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A Review on Formulation and Development

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Abstract: *The formulation development is crucial component of pharmaceutical development and important for therapeutic and commercial acquirement of product by delivering quality, safety and efficiency. The main part of formulation development are product development methods like drug discovery, research etc. It is an essential factor not only in starting stage of drug development, but also in later marketing success of drug product. It ties the exploration of a new drug substance to the successful development of drug product. Formulation can determine patentability, lifecycle the success of a pharmaceutical product.*

Keywords: Formulation Development, Preformulation study, Evaluation test

I. INTRODUCTION

Pharmaceutical formulation is a multistep process where the active drug is mixed with all other components by considering the factors of particle size, polymorphism, pH, and solubility and becomes the final beneficial medicinal product.

For medications to be administered to patients in an efficient manner, all pharmaceutical products are made according to precise dosage forms. Oral tablets, capsules, solutions, suspensions, topical ointments, gels, and injections for intravenous (IV), intramuscular (IM), and subcutaneous (SC) administration are examples of common pharmaceutical dosage forms. Furthermore, a number of medication delivery methods have been created for pulmonary, intranasal, and transdermal administration. Different dose forms typically pose different technical obstacles for formulation development and call for different pharmaceutical technologies.

Formulation development is a crucial aspect of pharmaceutical industry, as it directly influences the therapeutic outcome experienced by patients.: The successful creation of a commercial drug product is correlated with the discovery of a novel drug substance, according to pharmaceutical formulation development. Based on patient demand, formulation development experts must choose the best course of action for attaining successful drug delivery.

Concept of cGMP:

Definition: Current good manufacturing practices (cGMP) are those that follow the recommendations made by the appropriate authorities. These organizations are in charge of approving and licensing the production and distribution of pharmaceuticals, nutritional supplements, cosmetics, food and drink items, and medical equipment. A number of controls for quality-focused operations are included in cGMP systems, such as:

1. Management system
2. Superior Raw Materials
3. . Managing protocols
4. Identifying deviations
5. Examining deviations
6. Dependable testing.

FDA is responsible for establishing cGMP requirements. Drug product production, processing, and packaging processes, facilities, and controls must meet the minimal requirements set forth in the cGMP rules for drug content.

Steps in Formulation Development:

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A) Identification and characterization of drug:

Any material intended to have a particular biological impact on the body is referred to as a drug or pharmaceutical compound. Depending on their intended application and mode of action, drugs can be categorized into a number of groups, including antivirals, analgesics, and antibiotics.

B) Excipients compatibility study

Studies on the compatibility of excipients are essential when developing pharmaceutical formulations. To guarantee stability and effectiveness, they evaluate how excipients and active pharmaceutical ingredients (APIs)interact.

These tests aid in ensuring the safety and efficacy of the finished medication by detecting any incompatibilities, such as chemical reactions or physical alterations.

C) Formulation development.

The systematic process of developing a reliable and efficient product recipe is known as formulation development. It includes choosing ingredients, figuring out how much of each to use, and testing for desired qualities including stability, safety, and effectiveness. This crucial phase is necessary to generate high-quality products in a variety of industries, including food, cosmetics, and medicines.

D) Formulation optimization:

Formulation optimization refers to the process of fine-tuning a product's ingredients and composition to achieve optimal performance and stability. It involves systemic experimentation and analysis to find the ideal combination of ingredients and conditions ensuring product quality and market competitiveness.

E) Evaluation of formulation

The procedure for verifying the identity of a medicine and evaluating its purity and quality. The procedure entails running tests, examining data, and contrasting outcomes with predetermined standards and legal requirements. Evaluation of a product's composition helps guarantee that it fulfills its intended use and conforms with safety and quality standards.

F) Stability Study

A stability study evaluates a product's integrity and shelf life over time, usually in a controlled environment. It entails keeping an eye on physical, chemical, and microbiological characteristics to make sure the product quality stays within acceptable bounds.

A) Requirement listing and procurement:

The process of need listing entails determining and recording the particular requirements for medications and equipment in a medical facility. The process of obtaining products and services for a company, including sourcing, buying, receiving, and checking them, is known as procurement.

Finding, acquiring, and guaranteeing the quality and compliance of these essential components are all part of the procurement process for medications and excipients required for a selected pharmaceutical formulation. To fulfill formulation requirements and guarantee product efficacy and safety, careful selection of medicinal components and excipients is essential. To ensure the supply chain's integrity, preserve product consistency, and ensure regulatory compliance, strict quality control procedures and documentation are necessary.

