**INDUSTRIAL TRAINING IN**

**PHARMACEUTICAL**

**COMPANY**

An Industrial training Report submitted

for the partial fulfillment of the Degree of Master of Science

By

Darshana Pambhar

[M.Sc. (Microbiology), SemesterIV]

Under the supervision of

(**Mr. Hitesh Dholariya**)

Head of QA and QC department

**ERVA HEALTH CARE Pvt. Ltd , Rajkot**

**DEPARTMENT OF MICROBIOLOGY**

**SHREE M. & N. VIRANI SCIENCE COLLEGE**

**'YOGIDHAM GURUKUL' KALAWAD ROAD**

**RAJKOT (GUJARAT) – 360005**

**2019-21**

# C E R T I F I C A T E

This is to certify that thistrainingreport entitled "**Analysis of quality of Raw material and formulation Tablets**" was successfully carried out by Miss **Pambhar Darshana** towards the partial fulfillment of requirements for the degree of Master of Science in Microbiology of **Shree M & N Virani scienececollage Rajkot.** It is an authentic record of her own work, carried out by her under the guidance of **Hiteshbhai Dholariya** for a period of …**2 Month**. during the academic year of**2020-2021** The content of this report, in full or in parts, has not been submitted for the award of any other degree or certificate in this or any other University.

Name & Signature of the Head of the Department

Name & Signature of the supervisor

# Acknowledgement

My thesis submission marks the end of a long and eventful journey which has certainly explained a vital fact of life that strength does not come from winning; it is your struggle which develops your strength.

I would like to take the privilege of acknowledging all those who helped and supported in their own decisive ways. I am not at all exaggerating when I admit that I am indebted to my project guide Dr. Shivani patel Precious guidance and powerful words of encouragement.

I would like to express my deep gratitude to Dr. Shivani patel (Head of department) for providing the entire basic infrastructure including library, internet and other research facilities as well as for developing a great work culture with a sense of teamwork and healthy competition in the department.

I am also thankful to Erva Healthcare Pvt. Ltd, Rajkot and their HR Mr. Vijay Damasiya and Designtated partner Mr. Hitesh Dholariya who gave me such opportunity to do work in production and Q.C. lab of Erva Healthcare.

# D E C L A R A T I O N

I hereby declare that the work incorporated in the present internship report entitled **"INDUSTRIAL TRAINING IN PHARMACEUTICAL COMPANY"** is my own work and is original. This work (in part or in full) has not been submitted to any University for the award of any Degree or a Diploma.

04 /05 2021. Darshana Jagdishbhai Pambhar

Date (Name and signature of Student)

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# Chapter 1: Introduction

## 1.1 company profile:

| | |
|---|---|
| Name: | Erva healthcare private limited |
| Type: | public |
| Foundation: | 2016 |
| Company address: | plot no. 11, Rk industrial hub, kuvadva-wakaner highway, at- ranpur, Rajkot, Gujrat, India. |
| Company office: | Sambhav office no. 204, nr. Satyam party plot, nana Mava main road, Rajkot. |
| Key people: | Mr. Jagdish Tarapada (Director)<br>Mr. Naresh Nathani (Director)<br>Mr. Hitesh Dholariya (Q C head)<br>Mr. Manojbhai sakariya (Director) |
| Website: | https://ervahealthcare.com |

## 1.2 History of company:

- Established in the year **2016,** we "Erva Healthcare Private Limited" are a prominent firm that is engaged in Manufacturer a wide range of Pharmaceutical Tablets, Pharmaceutical Capsules, Pharmaceutical Gel, etc. Located in Rajkot (Gujarat, India), we are a Pvt.Limited Company firm and manufacture the offered products as per the set industry norms.
- Our valued clients can avail these products from us at reasonable rates. Under the headship of our mentor "Mr. Naresh **Nathani"(Owner),** we have gained a remarkable and strong position in the market.
- Erva Healthcare has been established on a prominent foundation, imbibing Quality, Service & Care for the Society.
- Erva's team constitutes of a family inculcated with true principles & ethics to strive for the betterment of industry.
- The future symbiosis with many branches of pharmaceutical industry will extend our horizons to the deepest core of the fraternity.

## 1.3 company structure:


Figure 1.3.1 Erva Healthcare pvt. Ltd.

## 1.4 products of Erva:

- In Erva three types of product tablet, capsule, and external preparation.
- In tablet, two types of tablet coated tablet, and uncoated tablet. Acrylic polymer is used in coating process. The advantages of coated tablet are taste masking, odor masking, physical and chemical protection and to control its release profile. Uncoated tablet are white in color and plain.
- In capsule, two types of gelatin are produce by this company. Hard gelatin and soft gelatin. In hard gelatin capsule holds dry ingredients in powder foam.

