

Formulation Development Studies

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Abstract

Formulation development plays a critical role in transforming an active pharmaceutical ingredient (API) into a safe, effective, and patient friendly dosage form. The present work focuses on the systematic design, optimization, and evaluation of a pharmaceutical formulation aimed at improving the stability, bioavailability, and therapeutic performance of the selected drug. Pre-formulation studies were conducted to assess physicochemical properties, compatibility with excipients, and critical material attributes influencing product performance. Various prototype formulations were developed using a Quality by Design (QbD) approach, and key process parameter were optimized to achieve the desired critical quality attributes. The optimized formulation was evaluated for physicochemical characteristics, drug release behavior, stability, and overall product performance in accordance with regulatory guidelines. Results demonstrated that the finalized formulation meets all predefined quality standards and offers improved therapeutic efficacy compared to conventional preparations. This study highlights the importance of systematic formulation development in ensuring product quality and enhancing patient outcomes.

1. Introduction

Drug development is a high trend in the pharmaceutical and Biotechnology industries. With growing responsibilities to study drugs candidates from discovery to human Clinical Trials as soon as possible, most pharmaceutical and biotech companies are providing a portion of the development of their potential new drugs. Outsourcing decrease the timeline of product development and cost- effective alternative. Changing needs of the people can be considered and fast solution can be provided to the company and people is necessary outsourcing gives a multiple cost structure, increasing resources and spending and decreasing when demand subsides.

Formulation can determine patentability, lifecycle the success of a pharmaceutical product. Companies use this formulation development rules and regulations and personnel into their product development to grow better. In large pharmaceutical companies, specific departments may exist as the physical Characterization of drug substances and formulation issues. In many cases, various departments are work at different places so their handling is very much important by single authority so that the development get speed up and the formulation development timeline decreases. the concept of pre- formulation was known to us around 1950 as result of focus industrial pharmaceutical product development. it is stage of the pharmaceutical product development during which the physicochemical properties of the drug of drug substance are characterized and established the physicochemical and biopharmaceutical properties gives appropriate formulation and delivery methods



Fig No. 01

Ayurveda is invented by Dhanvantari, the physician to the gods in Hindu mythology, who received it from Brahma. Its earliest knowledge were given in the Vedas known as the Atharvaveda. The first modern, pharmaceutical medicine was invented in 1804 by Friedrich Sertürner, a German scientist. The first medicinal drugs made from natural sources and found in the form of herbs, plants, roots, vines and fungi. Up to mid-nineteenth century nature's pharmaceuticals were all that were available to relieve man's pain and suffering. The first synthetic drug which is chloral hydrate, was founded in 1869 and given as a sedative- hypnotic; it is still available today in some countries. The first pharmaceutical companies were doppelgänger of the textiles and synthetic dye industry and owe much to the rich source of organic chemicals which is obtained by the distillation of coal (coal-tar). The first analgesics, antipyretics, produced by phenacetin and acetanilide, chemical derivatives of aniline and p-nitrophenol, were byproducts of coal-tar. An extract of the bark of the white willow tree used to treat various fevers and inflammation from centuries. In white willow, salicin or salicylic acid, it is bitter in taste and also irritated the gastric mucosa, but a simple chemical modification was much more useful it was acetylsalicylic acid, known as Aspirin®, the first famous drug. Start of the twentieth century, the first of the barbiturate family of drugs listed the pharmacopoeia and the rest is history.

DEFINITION:

Pharmaceutical formulation development links the discovery of a new drug substance to the successful development of a commercial drug development. Formulation development scientists must determine the most appropriate route to achieving effective drug delivery based on patient need, then optimize the formulation's characteristics based on a knowledge of the drug product's bioavailability and processing requirements.