B) Procurement of equipment and instruments for formulation and analysis

It is the process of buying tools and equipment supplies from manufacturers, distributors, and other vendors, whether they are private or public.

obtaining tools and equipment for formulation:

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1. Compression machine for tablets
2. Friability Test Equipment
3. The Hardness Tester from Monsanto 4. Oven with hot air.

Choosing a vendor, allocating funds, and implementing quality control procedures to assist R&D and preserve product quality are key components of successful procurement strategies.

FIG 1.1: Formulation Development

Basic Techniques:

SOP Handling: Standard operating procedures (SOP) are written, step-by-step instructions that specify specific actions and processes to guarantee uniformity and adherence inside a company. SOPs are necessary to maintain quality standards, increase efficiency, and lower errors. The approach for both preventative and instrument maintenance is described in the standard operating procedure.

A) Preparation of SOPs for different instruments and equipment:

To guarantee safe and reliable operation, a comprehensive approach is used to create Standard Operating Procedures (SOPs) for various instruments and equipment to guarantee safe and reliable operation, a comprehensive approach is used to create Standard Operating Procedures (SOPs) for various instruments and equipment. Goals:

1. A standard operating procedure (SOP) aims to give every employee comprehensive guidance on how to perform a task appropriately each and every time.
2. To continue maintaining quality assurance and control.
3. To function as training materials to instruct users on the procedure for which the SOP was created.

Steps in the SOP preparation process:

1. Make a list of the procedures you feel require the creation of SOPs.
2. Arrange the procedure for creating and overseeing SOPs.
3. Gather data to support the information in your SOP.
4. Draft and check the SOP.
5. Adhered to standard operating procedures when using tools and equipment.

Various equipment and instrument handling:

Handling various types of equipment and instruments correctly is essential to ensure safety, accuracy, and efficacy in various settings including laboratories, workshops and industrial environments.

1) Tablet Compression machine:

A mechanical device with fast speed is the tablet press. It precisely compresses the components into the desired tablet shape. It has the ability to create the tablets come in a variety of shapes, though they are often oval or round. Hydraulic pressure is the fundamental idea underlying the tablet compression machine. Through the static fluid, this pressure is

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conveyed without being decreased. Static fluid distributes any externally applied pressure in a same amount in every direction. Additionally, it enables the force to be multiplied as necessary.

FIG 2.1.1: Tablet Compression Machine.

2) Tablet Coater:

Coating operates on a simple principle. Applying coating material to a moving bed of tablets while simultaneously using heated air is the technique of coating tablets. encourage the evaporation of the solvent. To apply the coating, the tablets are moved either perpendicularly (coating pan) or vertically (air suspension). The working principles of tablet coating machines are relatively simple.

Tablet coating machines work by applying coating ingredients in the form of a solution to a group of tablets in a bed that may move horizontally or vertically. A concurrent flow of heated air facilitates evaporation of the solvents.

FIG 2.2.1: Tablet Coater.

3) Capsule filling machine:

Capsule filling machines, also known as capsule fillers, encapsulation machines, or capsule filling machines, are a type of pharmaceutical processing equipment used to fill empty capsules with different substances that contain active pharmaceutical ingredients (APIs), such as liquids, granules, tablets, powder, pellets, or various combinations of these.

1. Capsule filling machines can be categorized as either personal or professional based on their characteristics and applications.

2. Manual capsule fillers are mainly used for individual use in manufacturing processes that require less or precisely the right amount of prescribed components to be placed in the capsule, whereas semi- and fully-automated capsule fillers are commonly used for pilot production or medium volume manufacture.

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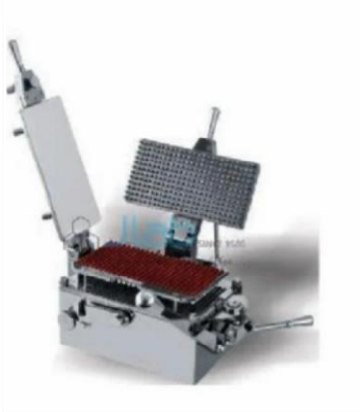

FIG 2.3.1: Capsule Filling Machine.

4) Fluidized Bed Dryer:

A fluidized bed dryer, also known as a fluid bed dryer, is a piece of process equipment that is widely used to lower the moisture content of powdered chemicals, food, pharmaceuticals, and granules. The device is renowned for significantly cutting down on the drying time of medication ingredients, which are usually larger than 50 microns and are used in tablets and capsules. In the past, producers have dried active pharmaceutical ingredients using vacuum dryers and trays.

FIG2.4.1: Fluidized Bed Dryer.

5) Extruder and Spheronizer:

The most often used process for creating pellets is extrusion- spheronization. The following steps are involved: (i) granulation, which prepares the wet mass; (ii) extrusion, which shapes the wet mass into cylinders; (iii) spheronization, which breaks up the extrudate and rounds the particles into spheres; and (iv) drying of the pellets.

