Presentation on

Industrial training performed at Samrudh pharmaceuticals PVT ltd. Boisar (MH)

Present by : Rohit Patil

T.Y. b.pharmacy

Smt. S.S.Patil college of pharmacy , chopda

Declaration

I Rohit ShivcharanPatil,hereby declare that, work presented in the industrial training report entitled in INDUSTRIAL TRAINING performed at Samrudh pharmaceuticals pvt Ltd. Boisar.

It is an authentic report of work carried out by me during 04/07/2022 to 03/08/2022 at Samrudh pharmaceuticals pvt Ltd.Boisar.Under the guidance of KBCNMU North Maharashtra University Jalgaon. Is being submitted for partial fulfilment of the requirement for the award of Bachelor degree in B. pharm. This is not been submitted anywhere else for the award of any other degree / diploma.

Date- 03/08/2022

Place – Boisar

Submitted by -Rohit Patil

SAMRUDH PHARMACEUTICALS PRIVATE LIMITED

Regd. Off. : A/101, Prarthana Apartments, Plot No. 15, Jawahar Nagar, S. V. Road,
Goregaon (W), Mumbai - 400 062. • Tel. : 2873 8643, 6123 0300, 6123 0301 • Fax : 6123 0310

23rd July 2022

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Mr. Rohit Shivcharan Patil, student of Mahatma Gandhi Shikshan Mandal's Sharadchandrika Suresh Patil College of Pharmacy, Chopda – Dist. Jalgaon 425107, has undergone Twenty days practical training in our various departments of Production, Quality Control, Quality Assurance and Stores from 4th July 2022 to 23rd July 2022. During the period of this training, he was observant, sincere & regular.

For SAMRUDH PHARMACEUTICALS PVT. LTD.

Authorised Signatory – Anil Joshi

Factory : J-174, J-168, J-168/1, M.I.D.C. Tarapur, Boisar, Tal & Dist. Palghar, Maharashtra - 401 506 • Tel. : 02525 - 661018, 661019
E-mail : info@samrudhpharma.com • Website : www.samrudhpharma.com
CIN : U24239MH1991PTC061667

ACKNOWLEGMENT

It is a matter of pleasure and happiness to make and submit this industrial training report during course of the completion of this industrial work. Many of the persons have offered their valuable and enormous support.

I'm thankful to all my teachers of Smt. S.S. Patil College, Institute of Pharmaceutical Education, Chopda. For their blessings and encouragement.

I would like to express my special thanks and gratitude to SAMRUDH PHARMACEUTICALS and Mrs. Smita Patil for providing all the essential facilities which were required for this training.

Finally, I express my regards to my beloved parents who inspired me throughout my studies and completion of this training.

Rohit Patil,

Third year B. Pharm (6th sem)

Index

1) Introduction

2) Vision mission and values

3) List of product

4) Layout

5) Introduction of Injections

6) Quality Control Department

7) Quality Assurance Department

8) Stores

9) Production Unit II

10) Production Unit I

11) Visual inspection

12) Packing Department

13) Conclusion

Introduction

Location :

J-174, Tarapur M.I.D.C., M.I, D.C, Tarapur, Boisar, Maharashtra 401506

Know about Industry :

“Samrudh” is a Sanskrit word, which means “Prosperity”. The driving force behind Samrudh is its Chairman Mr. Sharad Sheth. He is having more than four decades of experience in the handling and business development of injectable products.

The technical Inputs and Direction is provided by Mr. J. D’Souza, a post graduate in pharmaceuticals with having vast experience, in the area of injectables.

Exports and Marketing is being looked after by Mr. Alok Sheth, a Master’s degree in Business Administration having specialization in foreign trade.

The plant, started in 1993 has grown in leaps and bounds not only in volumes but also in stature for its commitments to quality.

Although Samrudh is deeply rooted in the Indian Pharma market it has spread its tentacles beyond the shores of

India. Samrudh has penetrated markets where others fear to venture, with its presence in more than twenty nations.

