A Training Report On

QUALITY CONTROL IN PHARMACEUTICALS

Carried out at

SPARSH BIOTECH PVT. LTD

Under (the trainer):

MR. BHAVESH R. HINGU

(QC MANAGER)

Submitted by

MR. FAIZAAN S. NOYDA -200601032

In the partial fulfilment of requirements for the degree of

Bachelor of Science in Biotechnology

to

Department of Biotechnology, Faculty of Science,

Atmiya University – Rajkot

ACKNOWLEGEMENT

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I would like to express my sincere gratitude to Sparsh Biotech Private Limited for providing me with the opportunity to undertake my internship in the Quality control Department. This internship has been an invaluable experience, which has allowed me to apply the theoretical knowledge gained during my studies to the realm of biotech industry.

I would like to extend my appreciation to my supervisor Mr. B. R. Hingu for his guidance, support, and valuable feedback throughout my internship. I have learned a great deal from him and the team, and I am grateful for the time and effort they invested in me.

Lastly, I would like to thank the entire Sparsh Biotech team for making my internship experience an enjoyable and enriching one. I will cherish this experience for years to come.

A special thanks to my parents, friends, and all my dear ones to keep me motivated throughout the process. I am grateful for each and every thing I have achieved so far.

PREFACE

***

Biotechnology deals with the living organisms and system to develop or make products or any technological application that uses biological system, living organisms and derivatives. Also make or modified products or processes for specific use. In this profession practical and theoretical knowledge both are important.

According to curriculum of a final year coursework of BSc Biotechnology, each student has an option to undergo practical training for a period of four-five week (specifically 120 hours) in various life science industries/company in India. It is a requirement for the partial fulfilment of the degree of Bachelors of Science in Biotechnology.

Therefore, I opted for the 120 hours industrial training at "SPARSH BIOTECH PVT.LTD which is located in Jamnagar and this report contains a "Quality control analysis" in QC Department of the above pharmaceutical industry which was observed during the training program.

Declaration

I hereby declare that the work incorporated in the present training report entitled as quality control in pharmaceuticals, which is being submitted to Department of Biotechnology, Faculty of Science as a partial fulfilment pf the Degree of Bachelors of Biotechnology, is carried out by me during my academic year 2022-2023 (Final Year Biotechnology).

I also hereby declare that the training report, which I am submitting here is solely my work and has not submitted by any other student of this university. The information and details written in this report is duly written by me and I take sole responsibility of this training report.

Thank You

Date: _____

Place: Atmiya University, Rajkot. Mr. Faizaan S. Noyda

SPARSH BIO-TECH PRIVATE LIMITED
CIN : U24231GJ2001PTC039373 ● GST : 24AAFCS5556F1ZC
Tel. : +91-96877 97780 / 90 ● E- mail : info@sparshbiotech.com ● Website : www.sparshbiotech.com

To Whom It May Concern.

MR. FAIZAAN NOYDA

has undergone an industrial training / internship with our organization whose details are as mentioned below.

Name of College / Institute :- Atmiya University, Department of Biotechnology-Rajkot

Department for an industrial training / internship : Quality Control.

Period of an industrial training / internship 120 Hours

Name of Trainer / Guide : Bhavesh Rasiklal Hingu

Designation of Trainer / Guide : Q. C. Manager

To get the knowledge of how the pharmaceutical company works with various norms of different regulatory authorities.

primary knowledge with respect to our standard operating procedure were explained and demonstrated to get the idea of practical work of our Quality Control Department to see working of various Quality Control Laboratory instruments like Thermoseperation HPLC with Auto Sampler, Gas Chromatography with head space, FTIR, UV Spectroscopy, Auto Karl Fisher Apparatus, Polari meter, Refractometer, pH meter Potentiometer, Conductivity Meter, Dissolution Test Apparatus, Disintegration Test Apparatus etc.

We wish him all the best for his bright academic career.

