WELCOME

K. K. WAGH EDUCATION SOCIETY`S

K.K Wagh Arts,Commerce,Science and Computer science collage Saraswati nagar ,panchavati ,nashik -422003(Affiliated savitribai phule pune university)

ON JOB TRINAINING/INTERNSHIP PRESENTATION

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Name Of Industry

(PHARMACEUTICAL INDUSTRIAL ANALYSIS)

NASHIK MAHARASHTRA

Contents

INTRODUCTION:

- I'm delighted share my journey and experience during my internship in pharmaceutical industrial analysis , over the course of 12 weeks.During these presentation I'll provide insights into the integral role of practical chemistry that involves a series of process for identification , determination quantification and purification. I also sharing my experience during working, skills acquired during these internship and impact of these work on my personal development and knowledge .

Information About Company

Top 10 Pharma Companies in India9/28

- Sun Pharmaceutical Industries Ltd
- Cipla Ltd
- Dr Reddy's Laboratories Ltd
- Mankind Pharma Ltd
- Torrent Pharmaceutical Ltd
- Zydus Lifesciences Ltd
- Lupin Ltd
- Alkem Laboratories Ltd
- Abbott India Ltd
- AurobinAdo Pharma Ltd.

Production Process Steps

1. Weighing: Measuring raw materials
2. 2. Milling and Sieving:Size reduction with sievesSize range: 20-200 mesh
3. 3. Mixing:Machine: Octagonal blenderSpeed: 50 RPM for 15 min
4. 4. Granulation:Dry and wet granulation methods
5. 5. Compression:Using tablet punching machines3-4 tons pressure

Sample quantity

Sample Quantity and SamplingSample Quantity:

- Batch Size: 18 kgSampling: 30-36
- gramsSampling Process:API: ~10%
- samplingExcipient: 2N + 1
- Certificate of Analysis (COA)

Tablet Types

- **Tablet Types and CoatingTypes of Tablets**

1]Uncoated Tablets

2]Film-coated Tablets

3]Color-coated Tablets

4]Enteric coating (delayed release)

4]Coating Materials:PVC, PVDC,

and Aluminum foil for packaging

Quality Assurance and SOP

- **Quality Assurance (QA) Guidelines**:Batch Manufacturing Record (BMR):A detailed document that records the entire manufacturing process of each batch.Includes information like raw materials used, process steps, and quality checks.
- **Batch, Manufacturing, and Records**:Documentation of each production batch to ensure consistency and traceability.Helps in identifying any deviations or errors during production.
- **Standard Operating Procedure (SOP**):Sanitizing Change Room:Before entering the production area, staff must sanitize themselves to maintain cleanliness.Includes hand washing, use of disinfectants, and wearing protective gear.
- **Overgowning Process**:Staff wear sterile gowns, gloves, hair covers, and masks to prevent contamination.Ensures a hygienic environment during tablet production.

Standard Testing Procedure (STP)Testing Methods:

- Standard Testing Procedure (STP)Testing Methods:
- 1. **Qualitative Testing:Purpose**: To check the physical characteristics of the tablets.Parameters:Appearance: Shape, size, and surface finish.Color: Uniformity and consistency.Texture: Smoothness or roughness of the tablet surface.
- 2. **Quantitative Testing:Purpose**: To measure the amount of active pharmaceutical ingredient (API) in the tablet.Parameters:Ensures each tablet contains the correct dosage.Verifies the uniform distribution of the API.

Description and SolubilityDescription:

1] Appearance:The tablet is typically a white, crystalline, or amorphous powder.Crystalline tablets have a defined shape, while amorphous ones have an irregular structure.The physical form can impact the solubility and absorption rate of the tablet.

2] Solubility Criteria:

Very Soluble:Dissolves in less than 1 part of the solvent.

Example: 1 gram of substance dissolves in less than 1 mL of solvent.

3] Freely Soluble: Dissolves in 1 to 10 parts of the solvent

.Example: 1 gram dissolves in 1-10 mL of solvent.

4]Sparingly Soluble:Dissolves in 30 to 100 parts of the solvent.

Example: 1 gram dissolves in 30-100 mL of solvent.

5]Practically Insoluble: Requires more than 10,000 parts of solvent to dissolve

.Example: 1 gram dissolves in over 10,000 mL of solvent.

Identification and Methods

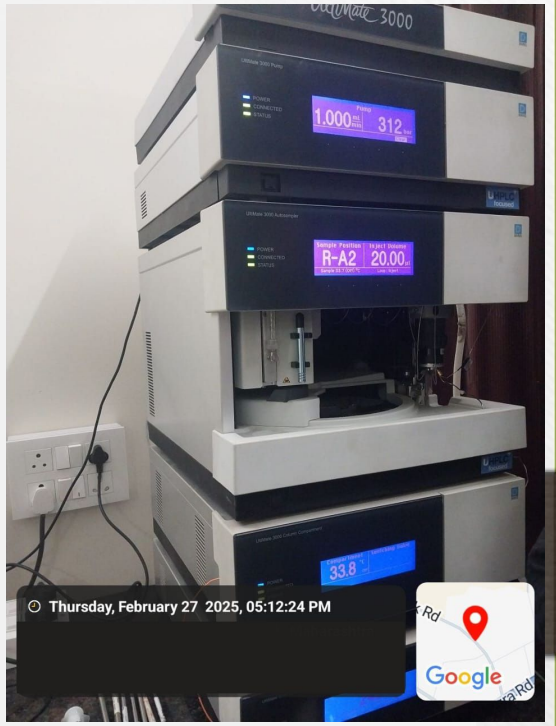
- **NMR Spectroscopy**:Nuclear Magnetic Resonance (NMR) for chemical structure analysis
- **Spectroscopy:**