STEPS IN FORMULATIONS:

1. Identification and characterization of drug:

The identification and characterization of drug is so much important because it very much affect the final product and also the effect of various characters make drug more potent or toxic

2. Excipients Compatibility Study:

More the excipient compatible with drug more the chances of drug formulation success and effect of drug also increase

3. **Formulation development:** The next stage deals with the formulation development so that with chemicals goes with with excipients is suitable for drugs.
4. **Formulation Optimization :** In this stage formulation like vaccine are produced this type of formulation have lots of studies than normal formulation and large amount of the knowledge needed.
5. **Formulation Evaluation :** The evaluation studies help to improve the already made formulation by changing the part of formulation like the vehicle types.
6. **Stability Studies:** It deals with the stability of the formulation by doing various tests so that the stability of formulation increase it also helps to improve the shelf life of formulation



Fig No.02



Fig No.03

GOOD MANUFACTURING PRACTICES:

The good manufacturing practices helps in following the guidelines given to maintain standard of the product to increase production. to maintain safety when one follows rules and regulation given by the G. M. P. the growth of the company is eminent in that cases and due to maintaining the given standard the companies images also developed and it is helpful in product sales also by maintaining quality and improving the product the customer satisfaction index rises by applying good manufacturing practices many problems arises at time of formulation development is decrease and the process fast forwarded due to the less time consumption in the process the new product comes in market as soon as possible .



Pre-Formulation Studies in Formulation Development:

Pre-formulation studies refer to the investigation of physical, chemical, and mechanical properties of a drug substance before developing a dosage form. They help formulators understand the drug and design stable, safe, and effective formulations

****Objectives of Pre-formulation Studies****

1. To understand the physicochemical properties of the drug
2. To determine compatibility with excipient
3. To select the proper dosage form (tablet, capsule, suspension,
4. To improve stability, bioavailability, and manufacturability.
5. To support regulatory requirements.

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 Physiochemical parameter of new API.
5. To generate useful data needed in developing safe dosage forms that can be manufactured on a commercial scale

PROPERTIES AND PHYSICAL FORMS:

[1] PHYSICAL PROPERTIES: The physical properties with organoleptic properties of the candidate drug molecule and excipients such as color odor taste by just analyzing them various properties of the drugs are shown like when analyzing odor the constituents present can be determined by checking colour one can determine the impurities.

[2] PHYSICAL FORMS:

1. CRYSTALLINE :

it has repetitious spacing of constituents atom or molecules In dimensional array it is more stable than amorphous

2. AMORPHOUS:

Does not have any fixed internal shape

3. PARTIAL SIZE AND SHAPE:

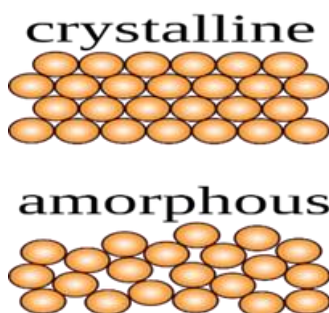


Fig No.04

It is most important characteristics it affect the bulk properties of the substance like taste colour performance, efficiency, solubility, stability uniformity and texture the particle size is obtained by surface area formulae

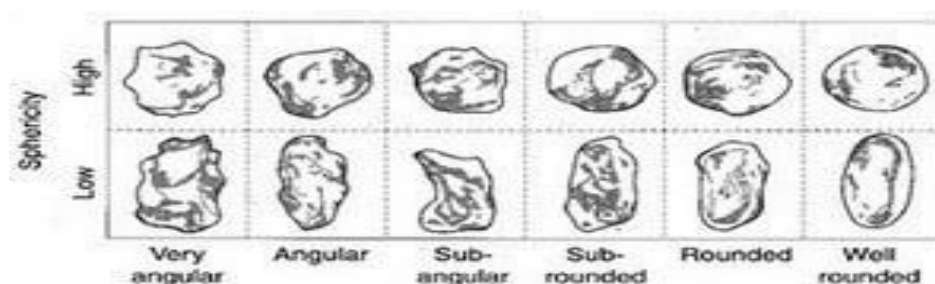


Fig No.05

4. **FLOW PROPERTIES:** It is critical in tablet orientation in case of large doses the powder should have proper flow properties it is found out by the Carr's index