Extrusion is a process that creates extrudates by applying pressure to a repaired plastic mass until it flows out through an aperture.

Plastic deformation causes the extruded, cylindrical particles to break into uniform lengths and progressively change into spherical shapes throughout the spheronization process.

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FIG2.5.1: Extruder and Spheronizer.

Experimental (Pre formulation study)

1) Pre formulation studies and preparation, of pre formulation datasheet:

Introduction:

The pre-formulation approach is based on industrial pharmaceutical development, where the physicochemical characteristics of the pharmacological ingredients are determined and described. Laboratory studies to ascertain the properties of active ingredients and excipients that may affect formulation, process design, and performance are known as pre-formulation studies. Pre- formulations are a collection of research investigations that highlight the physicochemical characteristics of novel drug candidates and their interactions with excipients that impact drug efficacy. Prior to the development of pharmaceutical formulations, the inherent chemical and physical features of each medicine were taken into consideration. The foundation for medication combinations with pharmaceutical substances is provided by this attribute. Review is given to pre formulation investigations conducted by different research professionals. Prior to the development of pharmaceutical formulations, the inherent chemical and physical features of each medicine were taken into consideration. The foundation for medication combinations with pharmaceutical substances is provided by this attribute. Review is given to pre formulation investigations conducted by different research professionals.

Goals and Objectives:

1. To establish its compatibility with common excipients and determine product stability.
2. To provide insights into how drug products should be processed and stored to ensure their quality.
3. To generate useful information to design a drug delivery system with good Bioavailability.
4. To develop the elegant, stable effective and safe dosage form by establishing kinetic rate profile and establish physicochemical parameter of new API.
5. To generate useful data needed in developing safe dosage forms that can be manufactured on a commercial scale.

Physical properties:

1. Physical form:

Crystalline: it has repetitious spacing of constituent atom or molecules in dimensional array it is more stable than amorphous. Amorphous: Does not have any fixed internal shape.

2. Partical size and shape: It is most important characteristics it affects the bulk properties of
the substance like teste colour performance, efficiency, solubility, stability uniformity and texture the particle size is obtains by surface area formulae.

3. Flow properties: The physical characteristics of a powder that determine how easily it flows in a specific piece of equipment.

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4. Solubility profile: It is based of the lipophilicity and hydrophilicity of the drugs. The maximum concentration of a drug that can dissolve in a solvent at a specific temperature and pressure. Application of pre formulation in dosage form:

1. To increase the bioavailability of drugs.
2. To provide and understand the degradation process.
3. Any adverse condition relevant to the drugs.
4. Pharmacokinetics and formulation of similar compounds.

Formulation of conventional or novel drug delivery system:

A. Formulation of conventional drug delivery system:

1) Tablets:

These are solid dosage forms that are compacted and contain medications, either with or without excipients, that are used to diagnose or treat illnesses. Tablets are solid dosage forms that include excipients and active medicinal substances. Tablets are convex, flat, round, and solid.

Ex. compressed tablets, multiple compressed, repeat action delayed release, sugar coated film buccal, sublingual, troches dental. Machines: single station, multi station, tablet compressing machines.

2) Capsules:

These are pharmacological dosage forms where a gelatine shell or any other appropriate substance encloses the drug or combination of pharmaceuticals to create a variety of shapes.

Gelatin, a commonly produced animal-based gelatin product, is used to make traditional capsules. HPMC (hydroxyprolymethyl cellulose) have emerged as viable substitutes in recent years and are now marketed for use in pharmaceutical and nutraceutical applications.

Type -hard gelatine, soft gelatine, enteric coating, sustains release, rectal, vaginal.

Machines: Fully or semiautomatic vibration assisted tablet filling machine with doster, auger dosing disc.

3) Oral Liquids:

Liquid Orals are the homogeneous liquid preparations containing one or more active ingredients with or without additives dissolved in a suitable vehicle, for oral administration.

Type: syrups, elixirs, linctus's, mixtures, oral solutions, oral suspensions, emulations, drops. Methods of formulation: Fillers: mixing, volumetric methods, diaphragm methods, time flow method Machines: liquid oral plants.

4) Semisolids like ointments, creams, lotions etc.:

Viscous dosage forms designed for topical and transdermal medication distribution are known as semi-solid dosage forms12. They can be placed to the skin, nasal cavity, vaginal cavity, or rectal cavity and serve medicinal, cosmetic, or protective purposes.