VISION, MISSION & VALUES

Vision:

Samrudh pharmaceutical are the leading healthcare professionals with a top ranking position .
Samrudh Pharmaceutical are leading manufacturer in Vitamins and Minerals Premixes and Exporter of the same.

Mission:

We shall ensure the Quality, reliability, and innovation thereby enhancing the sustainability and values for all stakeholders.

Values :

Knowledge- Expertise and Innovation Action- Entrepreneurship and Integrity

Care- Trusteeship and Humiluty

Impact- Performance and Resilience

The values that guide our culture are embodied in our purpose

"Doing Well and Doing Good.

List of Products

GENERAL-DRY POWDER INJECTION

Product Name	Therapeutic Category
Hydrocortisone Sodium Succinate Injection	Adrenocortical replacement
Omeprazole for Injection	Anti-Ulcer Agents, Proton Pump Inhibitors
Pantoprazole for Injection	Anti-Ulcer Agents, Proton Pump Inhibitors
Vancomycin for Injection	Antibiotic
Colistimethate Sodium for Injection BP (Only IV use)	Antibiotic
Artesunate for Injection	Anti-malarial

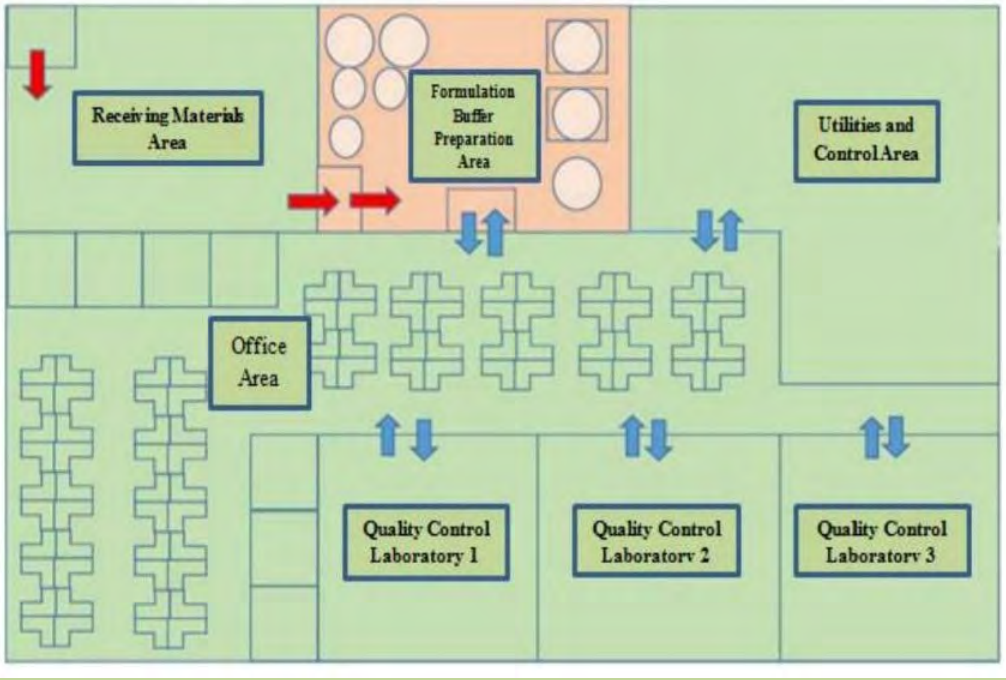
CEPHALOSPORINS DRY POWDER INJECTION

Product Name	Therapeutic Category
Cefoperazone Sodium & Sulbactam Injection	Antibiotic
Cefotaxime for Injection	Antibiotic
Ceftriaxone for Injection	Antibiotic
Ceftazidime for Injection	Antibiotic
Cefuroxime for Injection	Antibiotic
Cefazolin for Injection	Antibiotic
Cefepime for Injection	Antibiotic

