Microbial and Analytical analysis of products and lab testing

An Industrial Training Report submitted for the partial fulfillment of the Degree of Master of Science

By

Twinkal A. Dalsaniya

[M.Sc. (Microbiology), Semester IV]

Under the supervision of

Mr. Gaurav Pithadiya

Head of QA &QC Department

MEHTA HERBALS Pvt. Ltd., Metoda GIDC

RAJKOT

DEPARTMENT OF /MICROBIOLOGY

Shree M & N Virani Science College (autonomous),

Affiliated to Saurastra University, Rajkot 'YOGIDHAM GURUKUL'

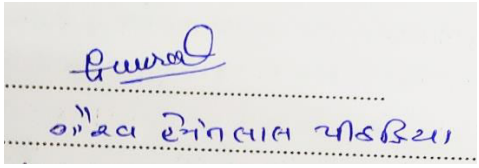
KALAWAD ROAD

RAJKOT (GUJARAT) – 360005

2019-21

C E R T I F I C A T E

This is to certify that this training report entitled “Microbial and analytical analysis of products and lab testing” was successfully carried out by **Miss. Twinkal A. Dalsaniya** towards the partial fulfillment of requirements for the degree of Master of Science in Microbiology of Shree M & N Virani Science College (autonomous), Affiliated to Saurastra University, Rajkot . It is an authentic record of her own work, carried out by her under the guidance of Mr. Gaurav Pithadiya for a period of Feb – March during the academic year of 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

D E C L A R A T I O N

I hereby declare that the work incorporated in the present dissertation report entitled **"**Microbial and analytical analysis of products and lab testing**"** 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.

Twinkal A. Dalsaniya

Date: 09/05/2021

INDEX

ABBREVIATIONS

gm	Gram
hr	Hour
min	Minutes
Kg	Kilo gram
ml	Mili litre
˚C	Degree Celcius

COMPANY PROFILE

- MEHTA HERBALS Pvt. Ltd. is a private incorporated on 18 November 1987.
- It's an ISO certified company.
- It is classified as non-govt Company and is registered at registrar of companies, Ahmadabad.
- The current status of Mehta Herbals Pvt. Ltd. is Active.
- The corporate identification number (CIN) of Mehta Herbals Pvt. Ltd. is U24231GJ1987PTC010147.
- The last reported AGM (Annual General Meeting) of Mehta Herbals Pvt. Ltd, per our records, was held on 31 December, 2020.

AIM & OBJECTIVE

- To discover safe and effective new drugs.
- To discover new ways, technologies and products to manage health.
- To promote drug research in all its branches, including the manufacture of drugs in india.
  To promote research and development of new drugs in the country.

INTRODUCTION

- Introduction of plant

  1) Mehta unani pharmacy & co. pvt. Ltd.

  2) Mehta herbal pvt.ltd.

- Product detail of each plant
- Learning a testing apparatus and instruments
- Methods and analysis
- Production details

METHODOLOGY

- Mainly three department are there quality control department and microbiology department and production department in this many method and test are running:

1. QUALITY CONTROL DEPARTMENT :

- The quality control department is responsible to ensure that all materials meet the established criteria through
- All phases of the process.
- Raw materials, components and packaging and labeling are examined and tested. Every raw materials
- Received is tested for identity and conformance to specifications.

2. QUALITY ASSURANCE DEPARTMENT:

- Documentation work

Tablet friability test apparatus

PROCEDURE:

1) Ensure that the instrument is clean & free from dust.
2) Weigh accurately the number of tablets and carry out the produre as described in the monogram.
3) Open the apparatus from one removable side of the drum.
4) Transfer the tablets in it and close the drum tightly.
5) Switch on the apparatus and count the resolutions as specified in the monogram.
6) The tablets are tumbled at each turn of the drum by a curved projected that extends from the middle of the outer wall.
7) Rotate the drum 100 times and remove the tablets.
8) Remove any loose dust or broken tablets &weigh.
9) Switch off the instrument when not required.

