

INTERNSHIP REPORT ON

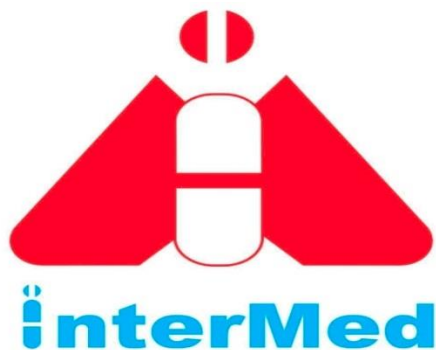
“DIFFERENT DEPARTMENTS LIKE FR&D, QC, QA, SOLID ORAL PRODUCTION, LIQUID ORAL PRODUCTION, TROPICAL PRODUCTS AND PACKAGING”

SUBMITTED TO

INTERMED,

4, G.K. INDUSTRIAL ESTATE, ARCOT ROAD, PORUR

CHENNAI-600116



SUBMITTED BY

HARSHITHA CH

40910007

MASTER OF SCIENCE IN CHEMISTRY

SATHYABAMA INSTITUTE OF SCIENCE AND TECHNOLOGY,

CHENNAI-600119



INTERNSHIP CERTIFICATE: -



interMed

(Government Recognized Export House)

FACTORY : # 4, G.K. INDUSTRIAL ESTATE, ARCOT ROAD, PORUR, CHENNAI - 600 116.
TEL : 91-044-2386 0360 / 2476 6460 FAX : 91-044-42180932
E-mail : adminchennai@Intermedindia.com

29-01-2021,
Chennai.

To Whomsoever It May Concern

This is to certified that Ch.Harshitha (M.Sc Chemistry) Final Year Student of SATHYABAMA UNIVERSITY, Chennai, has successfully completed her Internship Training in the different departments like FR&D, QC, QA, Solid orals Production, Liquid Oral Production, Topical products and Packing in our company from 17.01.2021 to 29.01.2021.

During the period of her Internship Training with us she had been exposed to different process was found punctual, Hard Working and Inquisitive.

We wish her every success in her Life and Career.



Dr.K.Balaji,

**FR&D Head,
Intermed.**

ACKNOWLEDGEMENT:

I want to thank my advisors and every one at the company for their patience and assistance during on-site training. Thanks to their guidance, I was able to develop my industrial skills and learn about instrumentation and preparation of tablets and packaging techniques. These skills will help me to extend my resume and advance my career.

I would also like to acknowledge with much appreciation the crucial role of the staff in Chemical Laboratory, who gave me a permission to visit the lab and staff who explained about the equipment, procedure and given permission to use all the necessary tools in the laboratory.

1. ABOUT THE COMPANY: -



INTERMED in PORUR, Chennai known as satisfactory cater to the demands of the customer base. The business came to an existence in 2003 and has, since then, a known name in its field. It stands located at No 4 G K Industrial estate ARCOT road PORUR-600116. It's has earned stamps like JD verified, JD Escrow, JD Trusted Substantiating the credentials of the business. The business strives to positive experience through its offerings.

This business has a wide range of product offering and the product/ catalogue list includes pharmaceutical, pharmaceutical product, tablet, rugged tablet pc etc.....

We have been gradually upgrading our factory by investing back the profits earned and we are a WHO-GMP approved with facilities to manufacture Tablets, Capsules, Syrups, Dry Syrups and Ointments and creams.

2. WHAT WE DID: -

On first day we were get to know about the industry and staffs. How they handle the instruments and what is the purpose of it and how they produce the tablets, syrup, Ointments, capsule, and transdermal patches. And then we know about how they fix the expiry date for the tablets, and we studied the Sop's how the industry should work. we just got the chance to see how they handle the machines, we can't Abel to Handel any instruments.

3. SOP'S STUDIED: -

DOCUMENTATION PRACTICES AND MANAGEMENT:

- 1.Purpose and scope of documentation practices and management.
- 2.Genral GMP document creation and maintenance requirement.
- 3.Use of GMP documents.
- 4.management of procedure printed as controlled copies.
- 5.Enter to GMP documents.
- 6.use of N/AS for blank field and section.
- 7.Requirements for sign and dates.