LIQUID INJECTION (SVP)

Product Name	Therapeutic Category
Sterile Water For Injection	Diluent
Sodium Chloride Injection	Diluent
Ondansetron Injection	Anti-emetic
Diclofenac Sodium Injection	Analgesic
Gentamicin Sulphate Injection	Antibacterial
Paracetamol Injection	Analgesic and Anti-pyretic
Iron Sucrose Injection	Haematic
Furosemide Injection	Diuretics
Citicoline Injection	Psychostimulant/ Nootropic
Hyoscine Butyl Bromide Injection	Anti-Spasmodic
Promethazine Hydrochloride Injection	Antihistamine
L-Carnitine	(Amino acids and derivatives) metabolic drug
Furosemide Injection (VET.)	Diuretic
Ivermectin Injection (VET.)	Anti-parasitic
Enrofloxacin Injection (VET.)	Antibacterial
Levetiracetam Injection	Antiepileptic

Layout



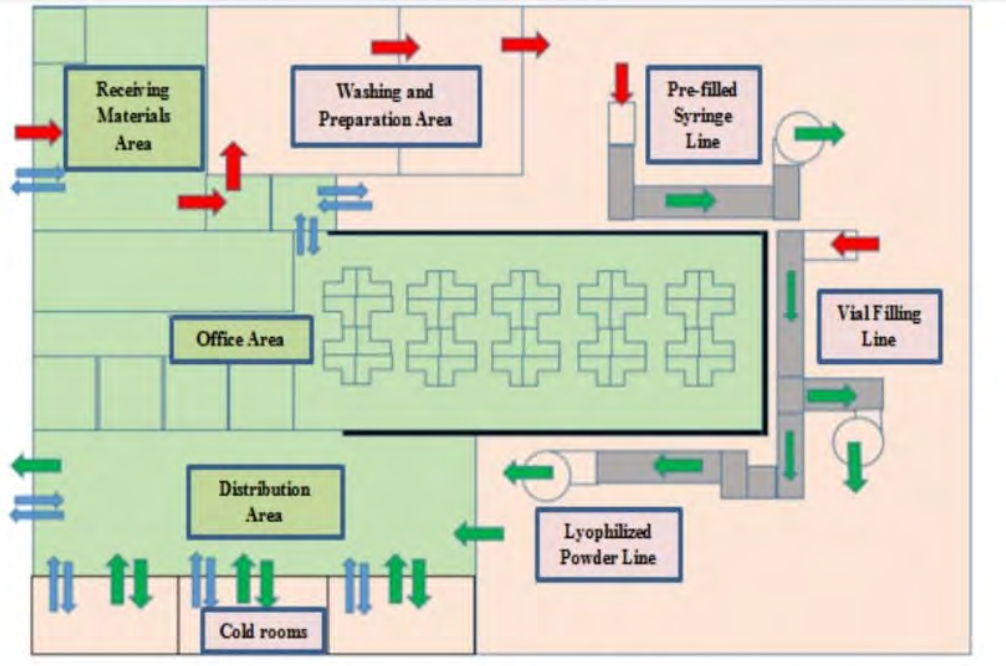


Fig. 9. Ground floor (Level 1) layout.

Introduction of injections

In medical terminology injection is referred as a shot or jab and is a popular way of infusing liquid medicines in to a patient's body. Besides taking oral medicines for health problems or topical applications of medicines in the form of lotions and creams, there are injections, which are considered the most frequently used medical procedures. According to a report by the WHO, an estimated 20 billion injections are administered each year world-wide.

What is an Injection (in Medical)?

Injection is defined as a process by which a small area of the skin is pierced or punctured with a syringe and needle to insert a substance for prophylactic, curative, or recreational purposes. It is to be noted that an injection follows a parenteral route of administration; that is, medicines are administered not through the digestive tract.