A semisolid pharmaceutical system is made up of a collection of goods that, when applied to the skin or other accessible mucous membranes, aid in the treatment or alleviation of a disease or offer further environmental protection.

5) Parenteral:

A parenteral dosage is a sterile medication product that can be administered by injection and comes in the form of a solution, suspension, emulsion, or reconstituted lyophilized powder.

The four types of parenteral routes include intravenous (IV), intramuscular (IM). subcutaneous (SQ), and intrathecal (IT) administration.

Type: liquid, powder, emulsion, suspension, oily, Infusion for injection.

MOF: in sterile environment with proper godliness high risk of death if contamination happen. B. Formulation of novel drug delivery system:

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The drawbacks of the conventional drug delivery methods—controlled drug delivery, nano carriers, vesicular drug delivery, and gastro retention drug delivery—are addressed by this innovative method of drug administration.

The carrier controls the drug's distribution rather than the physicochemical properties of the drug itself. Colloidal drug carriers include liposomes, neosomes, nanospheres, various emulsions, and ceramics.

Liposomes :

A liposome is a tiny, spherical, artificial vesicle that contains at least one lipid bilayer. Liposomes can be employed as drug delivery vehicles for the administration of pharmaceutical medications and nutrients, such as lipid nanoparticles in mRNA vaccines and DNA vaccines, because of their hydrophobicity and/or hydrophilicity, biocompatibility, particle size, and many other features. It is possible to prepare liposomes by rupturing biological membranes.

Nanosomes:

Nanosomes are used in a wide range of industries, including medical diagnostics, biosensors, bioimaging, chemotherapy, and cosmetics. An extensive summary of the advancements in the formulation and characterization of nanosomes for application in various drug delivery systems will be given in this chapter.

Microparticles:

Microparticles can also aid in the delivery of the drug's payload to the targeted site and offer controlled release of the drug over a prolonged period of time. By reducing the dosage and frequency, the use of microparticles can increase the drug's bioavailability.

Phytosomes:

Phospholipids and naturally occurring active phytochemicals bound in their structures combine to form phytosomes, which are produced by reacting plant extracts with phosphatidylchoine (or any other hydrophilic polar head group)in an approtic solvent.

I. CONTROLLED DRUG DELIVERY SYSTEM

The goal of a controlled drug delivery system is to deliver the right dosage of a medication precisely where it is needed and for the appropriate amount of time.

To produce the intended therapeutic effect, the drug delivery system makes it possible for the active pharmaceutical ingredient to be released. Traditional drug delivery methods (tablets, capsules, syrups, ointments, etc.) cannot provide continuous release due to their poor bioavailability and variations in plasma drug levels.

Type: Diffusion controlled, Dissolution controlled.

II. NANO – CARRIERS

Because they can transport medications to site-specific targets, nanocarriers are helpful in the drug delivery process. This means that medications can be delivered to specific organs or cells but not in others.

Type: liposomes, phytosomes, nanoparticles, microsphere.

A nanocarrier is nanomaterial being used as a transport module for another substance, such as a drug.

III. VESICULAR DRUG DELIVERY SYSTEM:

One method that can increase a drug's bioavailability and decrease toxicity by directing the medication to a particular location is the vesicular drug delivery system. In 1965, Bingham established the biologic origin of vesicular systems, leading to their naming as Bingham bodies. A Vesicular Drug Delivery System (VDDS) is a system that bridges the gap between the ideal and practical of innovative drug delivery systems by encapsulating active moieties in a vesicular framework.

IV. GASTRO RETENTIVE DRUG DELIVERY SYSTEM:

Gastroretentive delivery systems, such as bio adhesive, expandable, floating, and high-density drug delivery, are made to stay in the stomach for a long time and release their active ingredients, allowing for continuous and prolonged drug input into the upper portion of the gastrointestinal (GI) tract. It is a novel method to pharmaceutical formulation that attempts to solve issues related to the gastrointestinal tract's drug administration.

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V. NOSE BRAIN DRUG DELIVERY SYSTEM:

An intriguing method for getting a medication straight into the brain through the nose is the brain drug delivery system. Because it prevents first-pass metabolism and increases medication concentration in the central nervous system (CNS) at a low dose, intranasal drug delivery is highly advantageous. Numerous neurological conditions, including Parkinson's disease, Alzheimer's disease, schizophrenia, dementia, brain cancer, etc., are treated with this delivery technique. Depending on the drug's physiochemical characteristics, various formulations, such as nanoparticles (NPs), microemulsions, in situ gel, etc., can be utilized to treat certain kinds of illnesses.