4. Products they produce: -

❖ Transdermal patches: -

- menthol(painkiller) 5%
- Lidocaine 4% pain relieving patch (shoulder, neck, back pain)

❖ Capsules: -

- Fluconazole.

❖ Ointments: -

- B beauty cream.
- Chlotrimazole.

❖ Syrup: -

- Cofix.

❖ Tablets: -

- Paracetamol.
- Nifedipine.

5. INSTRUMENTS SEEN: -

- High Performance Liquid Chromatography
- Ultraviolet Visible Spectroscopy
- Gas Chromatography
- Centrifuge Machine
- Tablet hardness tester
- Hot Air Oven
- Vacuum Oven
- pH Meter

5.1 High Performance Liquid Chromatography: -

High Performance Liquid Chromatography (HPLC) is a form of column chromatography that pumps a sample mixture or analyte in a solvent (known as the mobile phase) at high pressure through a column with chromatographic packing material (stationary phase). The sample is carried by a moving carrier gas stream of helium or nitrogen. HPLC has the ability to separate and identify compounds that are present in any sample that can be dissolved in a liquid in trace concentrations as low as parts per trillion. Because of this versatility, HPLC is used in a variety of industrial and scientific applications, such as pharmaceutical, environmental, forensics, and chemicals.

Sample retention time will vary depending on the interaction between the stationary phase, the molecules being analysed, and the solvent, or solvents used. As the sample passes through the column it interacts between the two phases at different rate, primarily due to different polarities in the analysts. Analysts that have the least amount of interaction with the stationary phase or the most amount of interaction with the mobile phase will exit the column faster.



(High Performance Liquid Chromatography)

5.2 Ultraviolet Visible Spectroscopy: -

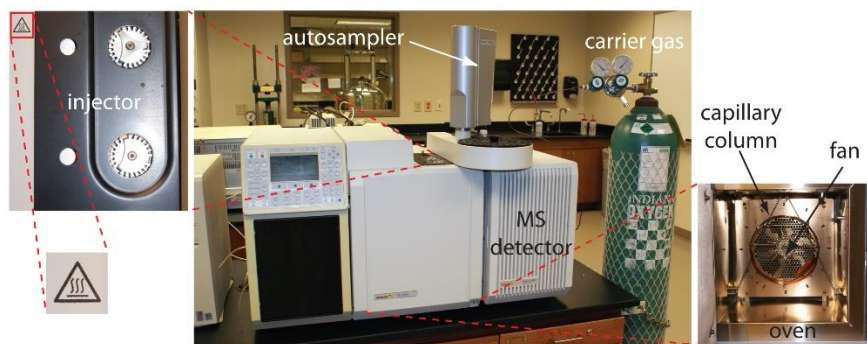
Ultraviolet–visible spectroscopy or ultraviolet–visible spectrophotometry (UV–Vis or UV/Vis) refers to absorption Spectroscopy or reflectance spectroscopy in part of the ultraviolet and the full, adjacent visible spectral regions. This means it uses light in the visible and adjacent ranges. The absorption or reflectance in the visible range directly affects the perceived colour of the chemicals involved. In this region of the electromagnetic spectrum, atoms and molecules undergo electronic transitions.



(ULTRAVIOLET VISIBLE SPECTROSCOPY)

5.3 Gas Chromatography: -

Chromatography used in analytical chemistry for separating and analyzing compounds that can be vaporized without decomposition. Typical uses of GC include testing the purity of a particular substance or separating the different components of a mixture.[1] In preparative chromatography, GC can be used to prepare pure compounds from a mixture.



(GAS CHROMATOGRAPHY)

5.4 Centrifuge Machine: -

A centrifuge is a device that uses centrifugal force to separate various components of a fluid. This is achieved by spinning the fluid at high speed within a container, thereby separating fluids of different densities (e.g., cream from milk) or liquids from solids. It works by causing denser substances and particles to move outward in the radial direction. At the same time, objects that are less dense are displaced and move to the centre. In a laboratory centrifuge that uses sample tubes, the radial acceleration causes denser particles to settle to the bottom of the tube, while low-density substances rise to the top.[1] A centrifuge can be a very effective filter that separates contaminants from the main body of fluid.