Methods of Injections Infusions: Types of Injection-

Injections can be given intravenously, intramuscularly, intradermally, or subcutaneously. Each type of injection is used for a specific health problem, specific purpose, but the procedures for preparing the injections are the same.

1) Intradermal Injections

This technique involves the injection of the fluids into the

top layer of the skin, which is soft and pliable. Mainly used for treating certain health problems, including many allergies and tuberculosis. The liquid medicine is inserted with an intradermal injection, which will lie just beneath the skin surface in between the layers of skin. The needle is extremely tiny, and it inserts the fluid properly under the surface of the skin.

2) Intramuscular Injections

This is the most common way of injecting medication directly into a patient. For rapid absorption of the medicine this is a very useful process because the medicine from this injection is inserted directly into the muscle. This allows the medicine to gain easy access to the blood stream and quickly begin its healing work. Intramuscular injections are the best and the safest way of injecting medication into a patient.

3) Subcutaneous Injections

Such type of injections are used where the medicine needs to be absorbed slowly. In this type of injection, the needle has to go through the first 2 layers of skin that is the epidermis and dermis. The needle should further penetrate into the fatty layer of the skin, known as the subcutaneous tissue. Medicines administered through subcutaneous injections have the least chances of having an adverse reaction. Insulin is one type of medicine that is injected in

this way, so also a number of immunizations.

In all these injections, the size of the needle varies. The deeper the injection, the longer the needle should be. In intramuscular injection, the needle is at least a few inches long. Subcutaneous injections have needles which are approximately an inch long. Intradermal injections use the shortest needle because they are only inserted just beneath the first layer of skin.

Quality control department:

Date: 04/07/2022 – 07/07/2022

According to the World Health Organization (WHO), the term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical.

Samrudh pharmaceutical Quality control department:

Department and Rooms:

1) Laboratory

2) Weighing balance room

3) Reagents storage room

4) Microbiology lab

5) Sample storage room

6) Hot Zone

7) Gas chromatography room

8) Wash room

Various type of test are carryout by Chemist in QC Laboratory :

1) Identification of HPLC

2) Water content by Karl Fischer titration

3) Sterility testing

4) Bacterial endotoxin

5) Related substance by HPLC

6) Essay by HPLC

7) Particle size

8) Density

9) Solubility

10 Identification test by UV spectroscopy

11) pH

12) Tapped density

13) IR spectroscopy

14) Melting point

15) Heavy metal

16) Single impurity

17) Residual solvent

18) Loss of drying

19) Chromatography

20) Microbial limit test

21) Total yeast and molds count

22) Humidity

Instruments & apparatus

1) pH meter

2) Polarimeter

3) Desiccator

4) Dissolved oxygen meter

5) Osmometer

6) Tap density apparatus

7) Digital conductivity meter

8) Melting point and freezing point apparatus

9) Automatically potentiometric titration meter

10) Karl Fischer apparatus

11) HPLC

12) UV spectroscopy

13) Gas chromatography

14) Total organic count analyzer

15) Polarography

16) Ecometer

17) Weighing balance

18) Hot air oven

19) Electric water bath

20) Ultrasonic bath

21) Centrifuge

22) Muffle furnace

23) Digital vaccum oven

Quality assurance

Date : 08/07/2022 to 11/07/2022

Definition:The purpose of pharmaceutical quality assurance is to ensure that the medication being manufactured will provide the desired effect to the patient. Quality assurance also guarantees that there are no contaminants present and that the medications will meet quality requirements and all relevant regulations.

What is SOP in quality assurance?

SOP are Level 2 quality documents and, along with other relevant quality documents, ensure the effectiveness and efficiency of quality systems. The ICH GCP guideline defines SOPs as “detailed, written instructions to achieve uniformity of the performance of a specific function”.

SOP NO 1 : Product Quality Review (PQR) :

QA - Compilation of data and review of trend , control sample review record.

APQR - Annual Product Quality Review

Shortly suscribe of QA is to compilation of data from QC Department, production department, Store's, warehouse etc and check it Data by given protocol.

