



K. K. WAGH COLLEGE OF PHARMACY

(B. Pharmacy & D. Pharmacy)

Hirabai Haridas Vidyanagari, Amrutdham, Panchavati, Nashik - 422 003. (Maharashtra) India.

☎ : 0253 - 2221121, 2517003, 2510262 Web : www.pharmacy.kkwagh.edu.in

Email: principal-bpharmacy@kkwagh.edu.in, disp-bpharmacy@kkwagh.edu.in

(Affiliated to Dr. Babasaheb Ambedkar Technological University, Lonere, MSBTE, Mumbai & Approved by PCI)

REPORTS



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A

Report of Field Work

INDUSTRIAL TRAINING REPORT
PERFORMED AT MICROPELLET
PELLET MANUFACTURER ,MIDC, AMBAD,
NASHIK.



K K WAGH COLLEGE OF PHARMACY NASHIK

PRESENTED BY

PATIL SAKSHI ANIL

PRN NO – 1954501823096

ROLL NO – 79



18TH Sep 2022

TO WHOMSEVER IT MAY CONCERN

This is to certify that **Miss. Sakshi Anil Patil** , B Pharm has undergone in- Plant Training at our facility, from **15th Aug , 2022 to 15th Sep, 2022** as part of the curriculum.

During this period she has shown keen interest to learn and we found her sincere and Hard – working . We wish her all the best in his future endeavors.

With Best wishes.

For Micropellet

Sarmant J. A.

Partner

Micropellet

K-30, Behind Taj Residency
MIDC, Ambad, Nashik-10



[Signature]
PRINCIPAL
K. K. Wagh College of Pharmacy
Nashik-422 003

Index

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FINAL YEAR B PHARMACY (SEM 7th)
ABOUT TRAINING ORGANISATION



Location : Micropellet Pellet Manufacturer ,
K 30, Behind Taj Recidency,
MIDC Ambad ,
Nashik 422010, Maharashtra, India .

About Micropellet : Micropellet was found in 2000 as a manufacturing unit. 22 years after its foundation the company has been able to adapt to the fast growing technological changes to have an edge in the global market place. Company also provide an exhaustive range of services including Product development in Solid Dosages Form, Formulation / Analytical Research & Contract Manufacturing, etc. Micropellet today serves all major pharmaceutical companies in India and abroad & various bakeries & other institutions.



Vision and mission :

Total Quality Management (TQM)

Our objective is to meet or exceed our own stringent product quality standards.

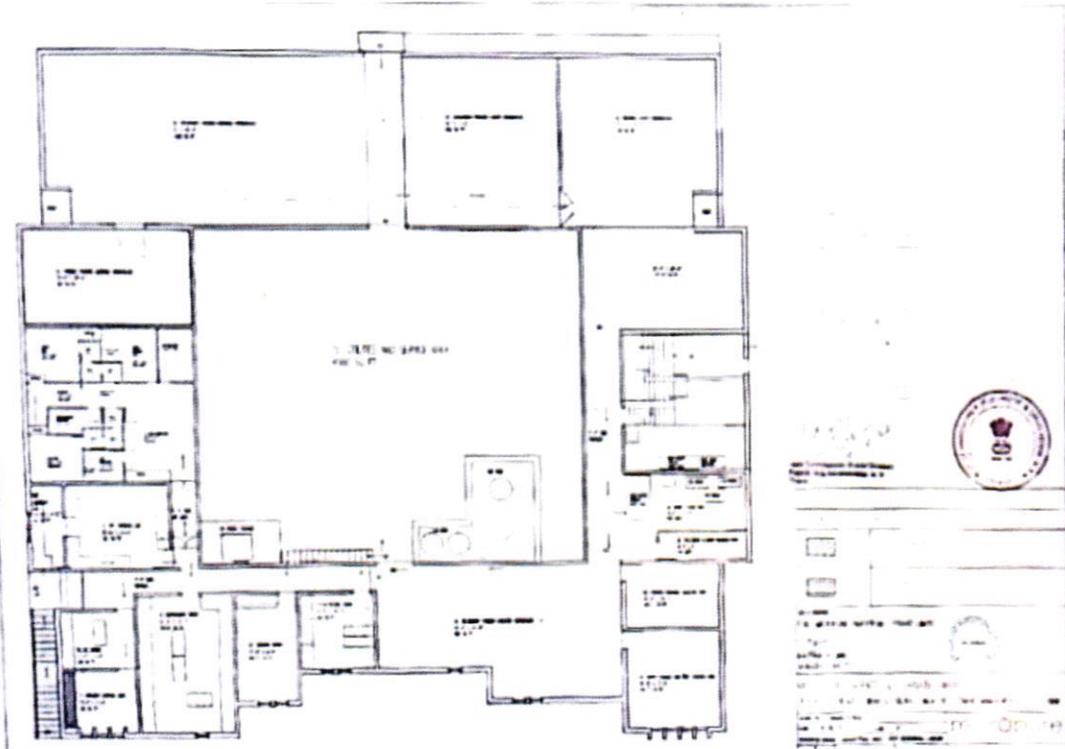
On time delivery of error free, technologically advanced products with superior Service / Support is what our customers expect and receive from Micropellet. Complete customer satisfaction is an open-ended process, which we continually strive to improve.