IR Spectroscopy:Wavelength range: 4000 nm to 800 nmDetects functional groups

- **UV Spectroscopy**:Range: 190 nm – 800 nmUses tungsten and deuterium lamps

Instruments used in Industry

1.Analytical Balance:
Manufactured by Wensar Company
An Analytical balance is a precision instrument commonly used in pharmaceutical industry, due to its meticulous ability to weigh small quantities of active pharmaceutical ingredients [API’s] excipient, or other substances used in the drug formulation.



Principle:

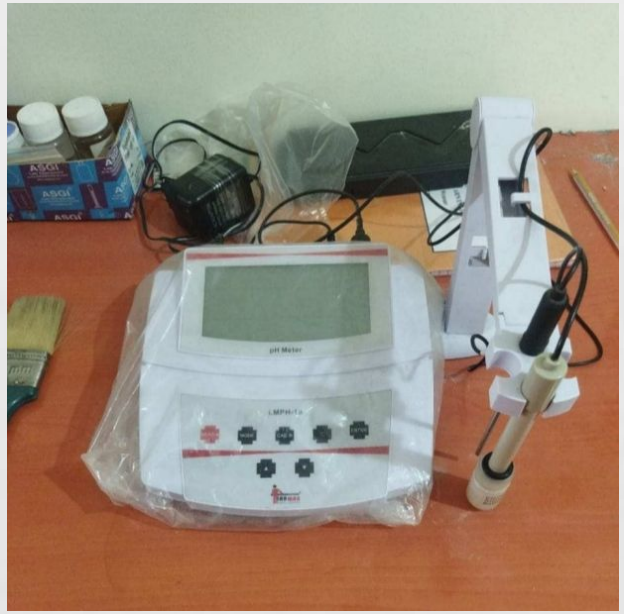
Analytical balance works on the principle of ‘’magnetic force distoration ‘’ it is an electromagnetic balance that measure the mass of an object using an electromagnet. This balances do not directly measure the mass ;rather,they measure the force that acts in the downward direction of the balancing pan. sAn electromagnetic motor measures this force and ultimately determines the mass of the object

Appratus & Equipments :

The electronic analytical balance consists of a stainless -steel balancing pan enclosed within a glass chamber, which shields against the interference of air currents or vibrations while weighing chamber.

2.Digital pH meter:

A pH is a unit use to measure hydrogen ion concentration in a water-based solution.Simply,it is a scale that determines the acidity and basicity of the solution.
The pH value of the solution ranges from 1 to 14 where PH =7 means a neutral solution,PH <7 means an acidic solution and PH>7 means a basic solution.A higher concentration of hydrogen ions in a liquid means the PH of the solution is lower. In a contrast, higher PH implies the presence of less hydrogen ions concentration in a liquid. The PH solution is measured in two ways; a PH strip[PH indicator] and a PH meter.



Applications of PH meter:

· It is used in the chemical industry,neutralizing effluent in the paper, steel and pulp,pharmaceutical manufacturing ,biotechnology and petrochemical industries.
· It is used to determine the PH value of the food products to maintain a high level of safety and quality.

Uses of HPLC

· Purification of water.
· Impurity detection in the pharmaceutical industry .
· Trace components are pre-concentrated.
· Chromatography based on ligand exchange
· Protein chromatography via ion exchange
· Carbohydrates and oligosaccharide anion-exchange chromatography at high PH.
· Analysis of any drug is to confirm and identity of drug and provide quantitative result and also to monitor the progress of the therapy of a diseases .

Application of HPLC:

Quality control testing of drugs
In qualitative and quantitative analysis
Separation and control of impurities.
Therapeutic monitoring of drug metabolism studies
Analysis of biological fluids:
Quantification of drugs in biological samples
In pharmaceutical industry tablet dissolution study of pharmaceutical dosage form.
Identification of steroids in blood , urine, etc
Quantitative analysis of several analgesics like aspirin ,caffeine,paracetamol,etc.

Conclusion

Tablet Manufacturing Process:The tablet production process involves several key steps:

Weighing: Measuring raw materials accurately.

Milling and Sieving: Reducing the particle size for uniformity.

Mixing: Blending ingredients thoroughly.Granulation: Binding the powder into granules.

Compression: Forming the final tablet shape under high pressure.

Coating and Packaging: Adding protective layers and packaging for stability and safety

.**Importance of Quality Assurance, Testing, and Proper Packaging**:

Quality Assurance (QA): Ensures each tablet meets the required standards of safety, effectiveness, and

Thank you