SOP NO 2 : DATA INTEGRITY

Types of Data :

A) Raw Data

B) Source Data

C) Meta Data

Data integrity Documents

1)Data integrity

2)Documents

3)Instructions Document

4)Master Document

5)Record

6)Raw data

7)Electronic (Dynamic) Record

BMR : Batch Manufacturing Review

1) Batch Deviation

2) Change Control

3) New Facility provide

4) Review of the results

QMS : Quality Management system

GDP : Good Documentation Practice

CAPA : Corrective and Preventive Action

AMT Protocol :

It is the Documented process that qualifies a laboratory (receiving laboratory) to use an analytical method that originated in another laboratory (transferring laboratory), whether that is internal or external to the receiving laboratory.

AMV Protocol :

Validation of analytical Method (AMV) is the process by which it is established, by laboratory studies, that the performance characteristics of the method meet the requirements for the intended analytical applications through certain standards of accuracy and reliability.

SOP NO 3 : GMP

Purpose :

• Unexpected Contamination in Drug

• Incorrect labels on container

• Uncontrolled Dosing

GMP covers :

All aspects of production from the starting material.

Detailed written procedure are essential for each Procedure that could affect the quality of finished product.

GMP Guideline :

GMP as per schedule M

GMP as per WHO

GMP as per USFDA

GMP as per ICH Guideline

GMP as per MHRA

GMP as per FDA

QA- Ensuring that Product

GMP- Ensuring that Product are consistently manufactured

QC- GMP Concerned Sampling, specifications and testing, documentation & release products

OTC- Over the Counter

List of Important Document in GMP :

1)Policies 2) SOP 3) specification 4) MFR (Master Formula record) 5) BMR 6) Manuals 7) Master Plans 8) validation protocol 9) Format 10) Records

Attributes of a Good Documents :

Accurate , clear , Complete , Consistent , Indelible , Legible , Timely , Direct , Authentic , Authorized , etc .

Documentation for :

- CGMP for Finished pharmaceutical
- Organization & Personnel
- Production and process control

SOP NO 4 : Essential Documents Record and Review

Essential of Documents means Documents in GMP Procedure

• Purpose of documentation

• quality based documentation system

• quality police c and its important

• quality manual

Type of GMP Documents

• Description document

• Data collection document

• Numbering system

• Data files

• Principle of good documentation

• Proof of quality

• Real time, format , dates , calculation number correction .

• Documentation practice

Report :

1) Process development report

2) Master production record

3) Production batch record

4) Production record review

5) Packaging instruction

6) Equipment record

7) Laboratory glassware

8) Material and packaging component record

9) Laboratory record

10) Laboratory data

11) Out of specifications and retesting

12) Data review

13) Stability record

14) Deviation record

15) Change control record

16) Training record

17) Organisation chart

18) Job description

19) Technology transfer document

20) Validation documentation

21) Management review

22) Response to regulatory inspection

23) Complaints

24) Product recall

25) Health and hygiene record

26) Pest control record

27) Revision and renewal Document

SOP NO 5 : Good Documentation and Review Practice

Responsibility :

1) Procedure

2) Review and approval of document

3) Designee and signature

4) Insurance of GMP documents

5) Recording / Data capture on GMP document

6) Signing of GMP document

7) Handling of missing entries and corrections

8) Missing document

9) Revision of GMP document

10) Distribution of GMP document

Review Practice :

1) Online inspection and review
2) Review of batch record
3) Record / Annexures
4) History record
5) Errata Heston Record
6) Review observation and compliance document
7) File not
8) First information report

SOP No 6 : Change history

1) Distribution list
2) Revision and review
3) Refference Documents

SOP NO 7 : Handling of Deviation

Classifications of Deviations

1) Critical deviation

2) Major division

3) Minor deviation

- Train analysis of division
- Change history of division
- Distribution list
- Revision and review of deviation
- Reference document for sop
- Extension of deviation

SOP NO 8 : Procedure for investigation

1) Department head

2) QA-Head or delegates

3) Subject matter expert

Procedure :

Immediate Action - Investigation Details - Summary -

conclusion.