ANGLE OF REPOSE:

$\tan \Theta = H/R$ GREATER ANGLE OF REPOSE INDICATE POOR FLOW

Θ = ANGLE OF REPOSE = , H = HEIGHT OF, PILE R = RADIUS OF PILE

COMPRESSIBILITY INDEX; CARRS INDEX =

$\frac{\text{TAPPED DENSITY} - \text{POURED DENSITY}}{\text{TAPPED DENSITY}} \times 100$



Fig No.06

5. solubility profile: it is based of the lipophilicity and hydrophilicity of the drugs it depends upon pK_a , pH , Partition coefficient $pK_a + pK_b = pK_w$,

FORMULATION OF CONVENTIONAL OR NOVEL DRUG DELIVERY SYSTEMS: 1. THE CONVENTIONAL DRUG DELIVERY SYSTEM:



Fig No.07

Conventional drug delivery systems are traditional dosage forms that release the drug immediately after administration and do not control the drug release rate. The drug is absorbed according to its physicochemical properties and the body's physiology.

CHARACTERISTICS:

- * Immediate release of drug
- * Frequent dosing may be required
- * No control over drug concentration in blood
- * Simple formulation and manufacturing
- * Low cost and widely available

GOALS:

- * Deliver drug for rapid onset of action
- * Achieve therapeutic effect efficiently
- * Provide safe and stable dosage forms

TYPES OF CONVENTIONAL DRUG DELIVERY SYSTEMS

Oral Drug Delivery Systems**

Most common route.

Examples:

- **Tablets**: compressed, coated, chewable
- **Capsules**: hard gelatin, soft gelatin
- **Syrups, solutions, suspensions**
- **Powders and granules**

ADVANTAGES:

- * Convenient and non-invasive
- * Economical
- * Accurate dose

LIMITATIONS:

- * First-pass metabolism
- * Gastric irritation
- * Slow onset (for some drugs)

PARENTERAL DRUG DELIVERY SYSTEMS:

Given by injection. **TYPES:** *Intravenous (IV)*Intramuscular (IM) *Subcutaneous (SC)

DOSAGE FORMS:

- * Solutions, suspensions, emulsions
- * Dry powder for reconstitution

NOVEL DRUG DELIVERY SYSTEM: It is a novel approach to drug delivery that addresses the limitations of the traditional drug delivery systems controlled drug delivery system, nano carriers, vesicular drug delivery system, gastro retention drug delivery system



Fig No.08

1. CONTROLLED DRUG DELIVERY SYSTEM: A controlled drug delivery system is aimed at releasing the correct dose of a therapeutic directly in the desired zone and during the required period of time.

- **TYPE:** DIFFUSION CONTROLLED, DISSOLUTION CONTROLLED
- **Mof:** the fundamental principle for evaluation of the kinetics of drug release was offered by Noyes and Whitney in 1897 as the equation (10): $dM/dt = KS (C_s - C_t)$

2. NANO CARRIERS:

Nanocarriers are useful in the drug delivery process because they can deliver drugs to site-specific targets, allowing drugs to be delivered in certain organs or cells but not in others.

- **TYPE:** liposomes, phytosomes, nanoparticles, microsphere,

3. VESICULAR DRUG DELIVERY SYSTEM: Vesicular drug delivery system is one of the systems that can

improve the bioavailability of the drug and the reduction in toxicity

by drug targeting to the specific site. Bingham pioneered the biologic origin of vesicular systems in 1965, and hence named them Bingham bodies.