- It is made of two parts, the body and caps each of different color. Soft gelatins are made up of dissolve the gelatin but for oil based solution.
- In external preparation, Ointment is used to leave a layer of oil on the surface of the skin, moisture on the skin.
- Gel is generally water based and transparent, are usually oil free, Cream's contain oil, but at a lower concentration than in ointment. It is usually thick and white.

### 1.4.1 Azithromycine Tablet

- ✓ **Mode of action:** Azithromycin prevents bacteria from growing by interfering with their protein synthesis. It binds to the 50S subunit of the bacterial ribosome, thus inhibiting translation of mRNA. Nucleic acid synthesis is not affected.
- ✓ **Purpose:** Azithromycin is an antibiotic. It's widely used to treat chest infections such as **pneumonia**, infections of the nose and throat such as sinus infection (sinusitis), **skin** infections, Lyme disease, and some sexually transmitted infections.
- ✓ **Side effect:** Stomach upset, **diarrhea**, **nausea**, vomiting, or **abdominal pain** may occur. If any of these effects

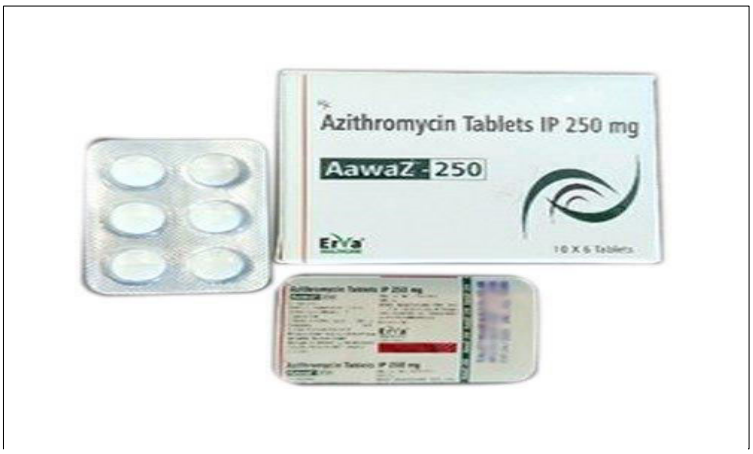


**Figure 1.4.1.1 Azithromycin Tablet**

persist or worsen, tell your doctor or pharmacist promptly.

### 1.4.2 levocitrizine Dihydrochloride Tablets

- ✓ **Mode of action:** Levocetirizine is an antihistamine used to relieve allergy symptoms such as watery eyes, runny nose, itching eyes/nose, and sneezing. It is also used to relieve itching and hives. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.
- ✓ **Purpose:** Levocetirizine is used to relieve runny nose; sneezing; and redness, itching, and tearing of the eyes caused by hay fever, seasonal allergies, and allergies to other substances such as dust mites, animal dander, and mold. It is also used to treat symptoms of hives, including itching and rash.
- ✓ **Side effect:** Dry mouth

  Fatigue

  Sore throat

  Dizziness


Figure 1.4.2.1 levocitrizine dihydrochloride Tablet

### 1.4.3 Itraconazole capsule

- ✓ **Mode of action:** Itraconazole acts by inhibiting the fungal cytochrome P-450 dependent enzyme lanosterol 14-α-demethylase. When this enzyme is inhibited it blocks the conversion of lanosterol to ergosterol, which disrupts fungal cell membrane synthesis.
- ✓ **Purpose:** Itraconazole capsules are used to treat fungal infections in the lungs that can spread throughout the body. Itraconazole capsules are also used to treat fungal infections of the fingernails. Itraconazole tablets and capsules are used to treat fungal infections of the toenails.
- ✓ **Side effect:** headache, dizziness, tiredness, rash, itching, swelling, fever, muscle or joint pain


**Figure 1.4.3.1 itraconazole capsule**

### 1.4.4. Pregabaline and methylcobalamine capsule

- ✓ **Mode of action:** Methylcobalamin is a form of vitamin B which helps in the production of myelin, a substance that protects nerve fibers and rejuvenates damaged nerve cells. Pregabalin is an alpha 2 delta ligand which decreases the pain by modulating calcium channel activity of the nerve cells.
- ✓ **Purpose:** This medication is used to treat pain caused by nerve damage due to diabetes, shingles (herpes zoster) infection, or spinal cord injury. This medication is also used to treat pain in people with fibromyalgia.It is also used with other medications to treat certain types of seizures.
- ✓ **Side effects**: dizziness, sleepiness, dry mouth, weight gain, swelling