(CENTRIFUGE MACHINE)

5.5 Tablet hardness tester: -

Tablet hardness testing is a laboratory technique used by the pharmaceutical industry to determine the breaking point and structural integrity of a tablet and find out how it changes “under conditions of storage, transportation, packaging, and handling before usage The breaking point of a tablet is based on its shape. It is similar to friability testing, but they are not the same thing.

Tablet hardness testers first appeared in the 1930s. In the 1950s, the Strong-Cobb tester was introduced. It was patented by Robert Albrecht on July 21, 1953. and used an air pump. The tablet breaking force was based on arbitrary units referred to as Strong-Cobbs. The new one gave readings that were inconsistent to those given by the older testers. Later, electro-mechanical testing machines were introduced. They often include mechanisms like motor drives, and the ability to send measurements to a computer or printer.

There are 2 main processes to test tablet hardness: compression testing and 3-point bend testing. For compression testing, the analyst generally aligns the tablet in a repeatable way, and the tablet is squeezed between a fixed and

a moving jaw. The first machines continually applied force with a spring and screw thread until the tablet started to break. When the tablet fractured, the hardness was read with a sliding scale.



(TABLET HARDNESS TESTER)

5.6 Hot Air Oven: -

Hot air ovens are electrical devices which use dry heat to sterilize. They were originally developed by Pasteur. Generally, they use a thermostat to control the temperature. Their double walled insulation keeps the heat in and conserves energy, the inner layer being a poor conductor and outer layer being metallic. Are electrical devices which use dry heat to sterilize? They were originally developed by Pasteur. Generally, they use a thermostat to control the temperature. Their double walled insulation keeps the heat in and conserves energy, the inner layer being a poor conductor and outer layer being metallic.



(HOT AIR OVEN)

5.7 Vacuum Oven: -

Vacuum ovens are very versatile pieces of equipment with applications in laboratory research, engineering, and industry. A vacuum drying oven is most often used for delicate drying processes, such as drying tiny parts or removing flammable solvents. The low-pressure environment also minimizes oxidation during drying.



(VACCUM OVEN)

5.8 pH Meter: -

A pH meter is an instrument used to measure acidity or alkalinity of a solution – also known as PH.

PH is the unit of measure that describes the degree of acidity or alkalinity. It is measured on a scale of 0 to 14. The quantitative information provided by the pH measurement expresses the degree of the activity of an acid or base in terms of hydrogen ion activity. The pH value of a substance is directly related to the ratio of the hydrogen ion $[H^+]$ and the hydroxyl ion $[OH^-]$ concentrations. If the H^+ concentration is greater than OH^- , the material is acidic, i.e., the pH measurement is less than 7. If the OH^- concentration is greater than H^+ , the material is basic, with a pH value greater than 7. If equal amounts of H^+ and OH^- ions are present, the material is neutral, with a pH of 7. Acids and bases have free hydrogen and hydroxyl ions, respectively.

The relationship between hydrogen ions and hydroxyl ions in a given solution is constant for a given set of conditions, either one can be determined by knowing the other.



(pH METER)

6. REAL TIME EXPOSURE IN LABORATORY

Stability studies- Testing Laboratory: -

Scope: The process performed in the Stability laboratory including instrumentation

Objective: To enhance my knowledge about stability laboratory.