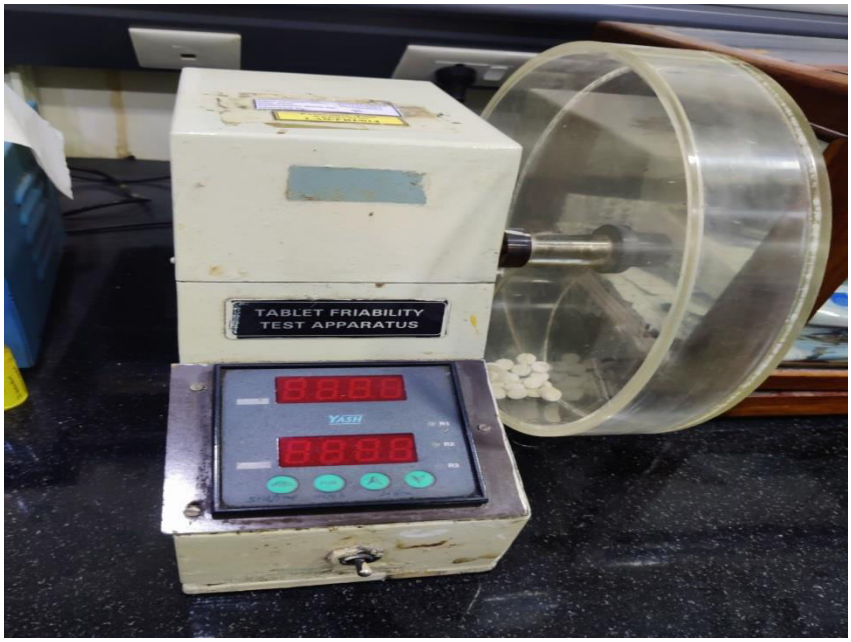


Image: Tablet friability test apparatus

MICROBIOLOGY DEPARTMENT

- There are mainly following types of testing is carried out.

1. Environmental monitoring of plant :

- Check the microbial status of environment in clean area of processing & packaging area.

2. Pathogen testing

- Check the pathogen present in API. It is carried out total viable count For specified microbial species

    A. Water testing

    B. *E.coli* test

    C. *Salmonella* test

DISSOLUTION TEST

- This test are designed to determine compliance with dissolution requirements for solid dosage forms administrated Orally this is intended for a capsule or tablets dissove in a solvent to produce a solution.
- However, for the sustances to Dissolve in a solvent, both the solute and the solvent must be compatible. For instance, a polar, a polar sustance may Not dissolve in a non-polar solvent.
- Among there solvents, water is the universal solvent that is good in dissolving.

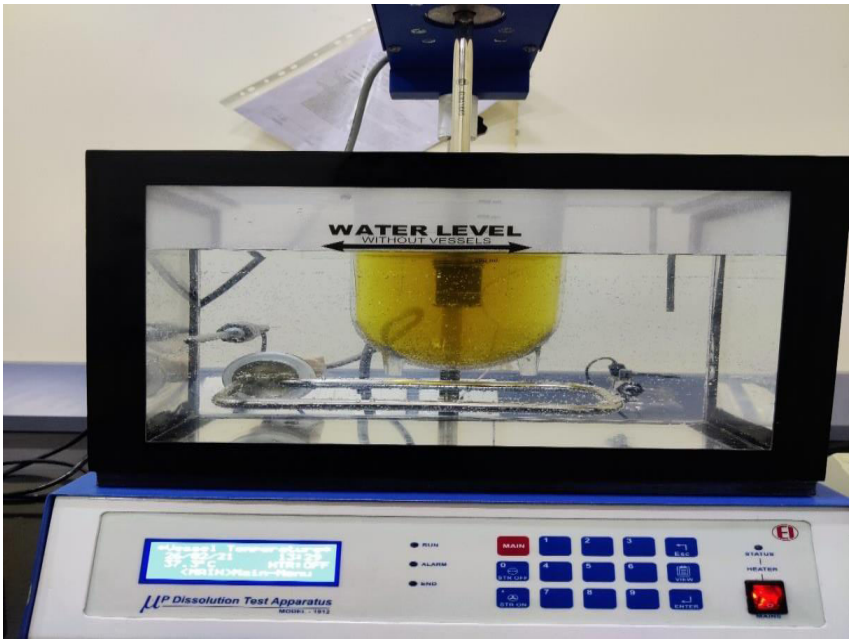


Image: Dissolution test apparatus

Result of Dissolution test:

- I Take a 20 Sennoralance Tablet.
- 20 tablet weight = 8.473 gm
- Tablet loss weight= 0.027 gm

Then, tablet weight = 8.364 gm

Total tablet weight= 0.109 gm

LICK TEST APPRATUS

- Collect the required num 10 strips/ blistered as per gide during packing of tablet half fill the vaccum desicator with methylene blue sodium place that bundle and strips in submerged position.
- Cover the desicator with lid and connect it to vacuum pump. Start the vacuum of 381 mmg Hg. Disconnect the desicator from vacuum pump.
- Maintain the vacuum for at least 1 min for strip puck and 2 min for blister pack.
- Open the strips and examine the tablet.
- Contain out the test at 2 hrs interved.