Figure 1.4.4.1 Pregabaline and methylcobalamine capsule

### 1.4.5 luliconazole cream

- ✓ **Mode of action:** Luliconazole is an antifungal that belongs to the azole class. Although the exact mechanism of action against dermatophytes is unknown, luliconazole appears to inhibit ergosterol synthesis by inhibiting the enzyme lanosterol demethylase.
- ✓ **Purpose:** Luliconazole is used to treat tinea pedis (athlete's foot; fungal infection of the skin on the feet and between the toes), tinea cruris (jock itch; fungal infection of the skin in the groin or buttocks), and tinea corporis (ringworm; fungal skin infection that causes a red scaly rash on different parts of the body).
- ✓ **Side effect:** application site reactions such as **skin irritation** (contact dermatitis) orMuscle pain


Figure 1.4.5.1 luliconazole cream

# Chapter 2 Materials and method

## 2.1 What is sop ?

SOP means Standard Operating Procedure, that has written document and also GDP, which is followed by employs in industry for proper work and help to mange legal risk and benefit to perform a properly work. A typical pharmaceutical industry has an average of 1200-1300 SOPs.

### 2.1.1 How to make sop ?

In this SOP written how to perform a particular work in pharma industry, in Table 1 given a how to make this like a title, Sop Originator, Approving Position etc.

| | | |
|---|---|---|
| Sop name and title | | |
| Document storage location/ source | | Document No. |
| Sop originator | Approving position | Effective date |
| Name | Name | Last editing date |
| Signature | Signature | Other |

Table 2.1.1.1 Format of sop

## 2.2 SoP made for bulk density:

- **Title:** SOP for cleaning and operation of bulk density apparatus.
- **Scope:** This SOP is applicable for the operation of bulk density.
- **PROCEDURE:**

  Operating procedure

**1** Fit 25 ml cylinder in the stand provide with sample.

**2** Set stoke with set rotary type button.

**3** Push alarm button.

**4** Start stroke and adjust for 50 strokes or required.

**5** And write a result and calculate the bulk density or tapped density.

- **Calculation:**

Bulk Density: Pb = M / V

Where: Pb = Bulk density, M = Weight of powder, V = Volume of powder

Tapped Density: pt = M / Vt

Where: pt = Tapped density, M = Weight of powder, Vt = Minimum volume occupied after tapping

## 2.3 SOP made for loss on drying:

- **Title:** SOP for cleaning and operation of loss on drying apparatus.
- **Scope:** The SOP is applicable for the operation of loss on drying.
- **PROCEDURE:**

Operating procedure

**1**. Take a sample and put into the Petri plate.

**2**. After weight the of this Petri plate.

**3**. Put into the oven and set the desired temperature.

**4**. After dried sample take away and weight the Petri plate.

**5**. Write a result and calculate the loss on drying.

- **CALCULATION:**

Loss on drying (%) = initial weight of sample – weight of sample after drying * 100

Initial weight of sample

## Various department of company

### 2.4 Production Department

In Production department samples are examination and tested through R&D and QC department and after approval of QA

### 2.4.1Hardness

It is the load required to crush the tablet when placed on its edge. To determine the need for pressure adjustments on the tableting machine. Hardness can affect the disintegration. So if the tablet is too hard, it may not disintegrate in the tablet is too hard, it may not disintegrate in the required periods of time. If the tablet is too soft, it will not withstand the handling during subsequent.

- **Factors Affecting the Hardness:**

Compression of the tablet and compressive force.

Amount of Binder. (More binder more hardness).

Method of granulation in preparing the tablet (wet method give more. hardness than direct method, slugging method gives the best hardness).

- **Limits:**

6 Kilogram minimum and 8 Kilograms maximum.

The hardness tester apparatus consist of 2 jaws facing each other, one of which move towards the other. Measurement is carried out on 10 tablets, taking care to remove all the fragments

of the broken tablets before each determination & then take the average hardness.


Figure  Hardness testing apparatus

### 2.4.2 Friability

- It is the tendency of tablets to powder, chip, or fragment and this can affect the elegance appearance, consumer acceptance of the tablet, and also add to tablet's weight variation or content uniformity problems.
- **For e.g.:** Coating, packaging, transport, which is not serving enough to break the tablet, but may abrade the small particle from tablet surface. To examine this, tablet is subjected to a uniform tumbling motion for specified time and weight loss is measured.
- Friability is a property that is related to the hardness of the tablet & also adds weight variation, content uniformity problem. An instrument called Friabilator is used to

evaluate the ability of the tablet to withstand abrasion in packaging, handling, and shipping.