Caring and Improvement of environment during Production.

We will be innovative in our approach to aim at doubling our company growth with reducing impact on environment. Our belief in continuous R&D and innovations has helped us to provide highest quality products at competitive prices. Ensuing stringent control over processes, hygiene & traceability of hazards has resulted in safe & black specs free product.



LAYOUT



VARIOUS DEPARTMENTS IN ORGANIZATION

- _Quality control department
- Quality assurance department
- Regulatory Affairs
- Formulation research and development
- Analytical research and development
- Manufacturing unit



PELLET

Introduction to pellet

In the pharmaceutical industry, pellets are simple small free-flowing spherical particles formed by agglomeration of fine powder or granules, which can be given in the form of tablets and capsules for various disease conditions, although tablets are more convenient than capsules. The size range of pellet size is of 0.5-2.0 mm.

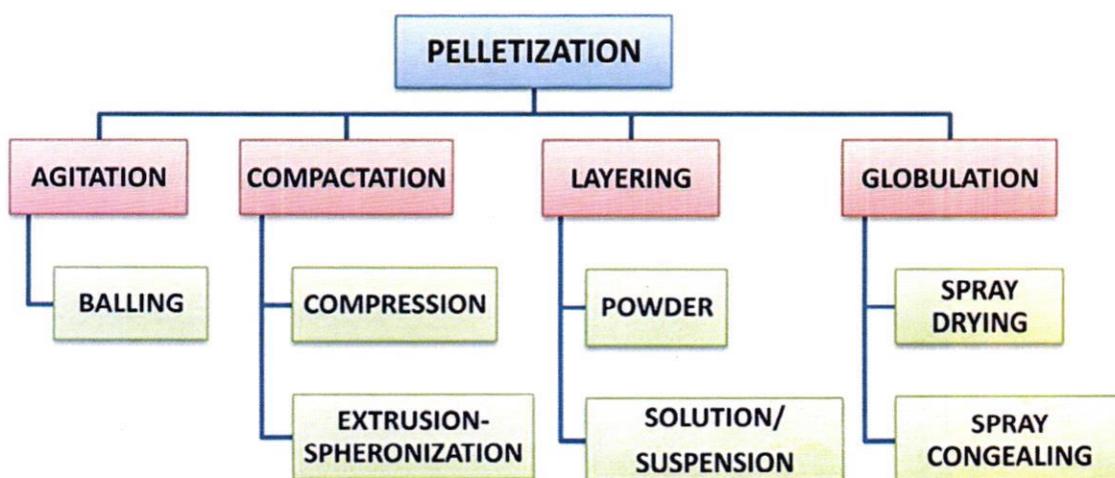
Advantages of pellets

- Pellets show excellent flowing properties, due to its elegance.
- Extrusion Spheronization technique gives uniformity of dose with excellent accuracy.
- Pellets provide safety by preventing dust formation which can cause health issues because of fine powders due to its dust explosives.
- The product appearance is improved.
- The efficacy of product is improved due to the safety of the active ingredient.