Evaluation:

a) Solid dosage form :

I. Dissolution test:

The components of the assembly include a motor, a drive shaft, a cylindrical basket (stirring element), and a tank, which can be covered and made of glass or another transparent, inert material that shouldn't absorb, react, or obstruct the preparation to be evaluated. The vessel is heated using an appropriate tool, like a heating jacket, or partially submerged in a suitable water bath of any practical size. Throughout the test, the temperature inside the vessel can be kept at 37 ± 0.5 ºC thanks to the water-bath or heating equipment.

Dissolution Time: 6 solid dosage form in each tube for coated 15 min uncoated 30 min plain 60 min for capsules 30 min and vice versa if not disintegrate do again with 12 ,16.

II. Disintegration test :

We utilize a basket that can accommodate one to six pills in order to perform a disintegration test. In order to replicate stomach conditions at 3737 ± 0.5 ºC, this is then elevated and lowered into a beaker of water. Perforated plastic disks are positioned on top of the tablets to keep them below the water's surface if the capsules or tablets float. When there is no more residue in the mesh, the pill disintegration time is calculated.

Type of Tablet	Time of Disintegration
Uncoated Tablets	15 min
Sugar coated Tablets	60 min
Film coated Tablets	30 min

III. Weight variation:

The weight variation calculation is a in-process quality control technique is used to determine the uniformity of dosage unit in pharmaceutical dosage form. Only certain unit dosages can be used for the weight variation (WV) test.

Formula= W average – W initial/W average 8*1000.

Average weight of Tablet	Max % difference allowed
130 or Less	10%
130-324	7.5%
More than 324	5%

IV. Drug uniformity:

Calculations are performed 100 times using 10 powdered tablets and 100 mg of equivalency powder dissolved in an appropriate solvent to create a 100 ml solution.

The degree of consistency in the quantity of the drug component across dosage units is known as "Uniformity of Dosage Units" or Content Uniformity (CU). Each dosage unit in a batch should have a drug substance composition that falls within a specific range around the label claim in order to guarantee consistency.

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V. Hardness test:

This test is also known as the "crushing strength test'. Tablet hardness has been is defined as the force required to break a tablet in diametric compression.

The hardness is measured in kg/cm2. Conventional tablets hardness: 2.5-5Kg/cm

Dispersible/chewable tablets hardness: 2.25-2.5Kg/cm

Extended release tablets hardness: 5-7.5Kg/cm

b) Liquid Dosage Form:

I. Leakage test: 10 containers filled with liquid dosage form and inverted for 24 hours, also check for leakage in case of rubber closure.

II. Clarity Test: Dilute the ingredients and use clean water as a control to see whether there is any cloudiness. In this test, black or dark particles were seen against a white backdrop, and transparent or white particles were seen against a black background.

III. Sterility Test: It is done for detecting the presence of viable forms of bacteria, fungi and yeast in parenteral products he test for Sterility must be carried out under strict aseptic conditions in order to avoid accidental contamination of the product during test.

Two main types: 1. Direct transfer method. 2. Membrane filtration method

IV. Pyrogen test: Pyrogens are metabolic products of microbes that cause fever with the body each:

SHAM TEST: 3 rabbits → 1 to 3 days observation → temperature check 30 to 40 min prior → administration of sample solution (37° C prior to injection) →thermometer in rectal cavity up to

7.5 cm →initial and second reading temperature 0.2 c →1 hour temperature determine →do not vary from 1 °C →rabbit displays 0.5 °C rise test pass otherwise 5 additional rabbits are used. LAL TEST: Limulus polymethyls gel's Limulus Amoebocyte Lysate (LAL) is utilized. Because of the characteristics of horseshoe crab gel, a 0.1 ml sample is incubated with the lal reagent for 1 hour at 37 ºC, and the clot is analyzed.

A) Semisolid dosage form:

I. Viscosity: To guarantee appropriate product consistency and patient acceptance, it is essential to assess the viscosity of semisolid dosage forms. Viscosity measures aid in evaluating the stability, spread ability, and ease of application of formulations such as gels and creams. A precise assessment of viscosity guarantees that the product satisfies requirements, can be used efficiently, and has the desired therapeutic effect.

II. pH: Since pH can affect stability, drug release, and skin irritation, it is essential to assess pH in semisolid dosage forms. The solubility, effectiveness, and patient comfort of optical drugs are ensured by maintaining a suitable pH. The significance of pH management in semi-solid medicines is highlighted by the possibility of formulation problems and diminished therapeutic advantages resulting from departures from the intended pH range.

LABELLING AND PACKAGING:

DEFINITION: packing and packing procedures for pharmaceutical preparations are referred to as pharmaceutical packaging or drug packaging. It includes every step of the process, from manufacturing to drug distribution routes to the final customer. For simple, safe, and appropriate drug assembly, the item or device that holds the pharmaceutical items may or may not come into direct touch with the product.