For, Sparsh Bio-Tech Private Limited

Authorised Signatory
(H. R. Manager)

Place : Jamnagar
Date : 26-Aug-2022

INTRODUCTION OF THE COMPANY

SPARSH BIO-TECH PVT. LTD. a private limited company incorporated under Company's Act 2000 in May 2001 with a global vision in mind has set up a State of the Art Pharmaceutical Formulation Unit having unique dedicated Betalactum building for Manufacturing of Capsules, Tablets & Dry Syrups in Export Processing Zone with well-developed infrastructure in the State of Gujarat.

The Management is vested with Directors who have a rich experience in manufacturing and developing of innovative products in the field of medicine has attracted the envious recognition in East Africa by exporting its Formulation to various East African Countries through Paras Exports.

Mr. P. N. Maru : Managing Director, a successful businessman & agile administrator over three decades has nurtured his excellence for a modest beginning of the project.

Dr. A. J. Maru: Dynamic Director having 26 years of experience as a General Practitioner for Human Medicine and a successful businessman of Pharmaceutical Exports in the last 8 years having wide experience in pharmaceutical marketing and is a mastermind behind this project.

Mr. R. H. Haria: NRI Director, based in East African Countries over two decades is a key person for the Marketing and Sales in African Sector.

Mr. P. J. Maru & Mr. S. P. Maru: Both the duo having wide experience of Finance, Sales and Administration are assets to the company.

INDEX

- COMPANY'S PRODUCTS (DRUGS)
- QUALITY CONTROL DEPARTMENT'S WORK
- CHART & TRANSFORMATION OF PRODUCTS
- ALL INSTRUMENTS OF QC DEPARTMENT
- BRIEF INSTUMENTATION
- REFERENCES
- OBERVATION & REVIEW
- OVERALL CONCLUSION

COMPANY'S PRODUCTS

- **Cloxispa (Brand name)**
  Cloxacillin Capsules (Generic name)

- **Miamoxy-250 (Brand name)**
  Amoxicillin Capsules B.P. (250 mg) (Generic name)

- **Spamcil-250 (Brand name)**
  Ampicillin Capsules B.P. (250 mg) (Generic name)

- **Zydoxil-500 (Brand name)**
  Amoxicillin Capsules I.P. (500 mg) (Generic name)

- **Spamclox Capsules-500 (Brand name)**
  Ampicillin & Cloxacillin Capsules (500 mg)
  (Generic name)

- **Moxtec-500 (Brand name)**
  Amoxicillin Capsules B.P. (500 mg) (Generic name)

- **Asclav-1000 (Brand name)**
  Amoxicillin and Clavulanate potassium tablets U.S.P.
  (1000mg) (Generic name)

- **Skyclav-1000 (Brand name)**
  Amoxicillin and Clavulanate potassium tablets U.S.P
  (Generic name)

(Note: here B.P., U.S.P., I.P. etc are pharmacopeia,
e.x. B.P.: British Pharmacopeia
I.P.: Indian Pharmacopeia
U.S.P.: United State Pharmacopeia)

QC DEPARTMENT'S WORK:

- In any pharmaceutical company quality control analysis is a very important process and generally given priority in all aspects and stages of the entire pharmaceutical manufacturing process which is also termed as Total Quality Management.