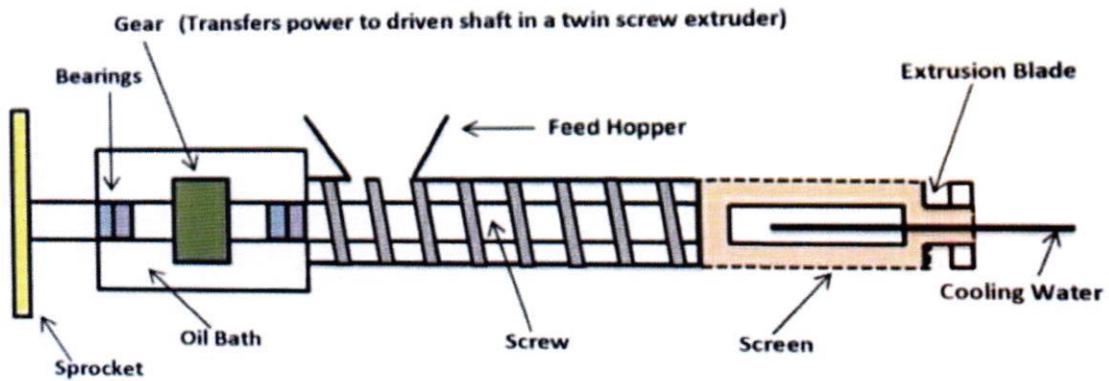
- **Disadvantages of pellets**
- Sometimes pellets are too rigid in nature which is difficult to compress as a tablet, therefore have to be encapsulated into a capsule.
- The process of pelletization is a highly sophisticated method because specialized equipments are used.
- The cost of manufacturing is high.
- It involves number of formulation variables and process variables which leaves the manufacturing process complicated.

Pelletization technique:

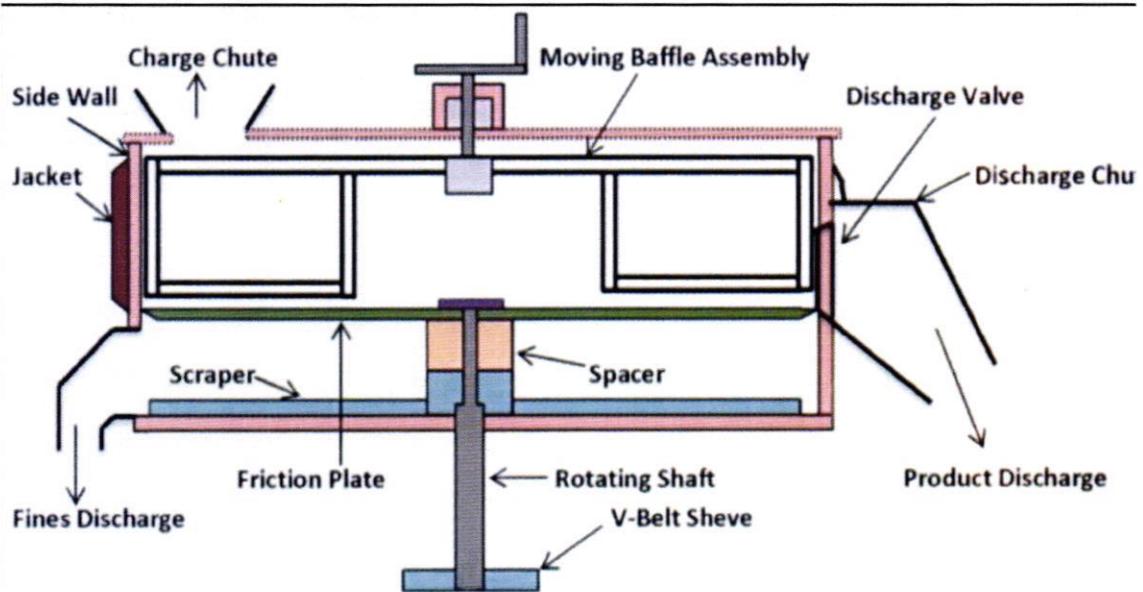


MACHINES AND EQUIPMENT

- **Extrusion-spheronization**



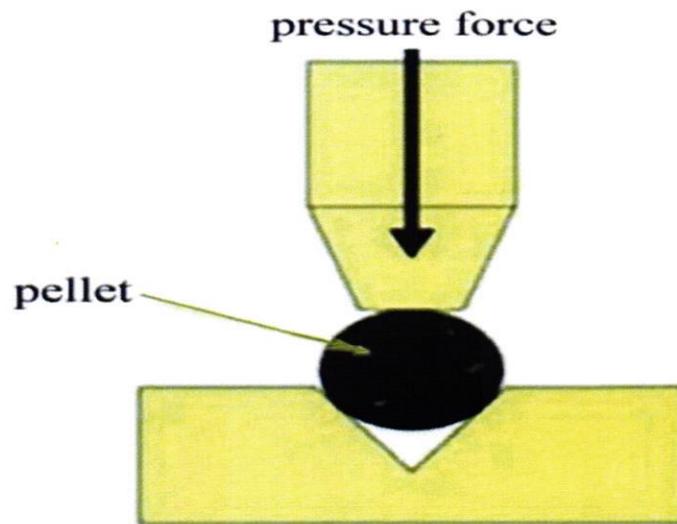
a. Extruder



b. spheronization



- **Kahl pellet hardness tester**



a. Hardness tester of pellet

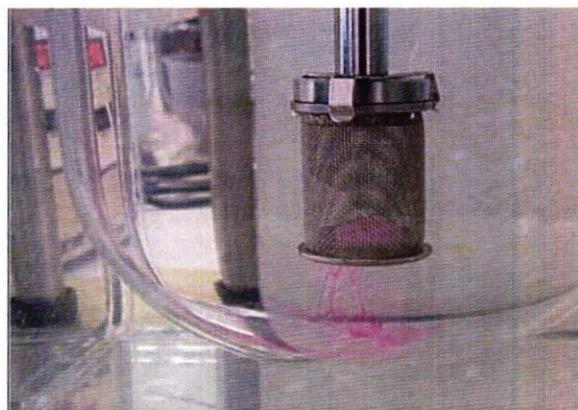
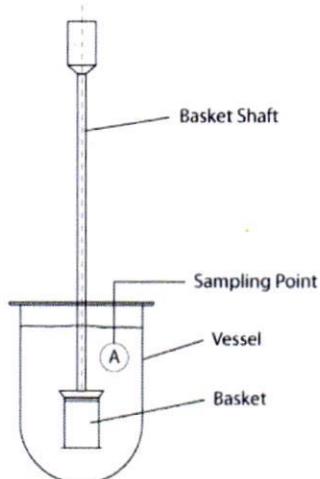


b. Kahl pellet hardness tester



Features of kahl pellet hardness tester

- Test pellets of different cross-sections
- Test pellets up to 22mm in diameter
- Ensures consistency and quality of the pelletizing process
- Test samples right at the source, immediately after cooling
- Make immediate process adjustments to ensure desirable outputs and efficient production
- **Dissolution apparatus (rotating basket)**

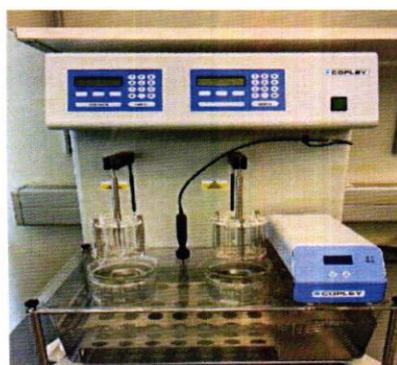


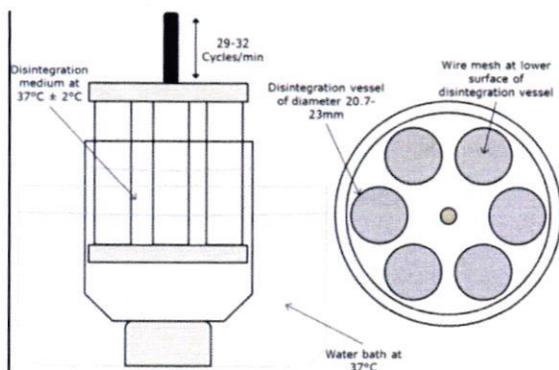
a. Dissolution apparatus (basket)



Features of dissolution apparatus:

- Basket types dissolution apparatus Made of borosilicate glass or suitable transparent materials with a hemispherical bottom and a nominal capacity of 1000 ml.
- Dissolution Test apparatus medium bath set to maintain at 36.5° to 37.5 °c during the test.
- The shaft has maintained at a position so that its axis is within 2 mm of the axis of the vessels, and the lower edge of the blade is about 23 to 27 mm from the inside bottom of the vessels.
- Motor with a speed regulator which is able to maintain the speed of rotation of the paddle within 4%
- **Disintegration apparatus**