Image: Lick test apparatus

Infrared moisture balance

- Turn the scale lamp “ON” by means of the toggle switch.
- By turning the scale adjusting knob, adjust the scale until the 100% mark coincide with the index.
- Move the pointer to the index by turning the point adjusting knob in a direction opposite to the in which the pointer must move to coincide with the index.
- Rotate the scale until the 0% mark coincides with the index.
- The pointer is now above the index.
- Carefully distribute about 5 gm of sample on the sample untill the pointer returns to the index.
- Lower the lamp housing and turn on the infrared lamp by means of the voltage regular knob.
- To ensure complete drying, wait one to three min. after the needle becomes constant, record the final moisture content & switch off the infrared lamp.

Image: Infrared moisture balance

Bulk and Tap density apparatus

- Bulk density:
- Weigh 10-15 g of product (to fill half a cylinder) and transfer carefully into the cylinder.
- Switch on the mains of the equipment.
- Set the number of strokes to 50.
- Put on the alarm switch.
- Put on the mains of motor.
- After 50 strokes when a beeping sound is heard, put off the mains of the motor.
- Calculate the bulk density of the blend according to the formula given below:

$$\text{Bulk density in b/ml} = \frac{\text{Quality of the blend weighed in gm}}{\text{Reading in ml read on the cylinder}}$$

- Tap density:
- Use micro controller based tap density instrument. This complies with USP specifications.
- The unit offers a simple & standard means of measuring the tapped density of powders, granules, pellets, flakes and other bulk substances.

Image: Bulk density apparatus

- Result of bulk and tap density:
- Bulk density= 11.932/25

  =0.477 gm/ml

  - tap density[30 times]= 11.932/16.5

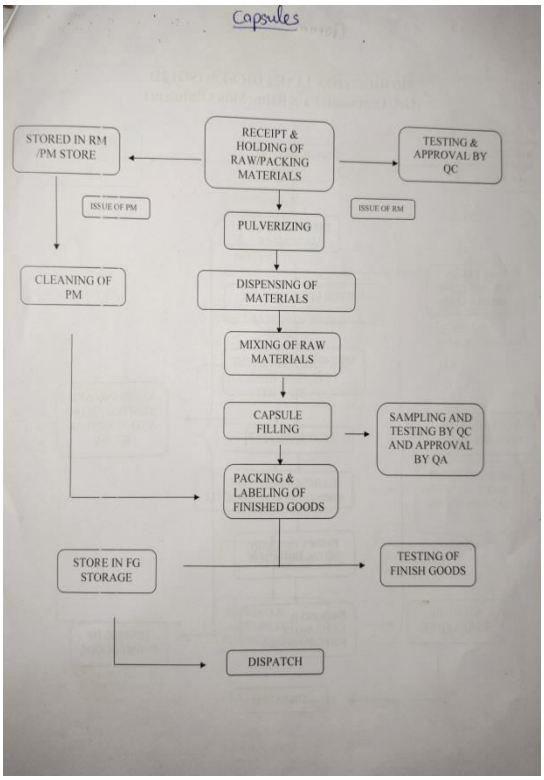
    =0.723 gm/ml

POWDER

PROCEDURE

- MIXING: Weigh all the oils as per 100 kgs. Batch size, mix in mixer pan, and filter it.
- MIXING OF MEDICINE: weigh Perfume, Peppermint and kappor and mix with above powder.
- MIXING OF 1&2: When the temperature of base is between 35 Celsius to 37 Celsius add mixture prepared in step 1 and carry out continuous stirring. (Time-30 mins.)
- Container filling: fill the powder into pp container as per specified weight. Set the B. No-exp. date mfg. date etc. after that filling will be started.
- PACKING: Follow the SOP number PDP/25. The filled pp container is now packed into corrugated carton.