SOP NO : 8 Process validation

Purpose :

To lay down the procedure for process validation of products confirm that a specific manufacturing process will consistently produce the product meeting it's predetermine specification and quality attributes

Procedure :

Stage 1: Process Design

Stage 2: Process Qualification

Stage 3: continue process validation

Record :

1) Change History

2) SOP Distribution

3) Revision and review

4)Refference Documents for SOP

ICH Guidlines:-

QSEM

Q - Quality guidelines (Q1 to Q14)

S - Safety Guidelines (S1 to S12)

E - Efficacy Guidlines (E1 to E20)

M - Multidisciplinary Guidlines (M1 to M14)

Stores Department :

Date 13/07/2022 to 14/07/2022

Job Description

1.To receive, segregate, identify and properly store all RM, PM coming from supplier.

2.To carry out dispensing of raw material activity.

3.To issue material to production department for use in manufacturing activities.

4.To maintain all records of receipt and issue in SAP system.

Precautions : while receiving incoming consignment of raw material packing material and miscellaneous will be check by the store person initially who note down the lorry receipt and challan detail in the register and inform to store department.

Storage

1) Raw , packing material storage

2) Approved Area

3) Sampling Area

4) Dispensing Area

Production unit 2

Date15/07/2022 to 19/07/2022

Production unit 2 are carryout by online process management

Manufacturing process for Vials and ampules

Manufacturing process of vials :-	Manufacturing process for Ampules:-
Vials Primary Packing material ↓ Washing Vials with sterile water , water for injection and recycling water ↓ drying & sterilization ! Preparation of Batch or compounding for Vials ↓ pH ↓ Filtration ↓ Volume setup ↓	Primary packing material for Ampules ↓ Washing Ampules with sterile water , water for injection , recycling water ↓ Sterilization ! Preparation of Batch for Ampules or Compounding for Ampules ↓ pH ↓ Filtration ↓ Volume setup

Filling ↓ Rubber fiting ↓ Celling ↓ Cross checking ↓ Collection ↓ Visual inspection ↓ Labeling ↓ Packing ↓ Warehouses **Temprature** :	↓ Filling ↓ Cealing ↓ Cross checking ↓ Collection ↓ Visual inspection ↓ Labeling ↓ Packing ↓ Warehouses Rooms in production areas 1) sterilization room

1) Drying zone : Not less than 80° C 2) Sterilization : Not less than 320°C 3) Cooling zone : 25 to 30 °C 4) stabilizing Zone : 25 to 30 °C **Humidity** : 50 to 60 RH	2) Rubber stoper preparation 3) Ampules filtration Area 4) Compounding for Ampules 5) IPQA **Temprature** : 1) Drying zone : Not less than 80° C 2) Sterilization : Not less than 320°C 3) Cooling zone : 25 to 30 °C 4) stabilizing Zone : 25 to 30 °C **Humidity** : 50 to 60 RH

Production Unit 1

Production unit 1 are carryout by manual process management.

Manufacturing process for Vials:-	Manufacturing process for Ampules:-
Vials Primary Packing material ↓ Washing Vials with sterile water , water for injection and recycling water ↓ Preparation of Batch or compounding for Vials ↓ pH ↓ Filtration	Primary packing material for Ampules ↓ Washing Ampules with sterile water , water for injection , recycling water ↓ Preparation of Batch for Ampules or Compounding for Ampules ↓ pH ↓ Filtration

⬇ Volume setup ⬇ Filling ⬇ Rubber fiting ⬇ Celling ⬇ Cross checking ⬇ Collection ⬇ Visual inspection ⬇ Labeling ⬇ Packing ⬇	⬇ Volume setup ⬇ Filling ⬇ Cealing ⬇ Cross checking ⬇ Collection ⬇ Visual inspection ⬇ Labeling ⬇ Packing ⬇ Warehouses