**Formula:**

Friability= initial weight of tablet – weight of tablet after rotation*100

Figure 1 Figure 2.4.2.1 friability testing apparatus

### 2.4.3 Compression machine

- Compression testing machine is used to establish a compressive force or crush resistance of materials. Compression machine are used to determine the material behaviour under load.
- These test are important to measure the elastic and compressive properties of raw materials.

- Compression machine are also use to determine elasticity, strength of material, proportional limit, and compressive yield point.
- Compression testing machine is the ability of the material to recover after a specified **compressive** force is applied and even held over a defined period of time by measuring fundamental variables


Figure 2.4.3.1 compression machine

### 2.4.4 Grinding mills

- Multi mill is used for high speed Granulating, Pulverising, Mixing, Shredding and Chopping, etc, of a wide range of wet and dry materials without special attachments.

- This machine utillises the principle of variable force swing hammer blades having both knife and impact edges rotating with a carefully selected screen to control size reduction.

Figure 2.4.4.1 Grinding mill machine

### 2.4.5 Fluidized bed dryer

- Fluid bed dryer works on a principle of fluidization of the materials. In fluidization process, hot air or gas flow is introduced through the bed of solid particulates.

- This gas or air will move upwards through the spaces between the particles.

- Fluidized bed dryer is used in the pharmaceutical industries to reduce moisture content of pharmaceutical powder of granules.

Figure 2.4.5.1 Fluidized bed dryer

### 2.4.6 Capsule filling machine

- Capsule filling machine is used to fill empty capsule or hard gelatine capsule of various size with powders and granules.
- Put the top half of the capsule over the bottom and press down. Once the bottom of the capsule filled, gently replace the top of the capsule.

- Hold the bottom of the capsule gently in one hand, then use the other to press the top of the capsule down. Store the capsules in a cool, dark place.

Figure 2.4.6.1 capsule filling machine

### 2.4.7 Tube filling machine

- Tube filling machine feed the tube into a rotary table and then fill the tube and seals with either heat seal or trim.

- These machine can fill tubes, lotions, food products, pharmaceuticals, gels and creams.

- tube filling and sealing machines include automatic tube loading, orientation, filling, sealing, and coding for plastic or aluminum tubes with speed ranges from 30 to 80 tubes per minute and sizes up to 200 ml.

Figure 2.4.7.1 Tube filling matching

**Packing and labelling:**

- The finished products is packed in drums as per requirement for example 5 kg,10 kg,25 kg etc.
- Then information regarded to product like name ,batch, manufacturing date, brand name, generic name, stereo etc...

## 2.5 Quality control Department

- QC Department are under they work to reduce risk in production, achieve rapid product release, and eliminate defects, impurities and contamination, from raw materials through to finished product - as well as supporting relevant quality assurance (QA) and regulatory standards.

- **Two laboratory** in QC department:

1. Wet analysis laboratory
2. Instrumental analysis laboratory

 Various tests are done in Wet Analysis Laboratory .They are given below:

**Solubility:**

To check the solubility of sample.

**Clarity:**

To check clarity of sample when it is dissolved in suitable solvent.

**Foreign Matter:**

To check the presence or absence of residue when sample is dissolved in suitable solvent.

**Clear Melt:**

To check the clarity of sample when it is melted.

**Density :**

To determine the density of sample.

**Assay :**

To check the percentage of activeness of sample.

**Acidity :**

To determine the acidity of sample.

**pH :**

To determine pH of sample.

**Moisture :**

To determine the presence of water in sample.

**LOD(Loss on Drying) :**

To determine the loss of sample/water on drying.

**FA & FAS:**

To determine the free amines and free amine salts in samples.

## Instruments used in QC department:

### 2.5.1 Analytical Balance:

- An analytical balance is a class of balance designed to measure small mass in the sub- milligram range.
- The measuring pan of an analytical balance (0.1mg or better) is inside a transparent enclosure with doors so that dust does not collect and so any air currents in the room do not affect the balance's operation.


Figure 2.5.1.1 analytical balance

### 2.5.2 pH Meter:

- A pH meter is a scientific instrument that measures the hydrogen-ion activity in water-based solutions, indicating its acidity or alkalinity expressed as pH.
- The pH meter measures the difference in electrical potential between a pH electrode and a reference electrode, and so the pH meter is sometimes referred to as a "potentiometric pH meter".