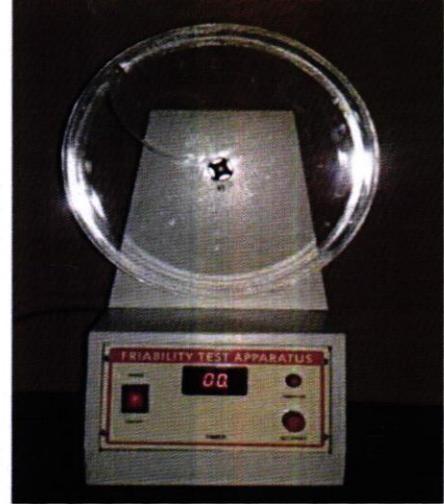
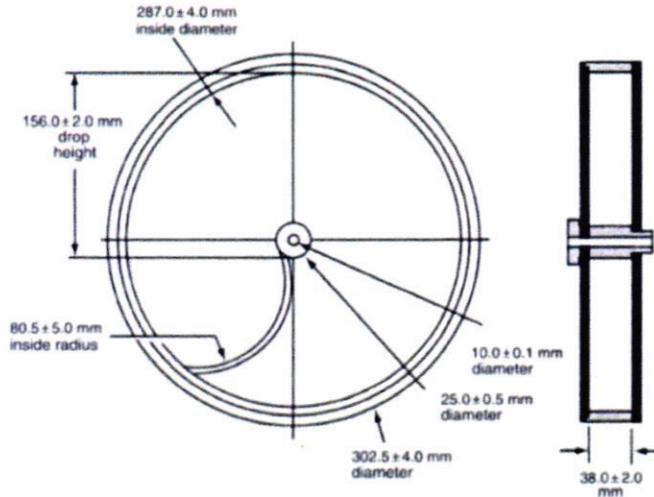
Disintegration apparatus

Features of Disintegration apparatus

- Complies with USP, IP specifications
- Extremely useful for pharmaceutical labs
- Microprocessor based, easy to use
- Seven segment LED display
- 10 Soft touch membrane type keys
- User friendly operation with current status indicators
- Supports Two USP baskets assemblies.
- Each basket is controlled by independent Timer and Motor
- Programmable temperature controller
- Auto parking of the basket at the top position at the end of the test.



● Roche friability tester



Friability tester

Features of friability tester

- Available in 1 or 2 drum models Meets specification of USP, BP, EP
- Compliant with IP, BP and USP standards Supplied with IQ, OQ & PQ documents
- Automatic pre-set count stop Audible alerts
- Provision to connect dot matrix printer In-built self validation program
- Weighing balance interface Easy to use front loading system



Formulation manufacturer by Organization

• **Micropellet**

Definition: SP base of sugar spheres and microcrystalline spheres coated with cationic polymers.



Application :

- Suitable for very low / high dosage forms and for drugs with a low therapeutic margin.
- Fillers for Dispersible Tablets.
- Used as cores to be coated in the manufacture of highly hygroscopic / soluble drugs / unstable drug.
- Using Micropellet - Sp products are interesting into a transfer strategy of capsule with Pellets to tablets.



- **NONPAREILS PELLETS Micropellet – Cores for Controlled – Release Formulations**



Definition :

- Micropellet – contains not more than 92 percent of sucrose. Calculated on the dried basis. The dried basis. The remainder consists of corn starch as per the European Pharmacopoeia.
- Compliance with Ph. Eur., USP/ NF and JP.
- Produced in accordance with the cGMP.

Application:

Used as cores to be coated in the manufacture of dry pharmaceutical forms especially for controlled release & specially formulations.



• Starch Pellet



- Starch or amyllum is a carbohydrate consisting of a large number of glucose units joined together by glycosidic bonds. This polysaccharide is produced by all green plants as an energy store. It is the most common carbohydrate in the human diet and is contained in large amounts in such staple foods as potatoes, wheat, maize (corn), rice, and cassava.
- Pure starch is a white, tasteless and odorless powder that is insoluble in cold water or alcohol. It consists of two types of molecules: the linear and helical amylose and the branched amylopectin. Depending on the plant, starch generally contains 20 to 25% amylose and 75 to 80% amylopectin. Glycogen, the glucose store of animals, is a more branched version of amylopectin.
- Starch is processed to produce many of the sugars in processed foods. Dissolving starch in warm water gives wheatpaste that can be used as a thickening, stiffening or gluing agent.



- Application:

Used as spherical seed cores for drug layering & film coating. Also used in manufacture of granules / beadlets with sustained / controlled release, taste masking & other special properties.



SUGAR Pellets Micropellet – Cores for Controlled – Release Formulations

Definition

Micropellet suger pellet contains not more than 92 percent of sucrose. Calculated on the dried basis. The dried basis. The remainder consists of corn starch as per the European Pharmacopoeia.

Compliance with Ph. Eur., USP/ NF and JP.

Produced in accordance with the cGMP.