Warehouses	Rooms in production areas
Temprature : 1) Drying zone : Not less than 80° C 2) Sterilization : Not less than 320°C 3) Cooling zone : 25 to 30 °C 4) stabilizing Zone : 25 to 30 °C **Humidity** : 50 to 60 RH	1) sterilization room 2) Rubber stoper preparation 3) Ampules filtration Area 4) Compounding for Ampules 5) IPQA **Temprature** : 1) Drying zone : Not less than 80° C 2) Sterilization : Not less than 320°C 3) Cooling zone : 25 to 30 °C 4) stabilizing Zone : 25 to 30 °C **Humidity** : 50 to 60 RH

Visual inspection

Date 26/07/2022 to 28/07/2022

Visual inspection of injections (parenteral) was originally developed and it's still mainly targeted in order to find and remove products containing unwanted particles. This is necessary to minimize the risk of introducing such particles to patient's body during the delivery of injectable medications.

Finally, more and more attention is put on minor defects often called “Cosmetic defects” which don’t affect directly safety and efficacy of the injection, but can cause worrisomeness and concern to the final user about perceived quality and safety of the product.

Visible and subvisible particles :

The requirements for “Particulate Matter in Injections” are divided into visible and sub-visible particles, and they prescribe that control is performed by completely different ways for those two categories.

Visible particles

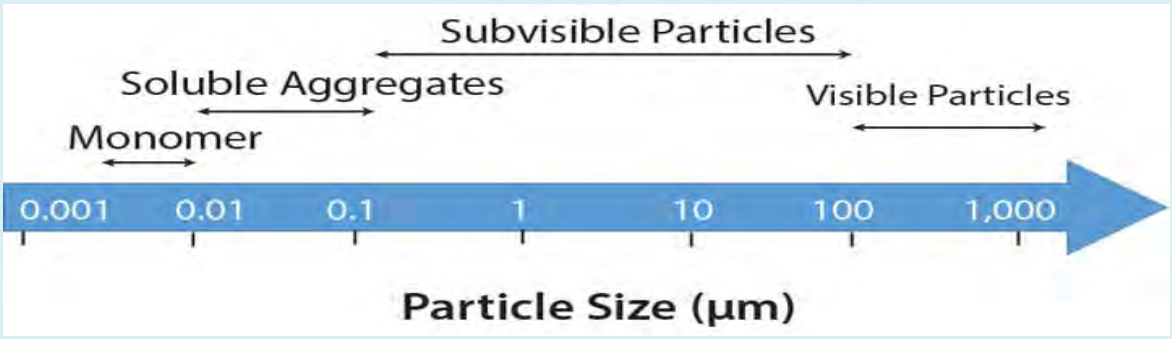
The requirements for visible particles can be found in USP General Chapter <1> Injections. It is required that every container is visually inspected before being released “to the possible extent” and that every container showing “observable foreign and particulate matter” is rejected.

It is further required that “the inspection process shall be designed and qualified to ensure that every lot of parenteral preparations is essentially free from visible particulates”

Even if there are still significant differences in USP, EP and JP pharmacopeias, they all agree on two essential points:

100% of containers of each batch/lot must be visually inspected under controlled conditions.

The inspection process is intrinsically probabilistic.



Defects:

Critical defects : Defects that may cause a lack of sterility and container integrity that can cause harm to the patient.