- The difference in electrical potential relates to the acidity or pH of the solution.
- The pH meter is used in many applications ranging from laboratory experimentation to quality control.
- pH meters measure the voltage between two electrodes and display the result converted into the corresponding pH value.
- They comprise a simple electronic amplifier and a pair of electrodes, or alternatively a combination electrode, and some form of display calibrated in pH units.
- It usually has a glass electrode and a reference electrode, or a combination electrode.The electric or probes are inserted into solution to be tested.

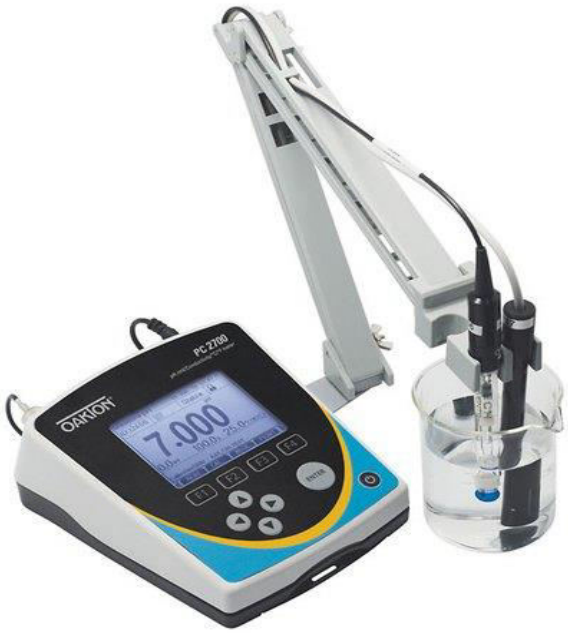


**figure 2.5.2.1 pH meter**

2.5.3 Karl Fischer Titrator:

- Karl Fischer titration is a classic titration method in chemical analysis that volumetric titration to determine trace amounts of water in a sample. It was invented in 1935 by the German chemist karl fischer.
- The main compartment of the titration cell contains the anode solution plus the analyte.
- The anode solution consists of an alcohol (ROH), a base (B), SO2 and I2.
- A typical alcohol that may be used is ethanol or diethylene glycol monoethyl ether, and a common base is imidazole.

figure 2.5.3.1 karl fischer titrimeter

### 2.5.4 Bulk Density meter :

Bulk density meter is used to measure the Apparent **Bulk Density** of any dry free-flowing Powders, Crystals, Granules, Particles or Flakes like Tea, Coffee Powder, Chicory Powder, Instant Coffee, Milk Powder, Soup Powde

Figure 2.5.4.1 bulk density apparatus

### 2.5.5 Sonicator:

- Sonicator can mix the solutions, accelerate the dissolution of a solid into a liquid, such as sugar into water, and remove dissolved gas from liquids.
- Sonicator is widely used in the laboratory to disperse the nanotube into polymer matrix.
- It is usually carried out by an ultrasonic bath or a horn/probe which is also known as the **sonicator.**

Figure 2.5.5.1 sonicator

### 2.5.6 Hot air oven:

- It is a type of dry heat sterilization. Hot air ovens are electrical device which use dry to sterilize.
- Hot air oven is **used** on equipment that cannot be wet and on material that will not melt, catch fire, or change form when exposed to high temperatures.
- It is a physical method for sterilization due to dry heat.


Figure 2.5.6.1 Hot air oven

### 2.5.7 Muffle furnace:

- Muffle furnace is used for the demand of testing the sample at high temperature and to determine the percent of ash content in those materials.
- the **furnaces** are **used** for treating the samples at high-temperature include: pharmaceutical industry.

Figure 2.5.7.1 muffle furnace

**Analytical development laboratory:**

- The R&D facility is well supported by Analytical Development Lab which is equipped with instruments like HPLC, UPLC, GC, GC-HS, LCMS, dissolution apparatus and other supporting equipments required for testing.
- The analytical laboratory carries out the following operations:
- Development/Validation and transfer of analytical method for in process and API's as per regulatory requirements.
- Synthesis, Isolation and characterization of process impurities.
-

**Polymorphic studies.**

**2.5.8 HPLC ( High performance liquid chromatography):**

- High-performance liquid chromatography (HPLC; formerly referred to as high-pressure liquid chromatography) is a technique in analytical chemistry used to separate, identify, and quantify each component in a mixture.
- It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material. Each component in the sample interacts slightly differently with the adsorbent material, causing different flow rates for the different components and leading to the separation of the components as they flow out of the column.

The schematic of a HPLC instrument typically includes a degasser, sampler, pumps, and a detector. The sampler brings the sample mixture into the mobile phase stream which carries it into the column, generating composition gradient in the mobile phase. Various detectors are in common use, such as UV/Vis, photodiode array (PDA) or based on mass spectrometry.