1. TYPES OF PACKAGING

Primary packaging: They have direct contact with drugs ex. cap liner label.

Secondary packing: external to the primary packaging add additional physical protection, leaflets cartons etc.

Tertiary packaging: provides protection handling Wearhouse storage and transportation ex brown cardboard boxes wood pallets etc.

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Ampoules. Vials. Containers. Strip package. Blister Packaging. Syringe. Dosing Doppler. Sachet Packaging Containers. aluminium foil. Injectables / Vials .Bottles .Cartons. Paper Board. Latitudes. Paper etc.
Airtight containers. These containers prevent the contents from dust, moisture, and air. Internal All Employees
Light resistant containers. Multi-dose containers. Single-dose containers. Well closed containers. Aerosol containers. Childproof containers etc.

2. PACKAGING MATERIAL :

Glass: they are most commonly used for storing pharma products due to superior protecting quality Borosilicate glass type 1 :80 % silica 10% boric acid small amount of sodium oxide Soda lime
glass: Sulphur treatment more resistance than type 3 Regular soda lime glass : 75% silica 15% sodium oxide 10% CALCIUM OXIDE Products :colored glass ampoules, bottles etc. .
Plastic: they are made of one or more polymers and additives that make it simple to give them the desired shape. Polyethene, polystyrene, polycarbonate, polyvinyl chloride, polypropylene, and other materials were utilized.
Metals: Among all the goods that are utilized, metals are more adaptable. Examples include tablets, blisters, cans, sachets, poches, membranes, and collapsible tubes.
Paperboard: this traditional material has been utilized for ex-boxes, sachets, and other items. Rubber is used for closure stoppers, liners, and bumpers of type 1 (the most favored and stringent requirement type 2), which has mechanical qualities.
Materials: silicon, butyl, nitryl, neoprene, natural, and Chornobyl. Cotton: utilized to prevent collisions by wadding solid preparations.
Limitations of film foil: they were employed to support ornamentation with barrier heat sealing. Adhesive links: they are used to identify adherence.

3) EVALUATION TEST FOR PACKAGING MATERIALS:

IDENTIFICATION: both the product substance and the package material's appearance are examined.
Physical test: light absorption, appearance, pH, heavy metals, nonvolatile matter, buffering capability, and oxidizable compounds are checked.
Chemical tests: these include tests for paper or board, alkalinity of glass, ph. materials, chloride sulphates, and container compatibility.
Mechanical test: to verify strength and functionality.
Biological test: USP offers methods for intracutaneous, systemic injection, and implantation tests. Environmental test: environmental materials test.
The following tests should be performed: compatibility, light absorption, surface resistance, thermal shock, metallic additions, nonvolatile residue, leakage, collapsibility, clarity, transparency, and water vapor permeability.

4. LABELLING OF DIFFERENT DOSAGE FORM:

Definition: All labels and other written, printed, or graphic material on an item's immediate container, as well as on or within any package or wrapper that it is encased in, with the exception of outside shipping containers, are referred to as "labelling." Drug labels, often known as prescription labels, are written, printed, or graphic materials that are attached to or placed on medications, their containers, or both. In addition to identifying the drug's components, drug labels aim to include precise directions.

Hands on Activity:

A) Identification and characterization of drug by melting point, solubility study, UV spectroscopy: Melting point:
Heating the medicinal material and monitoring the temperature at which it transforms from a solid to a liquid is known as melting point determination.
Every substance has a unique melting point range that may be identified by comparing it to reference data.
The melting point may be impacted by contaminants or various polymorphic forms.

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Solubility study:

In solubility tests, the drug's capacity to dissolve in different solvents is evaluated. Since solubility can change with temperature, measurements are frequently conducted at several temperatures.

The drug's crystalline shape and purity can be determined from the solubility profile.

UV spectroscopy:

In UV spectroscopy, the amount of ultraviolet (UV) light absorbed by the drug in solution is measured. The chemical structure of each molecule determines its specific UV absorption spectrum.

Both qualitative and quantitative analysis can be done with this method. Comparing the outcomes of these methods to references to data or standards for the substance in question is usually how a drug is described. This aids in verifying the drug's identity and determining its purity. Importantly, for a thorough characterization of pharmaceutical substances, other methods like nuclear magnetic resonance (NMR) and infrared spectroscopy (IR) may also be employed.

B) To study the dissolution of solid dosage form :

Examining how a drug dissolves in a particular solvent over time is part of studying the dissolution of a solid dosage form. These are the fundamental procedures for carrying out such a study.