4. GASTRO RETENTIVE DRUG DELIVERY SYSTEM: Gastro retentive delivery systems are designed to be

retained in the stomach for a prolonged time and release their active

ingredients and thereby enable sustained and prolonged input of the drug to the upper part of the gastrointestinal (GI) tract. Examples: Bio adhesive Drug, Expandable Drug, floating Drug, high density drug delivery

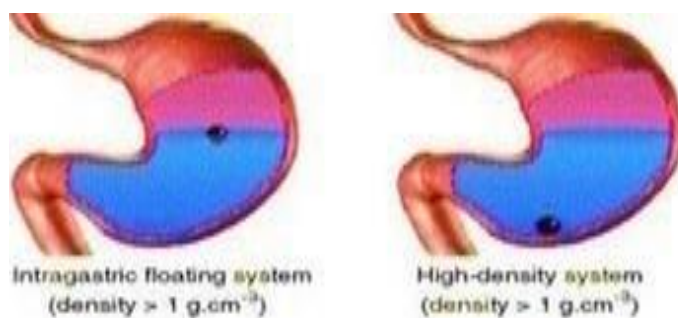


Fig No.09

5. NOSE BRAIN DRUG DELIVERY SYSTEM: o.s.e to brain drug delivery system is an interesting approach to deliver a drug directly in the brain through the nose. Intranasal drug delivery is very beneficial because it avoids first-pass metabolism and achieves a greater concentration of drugs in the central nervous system (CNS) at a low dose. This delivery system is used for the treatment of various neurological disorders such as Parkinson's disease, Alzheimer's disease, schizophrenia, dementia, brain cancer, etc. To treat such types of diseases, different formulations like nanoparticles (NPs), microemulsions, in situ gel, etc. can be used depending on the physiochemical properties of the drug.

6. TRANSDERMAL DRUG DELIVERY SYSTEM AND IMPLANTS: transdermal drug delivery systems (T D DS), also known as "patches," are dosage forms designed to deliver a therapeutically effective amount of drug across a patient's skin. The adhesive of the transdermal drug delivery system is critical to the safety, efficacy and quality of the product.

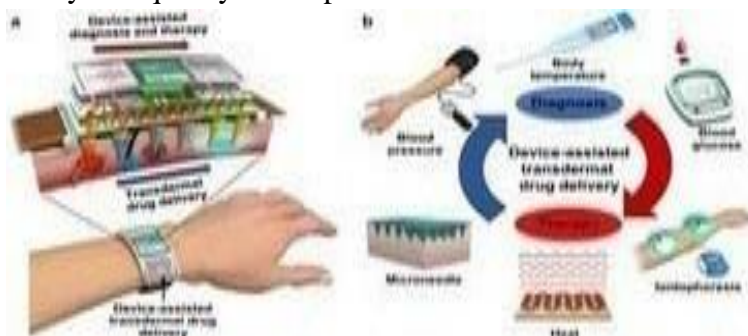


Fig No.10

EVALUATION TEST:

Medication evaluation is a continuous activity. The review begins before a drug is dispensed, and continues during and after dispensing. A continuous review is crucial to identifying and resolving drug-related problems

2. SOLID DOSAGEFORM:

The solid dosage form needs various tests of evaluation so that it shows proper properties of drugs

i. **DISSOLUTION TEST:** The assembly consists of the following: vessel, which may be covered, made of glass or other inert, transparent material, which should not sorb, react or interfere with the preparation to be tested; a motor; a drive shaft; and a cylindrical basket (stirring element). The vessel is partially immersed in a suitable water-bath of any convenient size or heated by a suitable device such as a heating jacket. The water-bath or heating device permits maintaining the temperature inside the vessel at $37 \pm 0.5^\circ\text{C}$ during the test.