Figure 2.5.8.1 HPLC

## 2.5.9 UV spectrometer:

- It is based on lambert beer law. Ultraviolet –visible spectroscopy or ultraviolet–visible spectrophotometry (UV– Vis or UV/Vis) refers to absorption spectroscopy or reflectance spectro scopy in part of the ultraviolet and the full, adjacent visible spectral regions.

- The absorption or reflectance in the visible range directly affects the perceived color of the chemicals involved. In this region of the electromagnetic spectrum, atoms and molecules undergo electronic transitions.


Figure 2.5.9.1 UV spectrometer

## 2.5.10 Dissolution apparatus:

- **Dissolution** is a standardised method for measuring the rate of drug release from a dosage form and the “standardisation" because for any results to be meaningful, it is essential that all the **apparatus used** for the testing, produces the same sets of results given all other parameters are equal.

- The drug is placed within the medium in the vessels after it has reached to the sufficient temperature and then the **dissolution apparatus** is operated.
- Sample solutions collected from **dissolution testing** are commonly analyzed by HPLC or Ultraviolet–visible spectroscopy.

Figure 2.5.10.1 dissolution apparatus

## 2.6 Quality Assurance department:

- Quality assurance (QA) is a way of preventing mistakes and defects in manufactured products and avoiding problems when delivering
- products or services to customers; which ISO 9000 defines as "part of quality management focused on providing confidence that quality requirements will be fulfilled".

### 2.6.1 What is Quality?

- Quality is extremely hard to define, and it is simply stated: "Fit for use or purpose." It is all about meeting the needs and expectations of customers with respect to functionality, design, reliability, durability, & price of the product.

### 2.6.2 What is Assurance?

- Assurance is nothing but a positive declaration on a product or service, which gives confidence. It is certainty of a product or a service, which it will work well. It provides a guarantee that the product will work without any problems as per the expectations or requirements.

### 2.6.3 What is Quality Assurance?

- Quality Assurance (QA) is defined as an activity to ensure that an organization is providing the best possible product or service to customers. QA focuses on improving the processes to deliver Quality Products to the customer.

- An organization has to ensure, that processes are efficient and effective as per the quality standards defined for software products. Quality Assurance is popularly known as QA Testing

### 2.6.4 How to do Quality Assurance: Complete Process

- Quality assurance has a defined cycle called PDCA cycle or Deming cycle. The phases of this cycle are:

Plan

Do

Check

Act

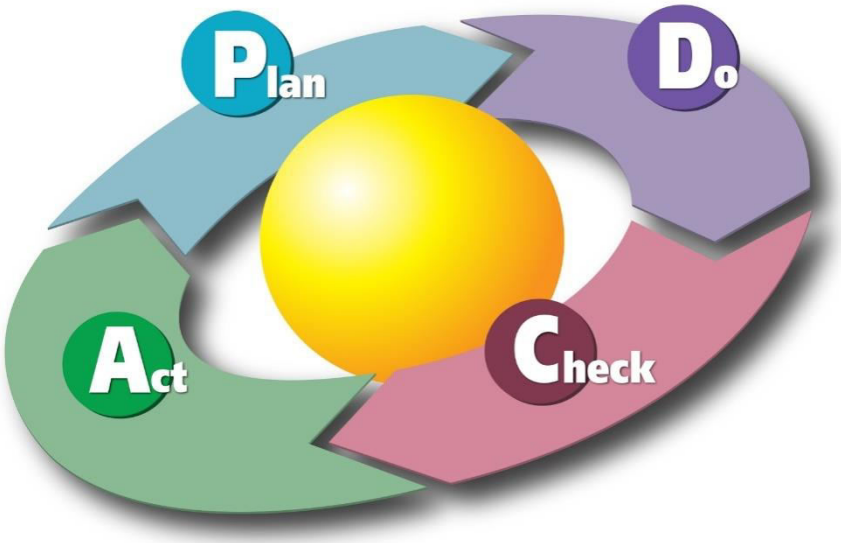


Figure 2.6.4.1 PDCA

- These above steps are repeated to ensure that processes followed in the organization are evaluated and improved on a periodic basis. Let's look into the above steps in detail -

**Plan –**

Organization should plan and establish the process related objectives and determine the processes that are required to deliver a high-Quality end product.

**Do –**

Development and testing of Processes and also

"do" changes in the processes

**Check –**

Monitoring of processes, modify the processes, and check whether it meets the predetermined objectives

**Act –**

Implement actions that are necessary to achieve improvements in the processes

An organization must use Quality Assurance to ensure that the product is designed and implemented with correct procedures. This helps reduce problems and errors, in the final product.