Image: Powder



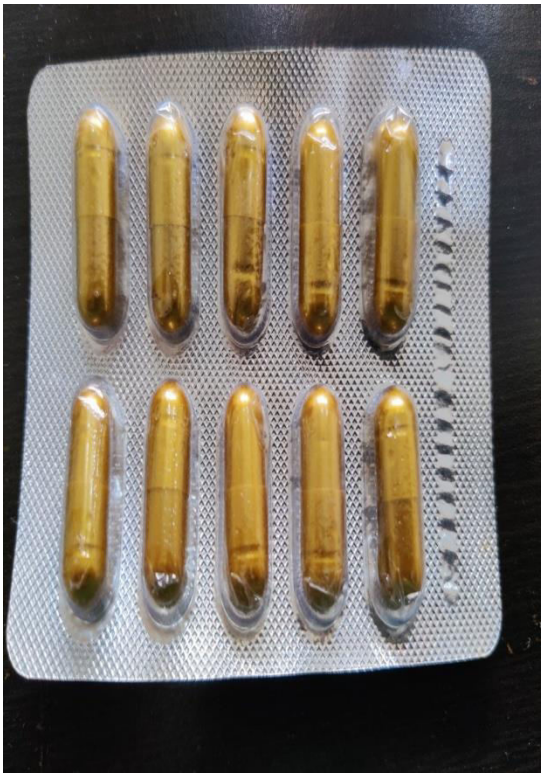


IMAGE OF CAPSULE PRODUCTION

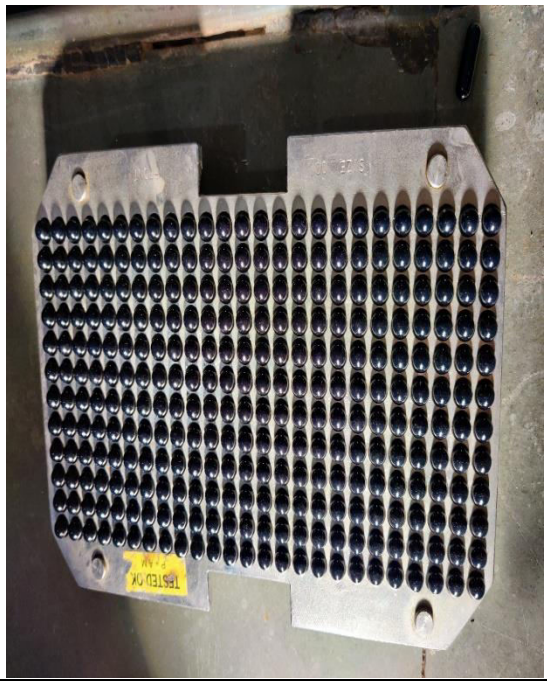



Image: Capsule

PRODUCTION OF SEMI SOLID

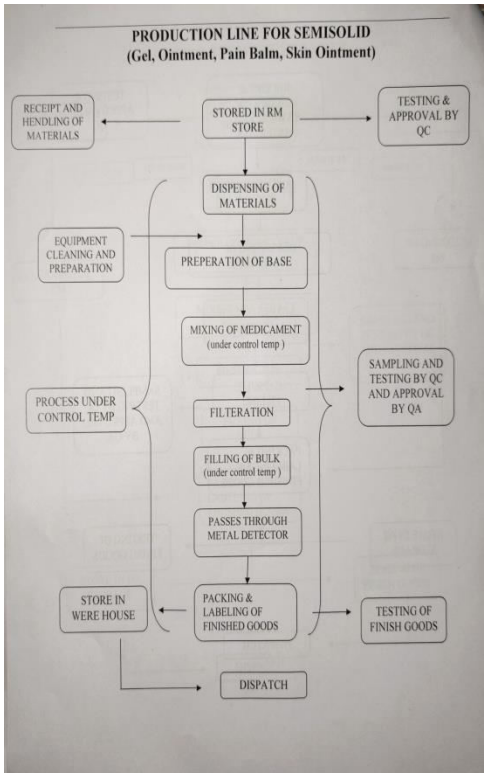
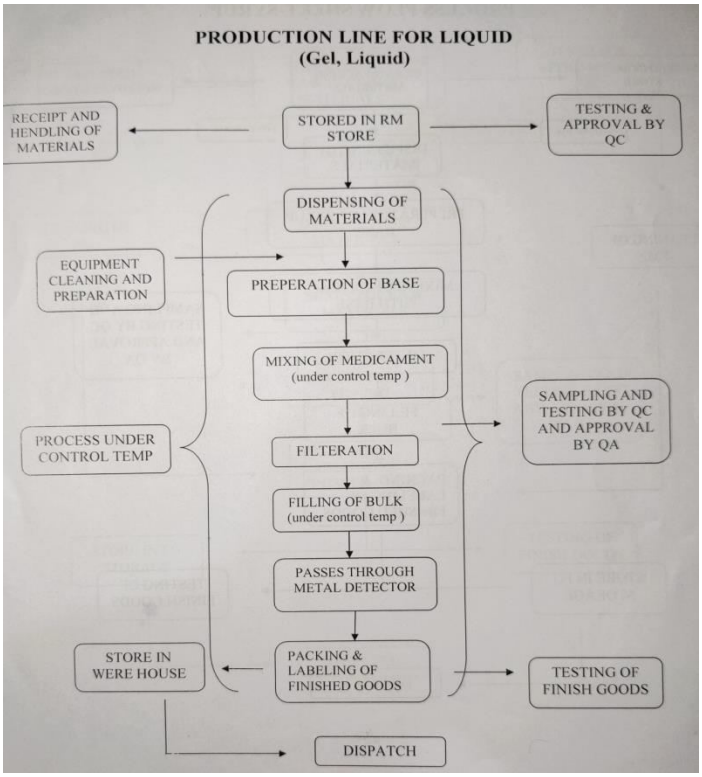