The purpose of this stability test is to fix the expiry date for the drugs; they will fix the expiry date based on stability check in three conditions

- Long term conditions
- Accelerated stability conditions
- Intermediate stability conditions

If the drug passes the accelerated stability conditions tests, then we can make a commitment with regulatory bodies and sell our products with a deal of submitting long term stability conditions tests within 36 months

Here the parenteral are kept in different chambers and each chamber will maintained at different conditions and this process is used to fix the expiry date at each condition

Climatic Zone		Temperatures	Humidity
Zone I	Temperate	21 °C (± 2 °C)	45% RH (± 5%)
Zone II	Subtropical, with possible high humidity	25 °C (± 2 °C)	60% RH (± 5%)
Zone III	Hot/Dry	30 °C (± 2 °C)	35% RH (± 5%)
Zone IV	Hot/Humid	30 °C (± 2 °C)	65% RH (± 5%)
Zone IVb	Hot/Humid*	40° C (± 2 °C)	75% RH (± 5%)
Refrigerated		5 °C (± 3 °C)	None
Frozen		-15 °C (± 5 °C)	None

Based on the temperature and humidity the world is divided into 4 zones

7. DEPARTMENTS: -

The main process of the department is: -

- ❖ Store
- ❖ QC (quality control)
- ❖ QA (quality assurance)
- ❖ Production
- ❖ Packing

STORE PROCESS: -

Steps involved in raw material warehouse: -

- ❖ Receiving
- ❖ Sampling
- ❖ Quarantine
- ❖ Storing
- ❖ Dispensing

RECEIVING OF RAW MATERIAL: -

- Raw material is supplied by vendors by placing order.
- After receiving the raw materials check the “observation on pack”.
- Segregate the raw material according to batch number.
- Pre entry cleaning of raw materials by vacuum cleaner.
- Weighing of the raw materials.

SAMPLING OF RAW MATERIAL: -

- Before sampling get line clearance by QA person
- QC persons test the sample of raw material under lab by different tests and fill it in OBSERVATION ON SAMPLING AREA & PACK” and “CERTIFICATE OF ANALYSIS”
- Will paste the labels of “APPROVED LABEL” and “SAMPLED LABEL”
- Next the raw materials are sent for storing.

QUARANTINE: -

- In the stage of raw materials is kept in a poorly ventilated and aerated room to maintain its temperature.
- Here the RH is maintained.

STORING OF RAW MATERIAL: -

- The raw material is stored in approved area at three different temperatures.
- AMBIENT: not more than 35c.
- CONTROLLED TEMPERATURE ROOM: Nearly 15 to 25c.
- COLD ROOM: between 2 to 8c.

DISPENSING OF RAW MATERIAL: -

- Raw materials are dispensed from dispensing booth under lab of the production area.
- In case of dispensing there is special provision for dispense the material.