# Chapter 3 Result and conclusion

## 3.1 Quality control test for Tablet, capsule and ointment

## 3.2 Microbial limit test

- The microbial limit test are designed to perform the qualitative and quantitative estimations of specific viable microorganisms present in samples.
- It includes tests for total viable count (bacteria and fungi) and E.coli. The most cae must be taken in performing the tests, so that microbial contamination from the outside can be avoided.
- When test samples have antimicrobial activity or when they include antimicrobial substances, these antimicrobial properties must be eliminated by dilution, filtration, neutralization, inactivation, or other appropriate means. The tests should be conducted for samples prepared by mixing multiple portions randomly chosen from individual ingredients or products.
- When samples are diluted with fluid medium, the tests must be conducted quickly.
- Due attention must be paid to the effective quality control and the prevention of biohazard.

### 3.3 MLT test for Ervadol spas Tablet

**Requirements:** petri plate For caps Seasor  Gowning Ervadol spas Tablet

Filter assembly

Sabouraud dextrose agar

Soyabean casein digest agar

Incubator

**Procedure:**

1. Approximately 1gm tablet dissolve in 10 ml peptone water.

Take 1 ml solution for above suspension and added in 99 ml peptone water.

2. Filter the solution through filter assembly.
3. Put the filter paper on the SDA and SCDA plates.
4. Incubate SCDA plates at 37c and SDA plates at 25c for 24-48 hours.
5. After incubation observe the plates.

**Observation:**

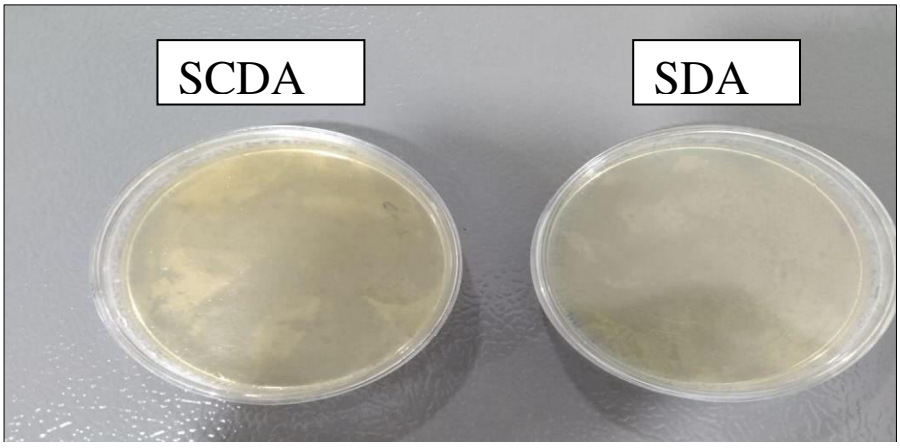


**Figure 3.3.1 observation of Ervadol spas tablet**

### 3.4 MLT test for Itracovil-200 capsule

Requirements: petri plate For caps Seasor Gowning Itracobil-200 capsule

Filter assembly

Sabouraud dextrose agar

Soyabean casein digest agar

Incubator

**Procedure:**

1. Approximately 1gm capsule dissolve in 10 ml peptone water.
2. Take 1 ml solution for above suspension and added in 99 ml peptone water.
3. Filter the solution through filter assembly.
4. Put the filter paper on the SDA and SCDA plates.
5. Incubate SCDA plates at 37c and SDA plates at 25c for 24-48 hours.
6. After incubation observe the plates.