Preparing the sample: Get a representative sample of the solid dosage form first, making sure it is undamaged and preserved correctly.

Choosing the right solvent (dissolution medium) is important because it should replicate the physiological circumstances in which the drug will be taken.

Water, artificial gastric fluid, or simulated intestinal fluid are popular options.

Equipment's: Dissolution Testing: place the dosage form in the dissolution in the dissolution medium, start the apparatus, and monitor the dissolution process. collect samples at specified time intervals. Sample analysis: Analyze the collected samples to determine the concentration of the active ingredients using appropriate analytical methods (e.g, UV vis spectroscopy).

C) Study of disintegration time of different marketed tablet.

Analyzing the disintegration duration of several commercially available tablets is a crucial part of pharmaceutical quality assessment and management. Usually, to carry out such a study, you would do the following:

To guarantee a diverse dataset, pick representative samples of the tablets from various manufacturing batches. Testing Equipment: To guarantee precision and repeatability, utilize a disintegration testing equipment that complies with pharmacopeial standards (such as USP, BP, and EP). Testing Conditions: As directed by the regulations, maintain constant testing parameters, such as pH, humidity, and temperature.

D) Tests for evaluation of different packaging materials.

Testing packaging materials is crucial to ensure they meet specific requirements for a given product. Here are some common tests to evaluate different packaging materials:

Tensile Strength Test: Measures the material's ability to withstand a stretching force without breaking.

Bursting Strength Test: Evaluates a material's resistance to bursting when pressure is applied.

Compression Test: Determine how well the material can withstand compressive forces.

Impact Resistance Test: Assesses the material's ability to absorb shocks and impacts without damage.

Test Resistance Test: Measures the resistance of the material to tearing or puncturing.

Flexibility Test: Determines how flexible the material is and whether it can conform to the shape of the product.

Permeability Test: Evaluates the materials barrier properties, including its resistance to gases, mositure, and light.

Heat Resistance Test: Determines how the material performs under different temperature conditions.

Chemical Resistance Test: Assesses the material's resistance to various chemicals that might come into contact with the product.

Strength Test: Important for packaging with seals or closures, it measures the strength of the seals. Abrasion Resistance Test: Evaluates how well the material resists wear and abrasion during handling and transportation

Opacity Test: Determine how well the material blocks light and prevents the product from being exposed to light.

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E. Study of flow properties of the designated formulation:

Studying the flow properties of a designated formulation typically involves conducting rheological tests and analysis. Rheology is the science of how materials flow and deform under various conditions. to study flow properties, you can consider the following steps:

Formulation Selection: Decide which particular formulation you wish to examine. This substance may be solid, liquid, or paste-like.

Instrumentation: Depending on the type of formulation, obtain the required tools, such as a flowable, viscometer, or rheometer.

Viscosity measurement: ascertain the formulation's viscosity. One essential characteristic that characterizes a substance's ease of flow is its viscosity. For this, a viscometer can be used.

Rheological experiments: To learn how the formulation responds to diverse circumstances, perform a variety of rheological experiments, including shear rate and stress measurements. This can assist you in identifying whether it behaves in a Newtonian or non-Newtonian manner. Flow behavior: Evaluate how the formulation flows. It thins and thickens with shear. Sensitivity to temperature and pressure: Assess the effects of temperature and pressure on the flow characteristics. Variations in pressure or temperature may cause some formulas to fluctuate in viscosity.

Flow curve analysis: plot shear stress to produce flow curves. This aids in choosing the proper processing conditions and offers insights into the behavior of the materials. Assess whether the formulation has a yield stress, which is the lowest tension necessary to start a flow. For handling and pumping applications, this is essential.

Documentation: Carefully record all test parameters, findings, and observations for reporting and future use.

Optimization: To obtain the required performance characteristics, adjust the formulation as necessary in light of the flow property data.

Data Interpretation: To make inferences on the flow properties, examine the data gathered throughout the tests. Make any required modifications after comparing the outcomes to the intended application of your formulation.

To guarantee product quality and performance, keep in mind that researching flow characteristics is crucial in a variety of industries, such as materials science, food processing, medicines, and cosmetics.

Examine the following: hysteresis (differences in flow behavior during loading and unloading) and thixotropy (recovery of viscosity over time), if applicable.