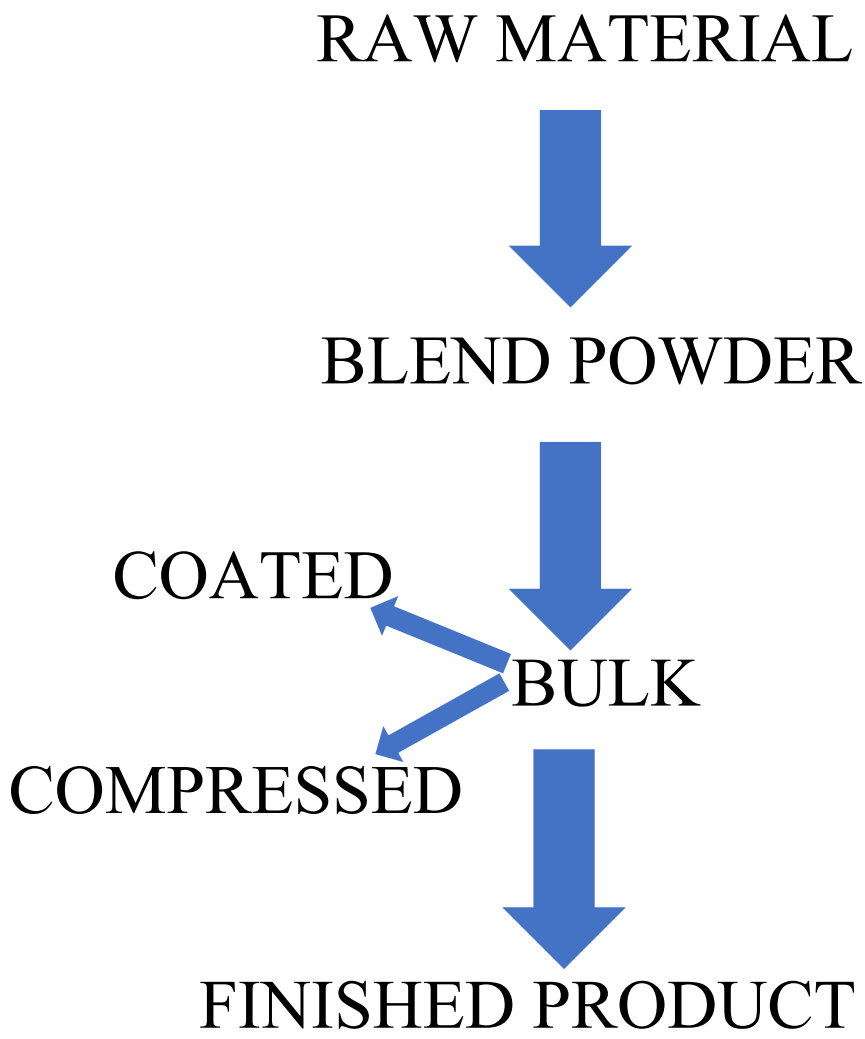
- It is responsible of monitoring and ensuring that each stage of production is followed by all the necessary procedures for safe use of machinery and that each product coming out of all the production process, complies with all standards and specifications that have been defined to assure the quality and specificity of drugs.

- The main work of the quality control department is to check the products of a particular pharmaceutical company.

- Pharmaceutical companies have their production department, in which they made different products, so quality control department check the quality of the products which are made by the production department.

- So quality control department check the quality of products like tablets, capsules, eyedrops, liquid drug, etc. at each and every step.

Chart & product's transformation:



- Raw Material: The first powder which is made in the production department.

- Blend powder : After some experimental approvals blend powder is made from raw material. To made blend powder there will be a process for batch material, and that will be the process of 45 to 60 minutes. And after that there will be a BMR which is known as batch manufacturing report. Like this way blend powder will be made.

- Bulk: Bulk means capsules which are made after blend powder. Bulk is divided in two parts :1) Coated bulk
  2) Compressed bulk

  - Cotted bulk: It is a solvent coating product.
  (isopropyl alcohol is solvent here)
  - Compressed bulk: It is directly made from blend.

  Every bulk should be test with 5 side shape testing from up, down, left, right, and middle direction, and the best quality result will be selected for the bulk production.

- Finished product: After the proper checking of bulk, there will be some aluminium foil and blister packing for the completion of the capsule. The blister packing is of 3 to 4 types.

(There is a powder which will be inserted in the capsules which is known as **standard powder.**)

PHOTOGRAPHS OF PRODUCTS:

RAW MATERIAL

BLEND POWDER

–

BULK

FINISHED PRODUCT

–

PRODUCT CONCLUSION:

- **RAW MATERIAL: The starting phase of the production.**

- **BLEND POWDER: The powder which we got after the BMR.**

- **BULK: Uncomplete or starting phase of capsule.**

- **FINISHED PRODUCT: Complete product after blister packing and aluminium foil packing.**

INSTRUMENTS ENCOUNTERED:

- **KARL FISCHER TITRATOR**
- **SPECTROPHOTO METER**
- **WEIGHING MACHINE**
- **PH METER**
- **MORTAR PASTLE**
- **BOILING WATERBATH**
- **COLD CABINET**
- **DISSOLUTION APPARATUS**
- **SONICATOR**
- **BULK DENSITY APPARATUS**
- **VACCUM OVEN**
- **HOT AIR OVEN**
- **INCUBATOR**
- **GLASS DOUBLE DISTILLATION UNIT**
- **PRECISION MELTING POINT APPARATUS**
- **HUMIDITY CHAMBER**
- **STABILITY CHAMBER**
- **AUTO POTENTIOMATRIC TITRATOR**
- **DESICATOR**
- **ACCELATOR (PART OF STABILITY CHAMBER)**
- **REAL TIME (PART OF STABILITY CHAMBER)**
- **PUMP (HPLC)**
- **AUTO INJECTOR (HPLC)**
- **DETECTOR (HPLC AND GC)**
- **WATER SAMLE (HPLC)**
- **COLUMN (HPLC)**
- **IR (INFRA RED)**
- **AUTO RANGING CONDUCTIVITY AND TDS METER**
- **FRIABILITY TEST APPARATUS**
- **DISINTIGRATION TEST APPARATUS**
- **POLARIMETER**
- **HPLC (HIGH PRESSURE LIQUID CHROMATOGRAPHY)**
- **GC (GAS CHROMATOGRAPHY)**
- **ACN WATER (MOBILE PHASE)**
- **METHENOL (SAMPLE IN HPLC)**
- **DEGASSER(HPLC)**

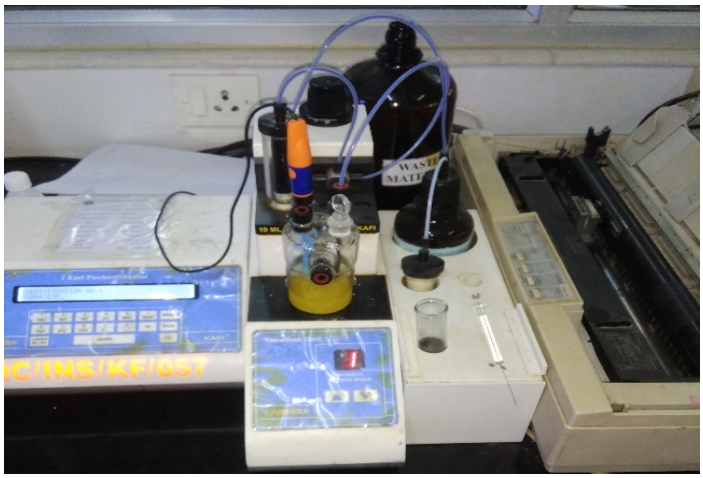
SPECIFICATION OF INSTRUMENTS:

(ACCORDING TO PRODUCTS)

- **RAW MATERIAL:** **HPLC, GC, IR**
- **BLEND POWDER:** **U.V AND TAPPED DENSITY**
- **BULK:** **DISSOLUTION APPARATUS, DISINTIGRATION TEST APPARATUS**
- **FINISHED PRODUCT:** **HPLC, DISINTIGRATION TEST**

COMMON USE OF INSTRUMENTS WHICH I HAVE ENCOUNTERED DURING THE TRAINING:

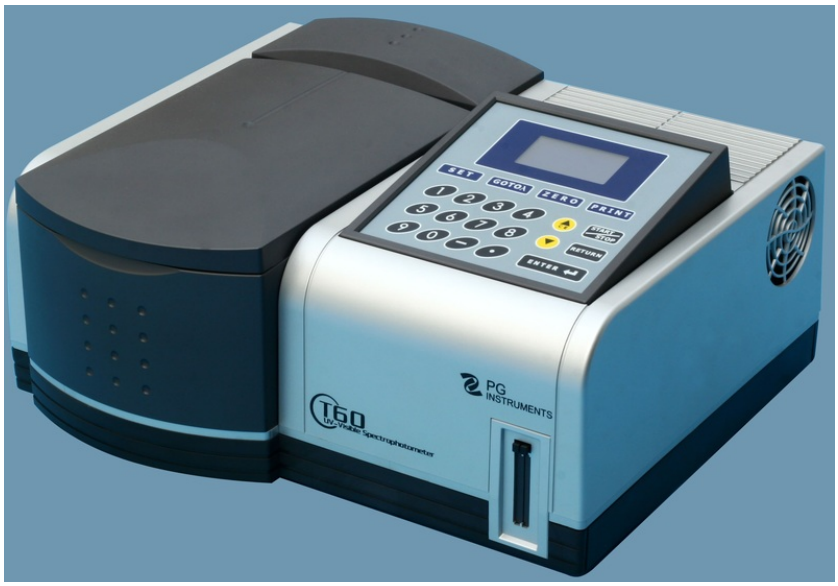
KARLFISCHER TITRATOR:



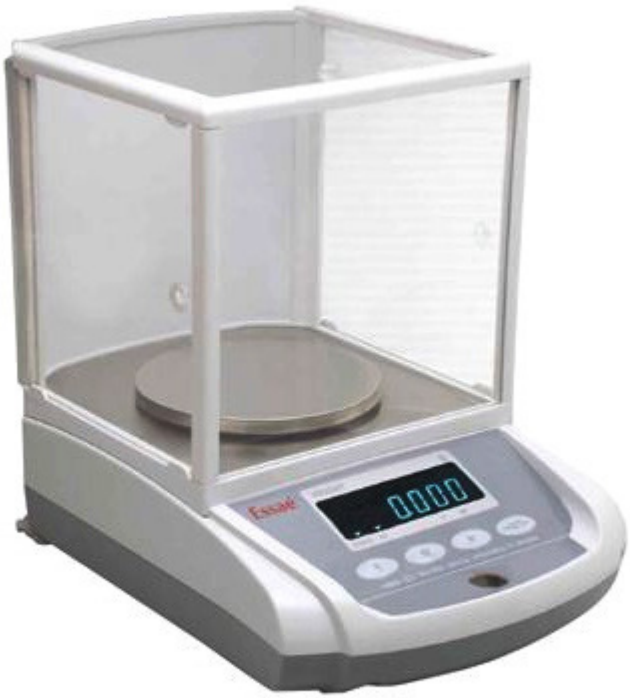
- It is very important instrument for pharmaceutical industries.
- As a reagent, there will be karl fischer reagent in it.
- In this there is mixture of sample and methanol.
- And here constant rotation occurs.
- The solution must be air tight by the silica balls.(moisture content)
- Purified water is injected in the liquid through syringe (10µl)
- Here the main part is speed control of titration in titration unit.
- For the determination of water content through electrometric titration.
- Karl fischer is required for the water content by how much moisture content is present.

UV SPECTROPHOTOMETER :

- **To know the wavelength of the sample.**
- **According to the drugs there will be different wavelengths. E.x: 260nm, 360nm.**

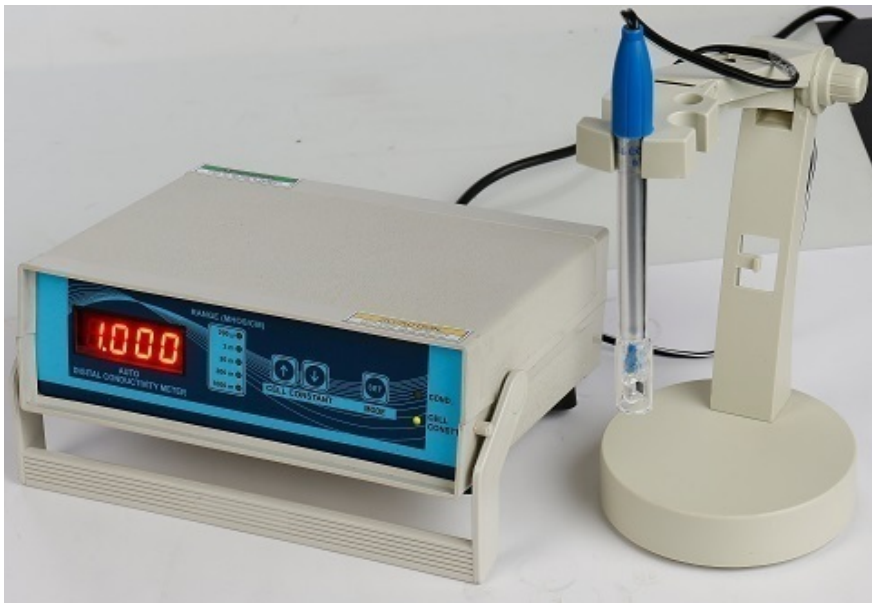


WHEIGNING MACHINE :