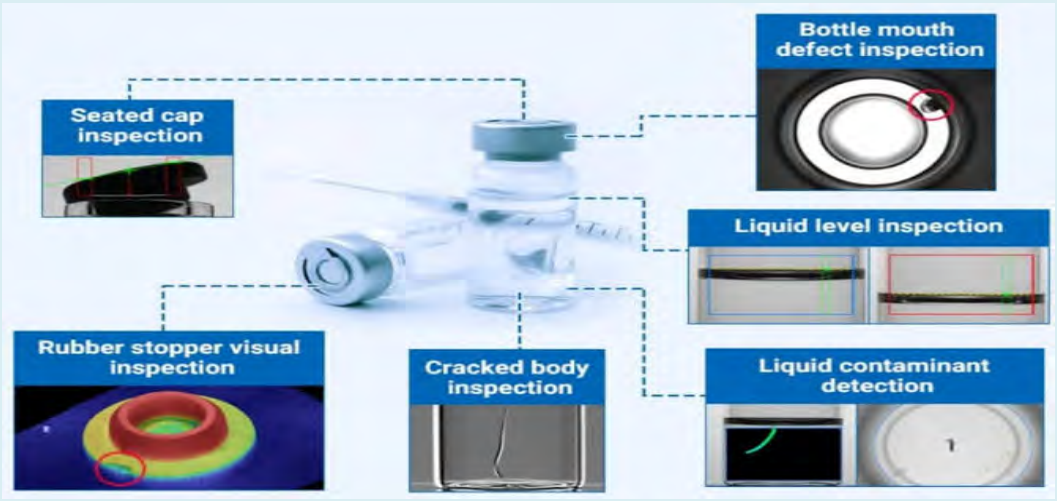
Major defects:

Defects that may alter or reduce the content or the function of the product/drug.

Minor defects:

Defects that do not affect patient health or product functionality but can affect the perception of quality of the product by final user.


Vaccine


Bottle mouth defect inspection
Seated cap inspection
Liquid level inspection
Rubber stopper visual inspection
Cracked body inspection
Liquid contaminant detection


Vaccine

Packaging

Pharmaceutical packing operation is a very critical stage of pharmaceutical manufacturing. Following are the guidelines for packing operation.

1. Segregate the products and packing components in the packing area by physical barrier or adequate special separation to pminimize mix-ups.

2. Pack and store only one product at a time on any one packing line.

3. Check the product and the respective packing components for conformance with identity and description as per Batch Manufacturing Record (BMR) before commencing operation.

4. Check all rejected excess or discarded printed packing material with respect to work order.

5. Report any discrepancies or irregularities during the packing operation to the production head and quality assurance

department.

6. Properly identify all printed, unprinted packing material and bulk products by code no. and lot no. during the process.

7. Destroy the used and unused stereos on completion of a batch/product as per SOP.

8. Destroy the rejected or unused printed packing material on completion of batch/ product and reconcile the same in BMR.

9. For excess packing material, return the same to the warehouse after filling up a return note.

10. Check the BMR for correct completion of all documentation pertaining to the packing, process before submitting it to Quality Control.

11. Q.A. to Check at regular intervals and take random samples to ensure the correction of packing operation.

12. Fill the various logs accurately and regularly to keep a detailed record of pacing operation.

13. Pre-inspect the work area & relevant equipment before commencing pacing operation.

14. Maintain a strict inventory control and reconciliation

of product and respective packing components in each BMR.

CONCLUSION

In the end I am glad to tell you that training in SAMRUDH pharmaceuticals, BOISAR was an excellent and fabulous experience. During the training I actually learned about the Pharmaceutical company and above its working the theoretical knowledge is worth for getting a degree, and it is accessible in the book. We can only imagine about the thing we read, but practical life is always different and excellent one. During My training period. I had seen the various instruments and apparatus in the industry. The highly sophisticated instruments that work precisely must

be operated with intense care for optimum use. We could acquire a lot of information regarding the latest instruments and their working procedures.

Similarly from practical point of view a pharmaceutical company is very difficult. During the training session I tried to my level best to gain practical knowledge as much as can. I improved my basic classified doubts and also understood the importance of maintaining of quality of products at Pharmaceutical company.

was successfully able to complete my short venture of training. Lastly I hope that my training report fulfill the intended requirements.

Regards Rohit Shivcharan Patil,

Third Year B Pharm

(Sem-6)