F) Determination of different bulk characteristics like bulk density and tapped density: Important properties of powders and granular materials that are frequently utilized in a variety of sectors, including materials research, food processing, and medicines, include bulk density and tapped density. They shed light on these materials' flow and packing characteristics. Here's how to identify them.

a) Bulk Density:

Bulk density is the mass of a powder divided by its bulk volume, including the void spaces between particles. To determine bulk density, you'll need a known mass of the powder and a cylinder or container with a known volume. Pour the powder into the container without compacting it and measure the volume it occupies. Make sure it's level with the top. Weight the container with the powder. Calculate bulk density = (mass of powder)/ (bulk volume)

b) Tapped Density:

The density of a powder after it has been tapped to settle the particles and minimize vacuum spaces is known as "tapped density." A tapped density tester, a tool made specifically for this use, is required. Usually, it includes a cylinder that has the ability to tap the sample. Make sure the powder is level with the top of the cylinder before filling it. Adjust the tapping parameter (such as the number of taps) in accordance with industry standards or the testing procedure. For the designated number of times, tap the cylinder. Use the tapped powder to weigh the cylinder.

Calculate tapped density= (mass of powder)/(tapped volume).

G) Determination of viscosity of liquid and semisolid dosage forms:

To guarantee product quality and consistency, viscosity in liquid and semisolid dosage forms must be determined. Viscosity, a material's resistance to flow, is essential in many sectors, including medicine. Viscosity in these dose forms can be assessed in the following ways:

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Brookfield viscometer: this is a common instrument used to measure the viscosity of both liquids and semisolid substances. It uses a rotating spindle immersed in the sample, and the torque required to rotate the spindle is used to calculate viscosity.

Cone and plate viscosity: this type of viscometer is suitable for both liquids and semisolids. A small amount of the sample is placed between a stationary cone and a rotating plate. The resistance to the rotation of the plate gives the viscosity reading.

Rotational viscometer: these come in various configuration and versatile for measuring viscosity in a wide range of samples. They use the principle of rotating a spindle or bob in the substance and measuring the resulting torque.

Ostwald viscometer: this is primarily used for determining the viscosity of liquids. It measure the time it takes for a fixed volume of liquid to flow through a narrow capillary tube.

H) Partition coefficient determination:

Determination the partition coefficient (P) involves measuring the distribution of a compound between two immiscible phases, typically a hydrophobic organic solvent and water. Here are the basic steps determine the partition coefficient:

Prepare the sample: dissolve the compound of interest in the organic solvent. Ensure that the compound is fully dissolved and in a known concentration.

Create a two phase system: add a known volume of water to the organic solvent containing the compound.

This creates a two phase system.

Mix thoroughly: vigorously shake or stir the two phases to allow the compound to distribute between them. Achieve equilibrium by ensuring through mixing. Internal All Employees.

Saturation solubility estimation: Estimating the saturation solubility of a compound typically involves experimental testing or using solubility prediction models. One commonly used model is the Hansen solubility parameter approach, which considers the polar, nonpolar, and hydrogen bonding interactions of a substance to estimate its solubility in a particular solvent.

To estimate saturation solubility: determine the Hansen solubility parameters for your compound and the solvent of interest. Use these parameters to calculate the distance between them in a multi-dimensional space. A smaller distance often indicates better solubility, but other factors like temperature, pressure, and impurities can also play a role. Keep in mind that solubility can vary widely depending on conditions, so experimental data is often the most accurate way to determine saturation for a specific case.

I) Saturation solubility estimation:

A method for determining a solute's (API) solubility in a solvent (lipid excipient) is called saturation solubility estimational. It entails mixing too much medication with distilled water and then examining the drug in the filterate. A saturated solution prepared at a higher temperature often includes more dissolved solute than it would at a lower temperature because most solids become more soluble at higher temperatures.

To estimate saturation solubility:Find the Hansen solubility parameters for your substance and the target solvent to estimate saturation solubility. Determine how far apart they are in a multi- dimensional space using these characteristics. Although temperature, pressure, and contaminants can also affect solubility, a shorter distance frequently denotes better solubility. Because solubility can vary greatly depending on the circumstances, experimental evidence is frequently the most reliable method of determining saturation for a given situation.

II. CONCLUSION

After the report on formulation development was completed, we had a clear understanding of the following:

Pre formulation studies and the creation of a pre-formulation data sheet; formulation of a novel drug delivery system and its evaluation; requirements listing and procurement; handling SOP; preparation of a pre-formulation data sheet; and an introduction to formulation development and cGMP concepts .Formulation development research, pre-formulation studies, numerous tests, and SOP handling are all crucial to the pharmaceutical industry.

Without these, the industries cannot operate effectively, and there would be no innovative answers to issues that come up during development. It is easy to comprehend that "small mistakes have big consequences" and that a substantial amount of work and knowledge are needed to construct formulations.

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Formulation development is an dynamic process that transforms API's into effective pharmaceutical product.
Using design of experiment formulation scientist evaluate the all-formulations factors in systemically and timely manner to optimize the formulation and manufacturing process.

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