- **To weigh the amount of a particular product.**

PH METER :



- **To got the amount of particular sample.**
- **Electrode is the main part here.**
- **It should be use very carefully.**

BOILING WATERBATH:

- **To increase the temperature of water.**

MORTAR PASTLE :

- **For pharmaceutical industries, it is useful to crush the tablets.**

COLD CABINET :

- **To store the products.**

SONICATOR:

- **Depending on sample and spec.**
- **It can dissolve the sample by the ultra violet sound.**

BULK DENSITY APPARATUS:

- **It is useful to find the density.**
- **Blend which we take will be in powder form, to know its density it is required.**
- **It works in clockwise direction.**
- **It compresses the blend powder.**
- **It can differentiate between the before tapped density and after tapped density.**

EQUATION : $\frac{\text{after stroking sample cylinder (ml)}}{\text{Sample (ml)}}$

VACUUM OVEN :

- **In pharmaceutical industries, it is useful to dry the substance.**

HOT AIR OVEN :

- **To provide particular temperature to the substance or product.**

INCUBATOR :

- **It provide controlled and contaminated atmosphere to the product.**

GLASS DOUBLE DISTILLATION UNIT :

- **For the double purification of water.**
- **It can purify the water by the double purification.**

PRECISION MELTING POINT APPARATUS :

➢ **In pharmaceutical industries, it is useful to heat the product to know its melting point.**

HUMIDITY CHAMBER :

➢ **Identify the humidity of the sample.**

➢ **System is divided in two parts:**

-Accelerator : 6 month continuous identification. (40^{o}c , 75RH)

-Real time: analysis from 3rd month. (30^{o}c, 75RH)

STABILITY CHAMBER :

- **Identify the stability of the sample.**
- **System is divided in two parts :**
  -Accelerator : 6 month continuous identification. (40^{o}c , 75RH)

-Real time: analysis from 3rd month. (30^{o}c , 75RH)

AUTO POTENTIOMETRIC TITRATOR :

- **It can do automatic titration of the rate of titration through its detector.**

DESICATOR :

- **It is useful to transfer the sample.**

INFRA RED (IR) :

- **In pharmaceutical industries it is useful to find the functional group.**
- **It is also useful to find the peak for identification.**
- **It can identify more results then HPLC.**
- **It shows graphs with different peaks which will be detected in computer.**
- **It can work for powder only.**
- **We can check raw material and blend powder with its help.**

AUTORANGING CONDUCTIVITY AND TDS METER

- **It can find the conductivity by identifying cathode and anode.**
- **it is connected with the cathode and detector.**

FRIABILITY TEST APPARATUS :

- **In pharmaceutical industries, it is useful to check the quality of tablets.**
- **In each rotation 20 tablets should be tested.**
- **It check the tablet by constant rotation, if any tablet will be weal in making then it will be break during the rotating.**
- **It works in upper to lower direction.**

DISINTIGRATION RATE APPARATUS :

- **It is a very important instrument, which is useful for the tablet testing.**
- **In both the ends, it is filled with 900ml water at the temperature of 37^{o}c.**
- **The tablet's time in which it exits should be checked.**

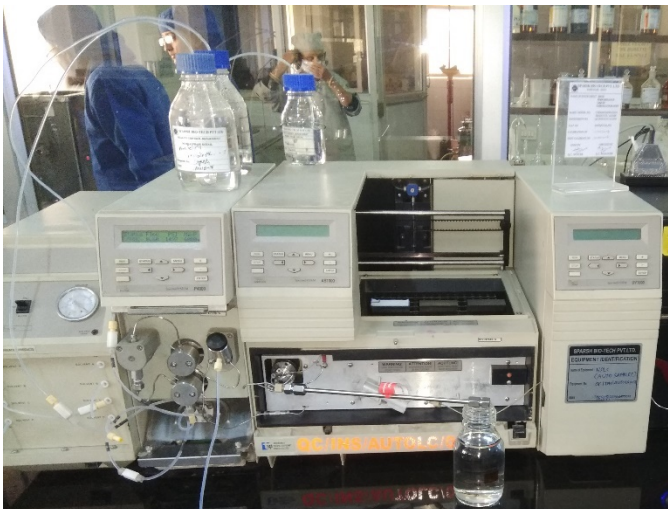
POLARIMETER :