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



Fig No.11

ii. **DISINTEGRATION TEST:** To carry out a disintegration test for tablets, we use a basket which holds 1 to 6 tablets. This is then raised and lowered into a beaker of water, which is used to simulate conditions in the stomach at $37 \pm 0.5^\circ\text{C}$. If the tablets or capsules float, perforated plastic disks are placed on the top of the tablets to keep them under the water level. The tablet disintegration time is taken when no residue is left in the mesh. Disintegration Time: 6 solid dosage forms in each tube for coated 60 min uncoated 45 min plain 60 min for capsules 30 min and vice versa if not disintegrate do again with 12,



Fig No.12

iii. **Weight variation test:** to find out the uniformity the weight, 20 tablets average weight is calculated individualw

in calculated, comparison is done Result's 30 FO- R WEIGHTVARIATIONS CASE OF
TABLETWEIGHINGUP

NF25LIMITS $130 \pm 10\%$, $130/324 \pm 7.5\%$, $324\text{mg} \pm 5\%$

formula= $\frac{W_{\text{average}} - W_{\text{initial}}}{W_{\text{average}}} \times 1000$



Fig No.13

iv. Drug uniformity test:

10 tablets powdered and 100 mg equivalence powder dissolve in suitable solvent make 100 ml solution and dilute it 100 time calculations are carried out-

Result: Pass test when not less than 85 % and not more than 115%



Fig No.14

3. LIQUIDEDOSAGEFORM:

The liquid dosage form needs various tests of evaluation so that it shows proper properties of drugs

i. LEAKAGE TEST: 10 containers filled with liquid dosage form and inverted for 24 hours, also check for leakage in case of rubber closure

DYE BATH TEST: to check ability of empty container or container with product, the container is deep in dye bath and pressure and vacuum applied to it and then after estimated time check for the dye marks



Fig No.15

ii. **CLARITY TEST:** dilute the preparations and check for cloudiness with control that is clean water. In this test transparent particles or white particles observed against the black background and the black or dark particles observed against the white background.



Fig No.16

iii. **STERILITY TEST:** It is done for detecting the presence of viable forms of bacteria, fungi and yeast in parenteral products. The test for sterility must be carried out under strict aseptic conditions in order to avoid accidental contamination of the product during the test. Two main types

Direct transfer method: non filterable product test by this method test sample 10% → culture medium 9 ml tubes to 75 ml bottles

→ direct inoculum → incubate 14 days → M. growth



Fig No.17

Membrane filtration method: sample → 0.22 to 0.4 µm pore size 47 mm diameter filter 100 → ml
 ml → membrane cut into 2 halves culture medium → incubated 30 to 35 °C 7 days → another half 20 to 25 °C for 7 days

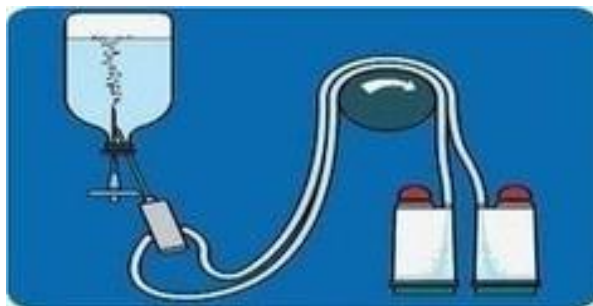


Fig No.18

iv. **PYROGEN TESTING:** pyrogens are metabolic product of the microbes produces fever with body each SHAM TEST: 3

rabbits → 1 to 3 days observation → temp check 30 to 40 min prior → sample solution administration (37 °C prior

to injection) → thermometer in rectal cavity up to 7.5 cm → initial and second reading temp 0.2 c → 1 hr temp determine → do not vary from 1 °C → rabbit shows 0.5 °C rise test pass otherwise 5 additional rabbits are used



Fig No.19

LAL TEST: Limulus Amoebocyte Lysate (LAL) of limulus polymethyls gel is used 0.1 ml sample with the lal reagent incubation for 1 hr at 37 °C clot is analysed due to properties of hors shoe crab gel



Fig No.20

4. **Semisolid dosage form:** 4. The liquid dosage for needs various test of evaluation so that it shows proper properties of drugs

the ph. is determine by means of the various methods like used of ph. meter electrode measures the ph.