**observation:**

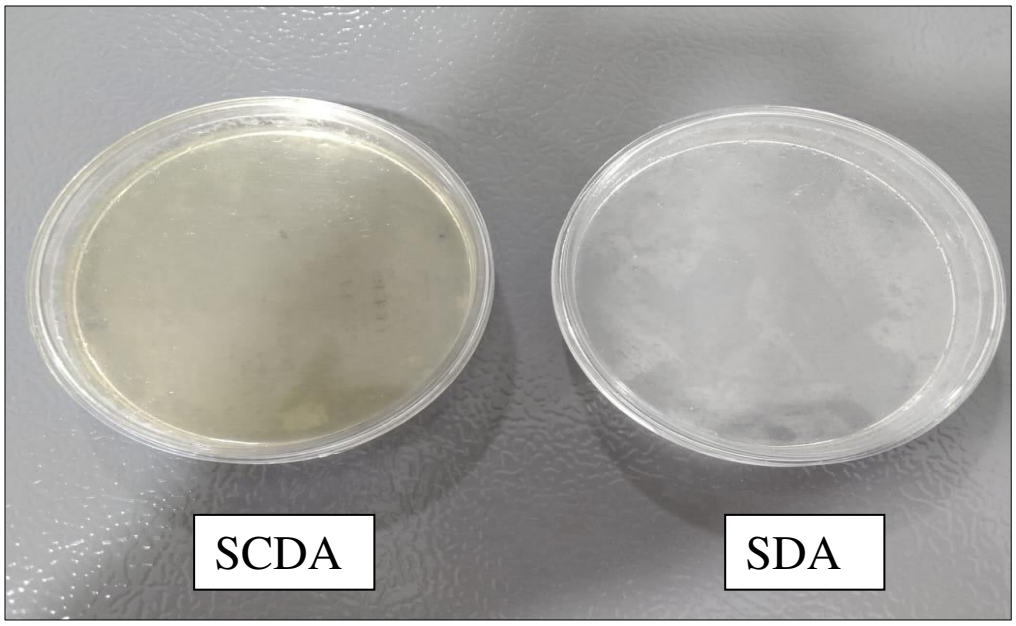


figure 3.4.1 observation of Itracovil 200 capsule

### 3.4 MLT test for benzoyl peroxide gel

**Requirements:** petri plate  For caps Seasor Gowning  Benzoyl peroxide gel

Filter assembly

Sabouraud dextrose agar

Soyabean casein digest agar

Incubator

**Procedure:**

1. Approximately 1gm capsule dissolve in 10 ml peptone water.
2. Take 1 ml solution for above suspension and added in 99 ml peptone water.
3. Take 1 ml suspension and pour on agar plates.
4. Incubate SCDA plates at 37c and SDA plates at 25c for 24-48 hours.
5. After incubation observe the plates.

**observation:**

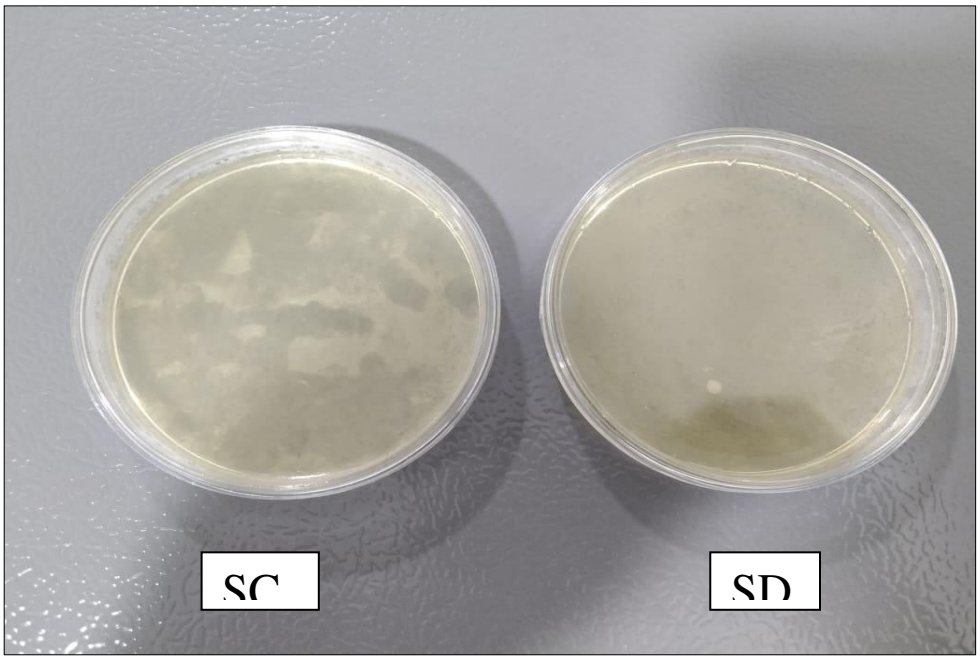


figure 3.5.1 observation of Benzoyl peroxide gel

**Conclusion:**

- From the above study, it can be concluded that there are different types of pharmaceutical products that are checked by different pharmaceutical procedure. And finally result are observed on the base of their limit.
- The pharmaceutical products for microbial limit test is complies as per the pharmaceutical limit for the microbial limit test.

## **Abbreviations**:

QA- quality assurance

QC- quality control

R & D – research and development

HPLC – High performance liquid chromatography

UV- Ultra violet

RM- raw material

Sop- standard operating procedure

SDA- Sabouraud dextrose agar

SCDA- soyabean casein digest agar

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