants are often responsible for collecting and organizing employee paperwork, such as job applications, employment contracts and benefits forms. Administrative assistants manage both hard copy and digital records by keeping them organized and easily retrievable.

14.2.3 Limited Bookkeeping Tasks:

In some cases, an assistant may take responsibility for limited bookkeeping tasks, such as maintaining a spreadsheet for a departmental budget. The assistant may also be responsible for submitting check requests and invoices to the accounting department, as well as handling employee expense account requests.

14.2.4 Conducting and Reporting on Research:

Assistants are often required to complete research projects and then organize, report on, and maintain any information gathered. Examples of the kinds of research projects that an assistant may undertake and manage are:

- Information about major competitors
- Relevant industry laws and regulations
- Contact information for professional associations
- Details about major clients, such as birthdays and work anniversaries

Also, HR assistants may research potential hires, including reference, social media and background checks. Both HR and administrative assistants may also spend time searching job boards and resume posting sites in hopes of finding candidates for open positions.

14.2.5 Onboarding New Employees:

While HR assistants are often more involved in onboarding and off boarding employees than administrative assistants, both are likely to be involved with welcoming new hires and assisting workers who are leaving the company. For example, HR assistants may be responsible for providing a new employee with information about benefits and office policies. Also, the HR assistant will work with the new hire to complete the necessary paperwork to qualify for and receive benefits, such as insurance.

Administrative assistants, on the other hand, may take responsibility for introducing a new employee to her new co-workers, show her around the office, and bring her up to speed on the location of internal files and records. The administrative assistant may also act as a liaison between the new hire and the IT department, getting her set up with a computer and email address.

14.2.6 Assisting with the Departure of Employees:

At the time of an employee's departure, the HR assistant may conduct an exit interview, provide information on terminating benefits or extending them through programs like COBRA, and, in some cases, supervising the employee as he cleans out his desk. An administrative assistant may communicate the departure to IT and building security so that the former employee's email is shut down and building key card deactivated.

14.2.7 Other Supportive Work:

Other tasks performed by assistants largely depend on the needs of a specific business, department or the assistant's superior. Other responsibilities may include:

- ✓ Booking travel for department personnel, job candidates or outside visitors
- ✓ Conducting initial phone interviews with job candidates
- ✓ Coordinating department special events, such as holiday parties
- ✓ Ordering office supplies

Chapter # 15
Conclusion

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It is concluded that Bosch Pharma is the first pharmaceuticals that is Halaal Certified in Pakistan, it always follows USP especially in Production (Strictly). First the material is arrived in ware house then it is dispensed, after dispensing it is transferred to production area and during the production samples are send to QC lab for testing at each and every step and when the material passed the tests the production exceeds to the further steps. QA lab department plays vital role in passing line clearance paper and giving a whole process in form of document. It mostly works on how production is taking place actually.
After completing the production of finish and good the material is sent to packaging area where primary and secondary packaging take place which includes also printing and filling of ampoules and printing of batch number.
After this the product is stored to ware house and further sell to market.
In all this other department do their jobs too such as IT, HSE and Purchase Department. Purchase department keeps eye on every necessary instrument or anything required for the industry while IT department keeps a digital record such as intimation from Production department. HSE department is responsible for the Health, Safety and Environment of employees, while administration department provides all facilities to employees such as transportation and lunch etc. Bosch Pharmaceutical might be the local pharmaceutical industry but it counts in first halal certified company which exports much product abroad, it follows USP and most of SOPs in department, prepared by managing staff is according to USP. It doesn't only train staff but provide every facility to their workers for perfect work. Bosch Pharmaceuticals comes in one of the most famous pharmaceutical industries in Pakistan having high GMP.

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