PHMEASUREMENT:



Fig No.21

VISCOSITY MEASUREMENT : it measured by Instruments called “rheometers” and viscometer



Fig No.22

VII. LABELLING AND PACKAGING: DEFINITION: Pharmaceutical packaging (or drug packaging) is the packages and the packaging processes for pharmaceutical preparations. It involves all of the operations from production through drug distribution channels to the end consumer.

It is article or the device witch contains the pharmaceutical products container may or may not direct contact with product used for easy safe and proper assembling of drug

1. TYPES OF PACKAGING : • **PRIMARY PACKAGING:** they have direct contact with drugs ex. cap cap liner label

• **SECONDARY PACKAGING:** external to the primary packaging add additional physical protection ,leaflets cartons etc

• **TERTIARY PACKAGING:** provides protection handling Warehouse storage and transportation ex brown cardboard boxes wood pallets etc

- **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. ...
- **Light resistant containers. Multi-dose containers. Single-dose containers. Well closed containers. Aerosol containers. Child-proof 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: sulfur treatment more resistance than type 3

Regular soda limeglass : 75% silica 15% sodium oxide 10% CALCIUM OXIDE

Products :coloured glass ampules, bottles etc

- **PLASTIC:** they contain one or more polymer together with additives desired shape can be given easily Materials used: polyethene, polystyrene, polycarbonate, polyvinyl chloride, poly vinyl dine chloride polypropylene etc.
- **METALS:** metals are more versatile of the all products that used Material used: aluminium,t in, Products tablets , blisters,collapsible tubescans , sachets,poches,membranes,etc.
- **PAPER PAPERBOARD:** they are traditional material used ever since ex boxes sachets etc
- **RUBBER:** THEY ARE USED FOR CLOSURES STOPPERS AND CAP LINERS AND BULBS

TYPE 1: most preferred strictest requirement type 2 ; mechanical properties

Materials:

natural, neoprene, nitril, butyl, Chornobyl, silicon

- **COTTON :** it is used for wadding in solid preparations prevent collisional
- **FILMS FOILS LAMINATIONS :** they used to support barrier heat sealing decoration
- **ADHESIVE LINKS:** they used for labelling adhesion

3. EVALUATION TEST FOR PACKAGING MATERIALS:

- **IDENTIFICATION:** appearance of packaging material alone combination of the product content is check
- **PHYSICAL TEST:** appearance light absorption, ph., non volatile matter, res on ignition ,heavy me buffering capacity, oxidisable substances are check
- **CHEMICAL TEST:** test include ph. materials chloride sulphates, paper or board, alkalinity of glass, compatibility test for containers
- **MECHANICAL TEST:** to check working and strength

- **BIOLOGICAL TEST:** usp.provides procedure for it implantation test, systemic injection test ,intracutaneous test,

- **ENVIRONMENTAL TEST: materials** test in environment

TABSOTBTION

4. LABELLING OF DIFFERENT DOSAGE FORM: DEFINITION: The term “labelling” designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container

Drug labelling is also referred to as prescription labelling, is a written, printed or graphic matter upon any drugs or any of its container, or accompanying such a drug. Drug labels seek to identify drug contents and to state specific instructions or warnings for administration, storage and disposal

For labelling of dosage form one should follow all the guidelines given Product Name, Drug Facts, Table, Active Ingredients, Purpose and Use, Warnings, Directions, Allergic Reactions active Ingredients, expiry date, date of manufacturing, various type of drugs properly should be mentioned

First label introduced at 1800 still now many changes occurred, and there is necessity to maintain all the details on the label

SOP HANDLING: DEFINITION: SOP HANDLING-

A standard operating procedure (SOP) is a set of instructions given by an organization to help workers to do routine operations. It aims to achieve efficiency, quality uniformity of performance, reducing miscommunication and failure to comply with industry regulations.