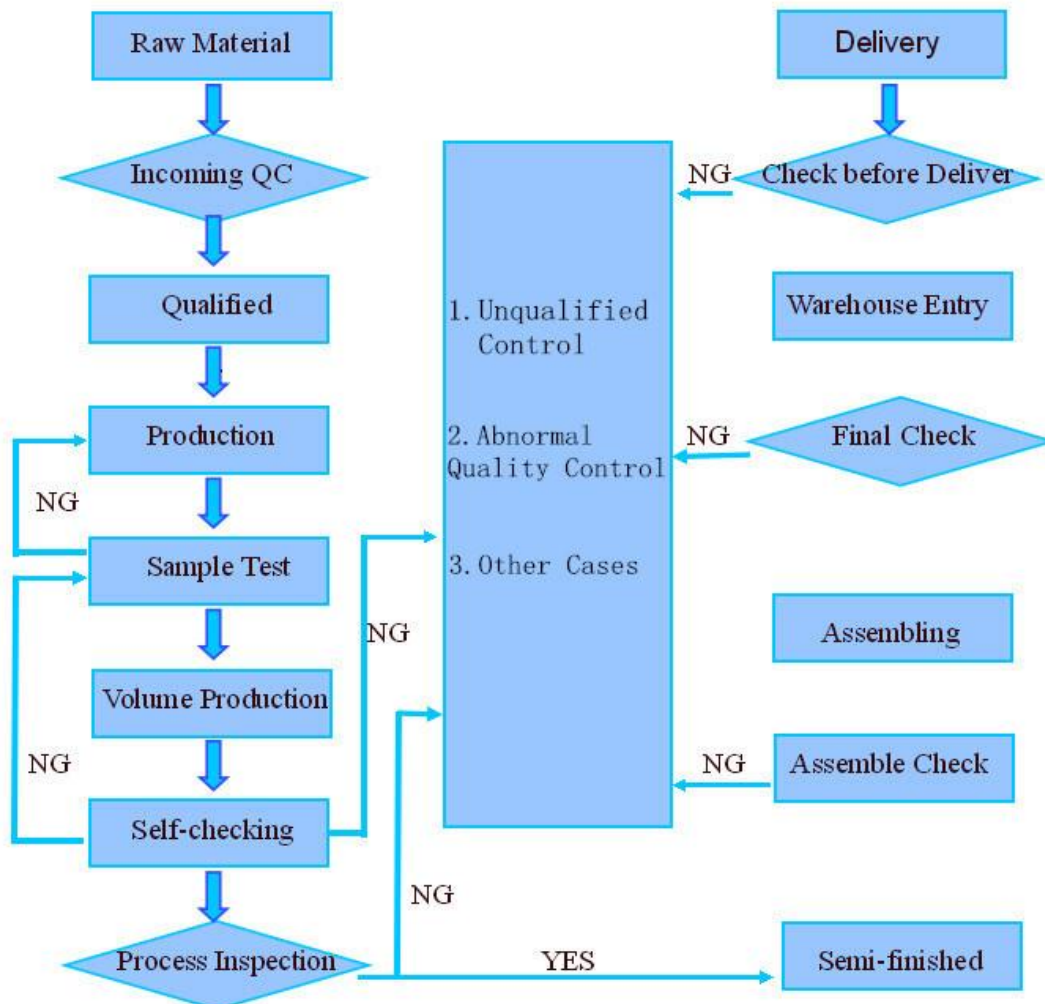
1. QUALITY CONTROL: -

Primary concern of the company is the provision of quality product and services to gain the trust of our clients.

We have implemented a quality and safety management system that complies with WHO-GMP regulations and requirements.

We are also continuously improving our process, products and quality and safety management system through teamwork with our staff, customers, and suppliers. Our Quality focus encompasses all areas of manufacturing operations-from the procurement of raw materials to best possible manufacturing technology, functional operations to the delivery of finished formulations. Vendor assessment and assortment is carried out as per stringent quality, product, manufacturing and service and delivery parameters to ensure the highest quality inputs.

Quality Control Flow Chart



QUALITY ASSURANCE: -

The quality assurance department is managed by qualified personal, who constantly examines quality considerations-performing systematic sampling and testing at every stage from raw material through each procedure of intermediate and finished pharmaceutical formulations.

A regular valuation process, test methods, water, and environment as well as periodic calibration of all instruments are carried out to ensure quality output of finished products.

2. QUALITY CONTROL LABORATORY: -

These norms are controlled by a superior high tech quality control laboratory and all activities are managed through four sections.

- Instrumental Analysis Laboratory.
- Wet Analysis Laboratory.
- Microbiological Testing laboratory.
- Packing material testing laboratory.

3. PACKING: -

Pharmaceutical packaging (or drug packaging) is the packages and the packaging processes for pharmaceutical preparations. It involves all the operations from production through drug distribution channels to the end consumer. ... Packaging is often involved in dispensing, dosing, and use of the pharmaceutical product.

❖ TYPES OF PACKING: -

- Primary packing.
- Secondary packing.
- Tertiary packing.

❖ PRIMARY PACKING: -

- Primary packaging means any single part of a container closure system. Typically containers (e.g., ampoules, vials, bottles).

❖ SECONDARY PACKING: -

- Secondary packaging is the exterior packaging of the primary packaging that groups packages and further protects or labels the drug product..

❖ TERTIARY PACKING: -

- Tertiary packaging is used for bulk handling, storage, and distribution.

CONCLUSION:

In recent decades pharmaceutical packaging technology is an important technique in pharmaceutical industry. After formulation, the next step is packaging. It is an important process in pharmaceuticals because it provides the protection for products, identification & protection against the physical damage and gives the attractiveness for the products & improves the patient compliances.

Quality control of tablets involves various tests which require keen attention and to ensure that established product quality standards are met, these tests must be performed during production (in process control) and verified after the production of each batch.

THANK YOU