Image: Semi solid product

PRODUCTION OF LIQUID



Cough-lozenges

- Syrup

  sugar + glucose + water (To heat 110˚C)

  Preparation tank capacity- 5000 kg

  Holding tank capacity- 2500 kg

- Cooker [heating]= 142˚C

- Batch size - 50 kg

  SS316 Material use for cough- lozenges.

Image: Syrup preparation tank

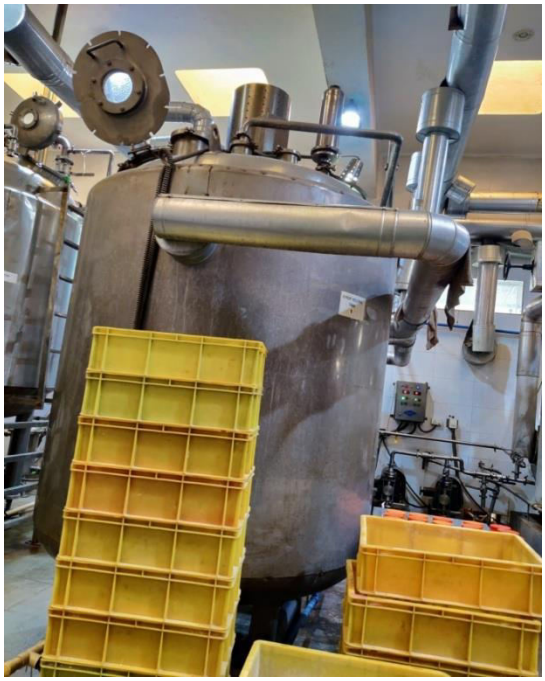


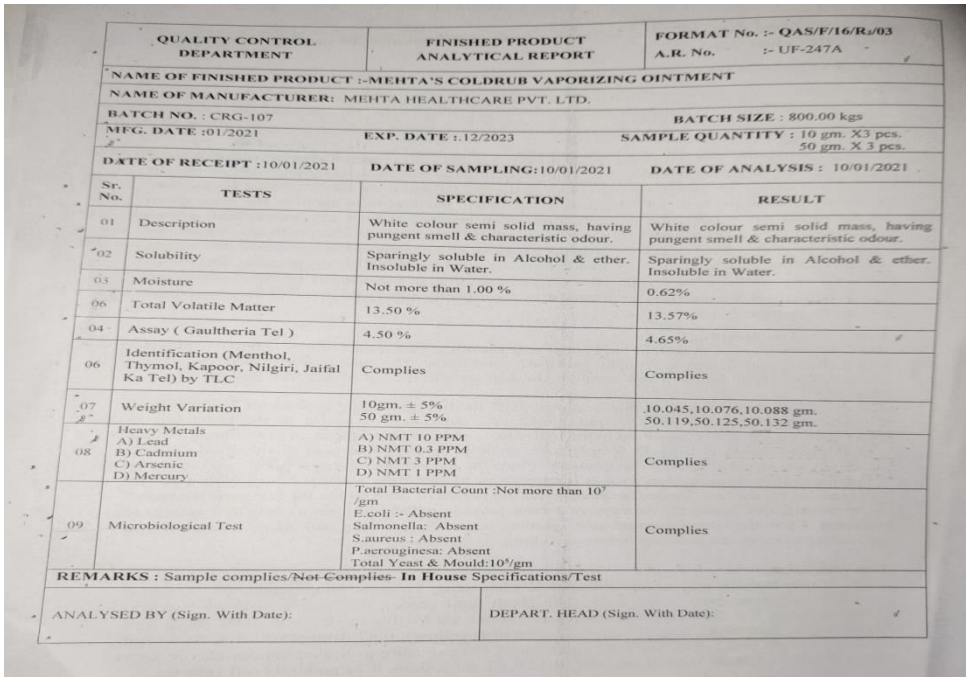
Image: Syrup holding tank

Image: Cooking plate

Image: Cough lozenges

NOSCAR CREAM

- Oil+ wax slow stirrer (10 min)
- Chemical 107 + 28.000 KGS water, high speed stirrer (30-40 min)
- Formulation oil (112) + Extraction oil (113- 117) High speed stirrer (10 min)
- Powder (108 + 109) + 13.500 KGS water, high speed stirrer
- Chemical (110) + 13.500 KGS water, high speed stirrer (10 min)
- Cooling with slow stirrer
- Colour (119)
- Perfume (111) at 40˚C, water content- 73%



QUALITY CONTROL DEPARTMENT	FINISHED PRODUCT ANALYTICAL REPORT	FORMAT No. :- QAS/F/16/R₀/03 A.R. No. :- UF-247A

NAME OF FINISHED PRODUCT :-MEHTA'S COLDRUB VAPORIZING OINTMENT

NAME OF MANUFACTURER: MEHTA HEALTHCARE PVT. LTD.

BATCH NO. : CRG-107 BATCH SIZE : 800.00 kgs

MFG. DATE :01/2021 EXP. DATE :.12/2023 SAMPLE QUANTITY : 10 gm. X3 pcs. 50 gm. X 3 pcs.

DATE OF RECEIPT :10/01/2021 DATE OF SAMPLING:10/01/2021 DATE OF ANALYSIS : 10/01/2021

Sr. No.	TESTS	SPECIFICATION	RESULT
01	Description	White colour semi solid mass, having pungent smell & characteristic odour.	White colour semi solid mass, having pungent smell & characteristic odour.
02	Solubility	Sparingly soluble in Alcohol & ether. Insoluble in Water.	Sparingly soluble in Alcohol & ether. Insoluble in Water.
03	Moisture	Not more than 1.00 %	0.62%
06	Total Volatile Matter	13.50 %	13.57%
04	Assay (Gaultheria Tel)	4.50 %	4.65%
06	Identification (Menthol, Thymol, Kapoor, Nilgiri, Jaifal Ka Tel) by TLC	Complies	Complies