The military sometimes uses the phrase standing operating procedure because a military SOP refers to a unit's unique works, which are not standard to another unit. The word "standard" states that only one procedure is to be used across all units.

The term can also be used to refer to practices that are unconstructive. In the Philippines, for instance, "SOP" is the term for corruption within the government and its institutions.

EQUIPMENT AND INSTRUMENT HANDLING

TABLET COMPRESSION MACHINE-

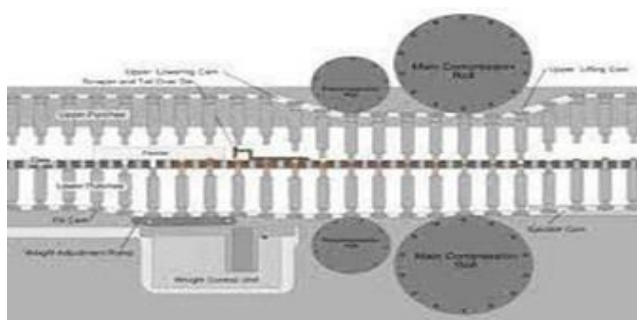


Fig No.23

The basic principle of tablet compression machine is hydraulic pressure. This pressure is transmitted without reducing through the static fluid. Any externally applied pressure is transmitted through static fluid to all the directions in the same proportion. It also makes it possible to multiply the force as needed.

Tablet coater:



Fig No.24

Tablet coating is a process by which dry, outer layer of coating material is given to the surface of a dosage form. It gives specific benefits over uncoated variety. Coatings applied to various oral dosage forms such as particles, powders, granules, crystals, pellets and tablets.

Fluidized bed dryer

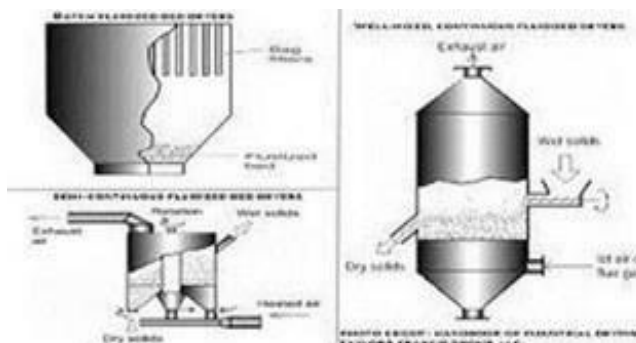


Fig No.25

Fluidized bed dryer (also called fluid bed dryer) is a kind of equipment extensively used in the pharmaceutical industries to reduce the moisture content of pharmaceutical powder and granules. The equipment works on the principle of fluidization of the feed material.

Extruder and Spheronizer

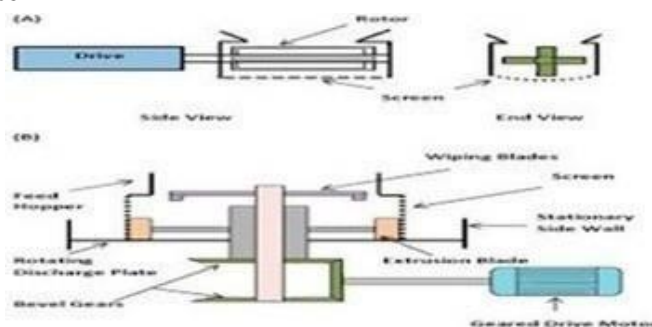


Fig No.26

Agglomeration through extrusion and spherization is one of the ancient techniques for manufacturing pellets. The ratio of liquid solid material with the size of the extruder holes can also determine the quality of the extrudates. The final drying ensures the pellet hardness.

Conclusion:

The formulation development studies along with the pre-formulation studies various tests and the SOP handling are the important aspects of the pharmaceutical industries without this the industries cannot work properly and the quality efficiency and the new

of the problems occurring during development cannot be solved one can know that the large amount of efforts required with

knowledge

required for formulation development because “small mistake big consequences”

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