- **In pharmaceutical industries, it is useful to identify the optical rotation.**

GAS CHROMATOGRAPHY :

- **In pharmaceutical industries, GC is very important to test products like raw material , blend powder ,etc.**
- **It has two types of columns: -capillary column**
  -glass column
- **N,N- Dimethyl aniline = glass column**
- **2-ethyl hexanoic acid = capillary column**
- **In GC, injector is situated at the top where there is a button which is required to inject the sample inside.**
- **It has mobile phase and stationary phase.**
- **Stationary phase is solid here and carrier gas is mobile phase.**
- **Three types of gas is present : nitrogen, hydrogen and oxygen.**
- **To find the residue of the tablet, there will be unique type of GC in which there will be only capillary column.**
- **Nitrogen gas is useful to give flame.**
- **Industries have different GC on the basis of their sample's need.**
- **PRINCIPLE: The sample solution injected into the instrument enters a gas stream which transports the sample into a separation tube known as the "column".**

HIGH PRESSURE LIQUID CHROMATOGRAPHY



PRINCIPLE: Any sample is separated on the basis of their volatility and polarity. (Depended on the sample)

- **HPLC has its very important parts: Auto injector**
  Degasser
  Pump
  column
- **Auto injector: -Through little plastic pipes the sample is transfer in the system.**
  -Its shape will be in a loop form and the sample is injected
  through the loop.
- **Degasser: -It removes the air bubble from the mobile phase.**
- **Pump: - It is important to give air pressure.**
  - It is useful for column washing and when the column was washing it should be got loose first.
- **Column: - A aluminium column is useful in the HPLC, it is the main thing to identify chromatogram.**
- **MOBILE PHASE: -Mobile phase is liquid here. For particular pharmaceutical industries, mobile phase will sometimes more than one too.**
  - It is depended on drug sample that how many mobile phases should be taken.
  Ex.: in ampicillin + cloxacillin one mobile phase will be needed.

    - **ACN WATER: - Useful for column washing.**
    - **METHANOL: -To rinse the syringe.**

DISSOLUTION APPARATUS :

- **It is one of the important instruments in pharmaceutical industries.**
- **Its main function is to dissolve the capsules.**
- **It has 14 peddles and 14 bowls.**
- **All the bowls will fill with 900 ml purified water.**
- **When the process of dissolving gets started, at the inner side there will be the temperature of 37.5^{o}c which is the temperature of human body.**
- **So, it will dissolve capsules according to the human body temperature.**
- **There will also a empty capsule which will be in it to identify the dissolving difference.**
- **The differentiation take place here, that in how much time the normal capsule got dissolve and in how much time the empty capsule got dissolve.**
- **Here empty capsule means the capsule from which the standard powder will take out from the inner part of capsule.**

(NOTE: All the instruments which are described here needs the perfect cleaning and calibration for its good working, on the basis of their calibration and cleaning time all the instruments should be checked)

Training Outcomes:

1. After a keen observation of several days of my training period, I learnt the total quality management of pharmaceutical drugs.
2. I observed the roles of various departments and how it functions.
3. I gathered the knowledge of the know-how of running a pharmaceuticals company at an international level (the export and import)
4. I learnt the financial prospectus, financial organization of pharmaceutical company (ex. Face valuation etc)
5. Finally, I learnt the importance of industrial quality control processes and its indispensable nature in drug manufacturing.
6. Furthermore, I did enhance my organizational, leadership, time management, asepsis and communication skills.

Future Aspirations:

Learn more about the Biopharma business sector and to expand my vision into this industry. Furthermore, with this knowledge I aspire to open a biotech business venture which amalgamates each and every aspect related to the problems of this field.

END OF REPORT

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THANK YOU