Specifications of particles size of sugar pellet :

Particle size distribution (analyzed by laser diffraction) shows the symmetrical character of the distribution. The single model profile, associated a very homogeneous population of Micropellet

Application :Used as cores to be coated in the manufacture of dry pharmaceutical forms especially for controlled release & specially formulations.



Sugar globules :

Homeopathy sugar pills made from sucross in best quality with sise 10-60 mm. Perfectly round in shape. We manufacture our products from certified and well-tasted sugar. Our sugar Pills are delivered in various size with zero defect at the desired destination with in stipulated time frame.



Homeopathy Globules :

Homeopathy Globules (unmedicated) made from pure sucrose (sulphur less) in size 10 to 60 mm Exlent.

Sugar Globules:

Unmedicated Sugar Globules made from 100% pure sugar/sucross in different size.



Activities Performed:

Day 1	Information of organisation and observation of plant.
Day 2-5	In QC department; hardness, friability and Disintegration testing of sugar pellet.
Day 6-10	In manufacturing unit; involvement in some operations of sugar and Starch manufacturing process.
Day 11-15	In QC ; hardness and friability testing of Micropellet, sugar and Starch pellet.
Day 16-20	Involvement in raw material storage department.
Day 21-25	In QC of handling of friability tester, kahl tester and also dissolution and Disintegration apparatus
Day 26-30	Involvement in manufacturing of sugar granules, Starch pellets



Documents handled in industry

- **Standard operating procedures (SOP's)**

Is a set of written instructions that document a routine or repetitive activity followed by an organization. In that SOP's of the equipments in the manufacturing process and SOP's of handing of equipments is handled.

- **Batch manufacturing record (BMR)**

The batch manufacturing record (BMR) is the necessary document which tracing the complete cycle of manufacturing of a batch or lot .

The BMR was in the local language.

In the BMR there is written form of batch record during pellet manufacturing process.

- **Distribution record**

It is written document which describing the distribution of drug product .

This document includes; name and strength of the product, description of dosages form etc.



- Master formula record (MFR)

Master formula record is the master of all the documents in the industry.

It is used to document the specific information for each individual batch and it is important component of regulatory compliance and effective process control.

It contains all the information about the manufacturing process of pellets and micropellet.

It is reference of all the SOP's, BMR.

- Specifications:

A specifications is a quality standard.

It establishes the criteria to which a substance should confirm for the manufacture of product

It complies the list of tests, reference to analytical procedures and appropriate acceptance criteria for the test described.



Conclusion

In the end I am glad to tell you that training in MICROPELLET- PELLET MANUFACTUREER, AMBAD, MIDC NASHIK 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.

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

Regards
Sakshi Anil Patil .
Final year B pharm
(Sem -7th)





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B

Report of Training



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RAP Training Session Report

Date: 07/01/2022 - 08/01/2022

Time: 10.30 pm to 4.30pm

Resource person: Mr. Rohan Pawar

The objective of the Session: To acquaint students with theory as well as practical of sophisticated instrument.

The outcome of the webinar: All the students got knowledge of principle and working of sophisticated instruments. Students are being able to handle sophisticated instruments (UV, GC, and HPLC).

Number of participants: 34

Event co-ordinator

Prof. S.S. Raut and Prof. K.P. Baviskar

Day 1 (Theory session 08-01-2022)

Mr. Rohan Pawar gave a talk about UV-visible spectroscopy, gas chromatography, and high-performance liquid chromatography. He talked over the principles, workings, instrumentation, and applications of all of these advanced instruments in detail. He also highlighted drug quantification using a UV-Visible spectrophotometer.

He also explained about how HPLC and GC were used to separate, identify, and quantify each component in a combination. He also discussed daily life applications of these instruments.

He also discussed on GLP. He explained to participants how to apply these good laboratory techniques into effect in regular practical sessions. He also described how GLP can assist enterprises and research centres in maintaining product uniformity, consistency, reliability, reproducibility, quality, and integrity.



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DAY 2 (Practical session 09-01-2022)

Demonstration of following instruments conducted by staff at Analytical Research and Training Center Nashik.

1) HPLC

Model No. – HPLC 3000 Series

Make – Analytical technology private limited

Software – HPLC Workstation

2) GC

Model No. – FL 9790

Make – Analytical technology private limited

Software – GC Workstation

3) UV –Visible Spectrophotometer

Model No. – UV 2012

Make – Analytical technology private limited

Software – UV VIS. Analyst



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Photographs





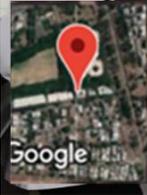
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GPS Map Camera