07	Weight Variation	10gm. ± 5% 50 gm. ± 5%	10.045,10.076,10.088 gm. 50.119,50.125,50.132 gm.
08	Heavy Metals A) Lead B) Cadmium C) Arsenic D) Mercury	A) NMT 10 PPM B) NMT 0.3 PPM C) NMT 3 PPM D) NMT 1 PPM	Complies
09	Microbiological Test	Total Bacterial Count :Not more than 10^7 /gm E.coli :- Absent Salmonella: Absent S.aureus : Absent P.acrouginesa: Absent Total Yeast & Mould:10^5/gm	Complies

REMARKS : Sample complies/~~Not Complies~~ In House Specifications/Test

ANALYSED BY (Sign. With Date): DEPART. HEAD (Sign. With Date):

Image: Analytical report

Soyabean casein digest agar (Tryptone soya Agar)

Procedure:

- Suspend 10 grams in 250 ml purified / distilled water.
- Heat to boiling to dissolve the medium completely.
- Sterilize by autoclaving at 121˚C for 15 minutes.
- Cool to 45 – 50˚C.
- Mix well and pour into sterile petri plates.
- Then make dilutions. (four test tubes)
- 9 ml distilled water add in each tubes.
- [100 ml flask- 10 gm tablet dissolve]
- Add 1 ml in 1st tube then make a dilution.

Image: Colonies on Soyabean casein agar plates

Result of agar plates:

- By performing this method we get the loan growth on Soyabean Casein Digest Agar medium, with pale yellow coloured, flat, translucent colonies. (Image-1)
- The dilution with both distilled and tap water the pale yellow colonies were observed. The tap water dilution has lawn growth and distilled water has some numbers of colony. (Image-2)

Conclusion:

- Sample has contamination. We can conclude that the soyabean agar has colony so the sample has contamination or we can say the dilution error or due to handling error also happens.

REFERENCES

- Central council for research in Ayurveda and Siddha
- Quality control manual for Ayurvedic, siddha & Unani medicine
- Indian pharmacopoeia 1996 volume I (A-O)
- Indian pharmacopoeia 1996 volume II (P-Z)