

# INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

## Review – Formulation Development Studies

<sup>1</sup>Azhar Chand Shaikh, <sup>2</sup>Simran Sallubhai Shaikh, <sup>3</sup>Dr.A.M.Shaikh, <sup>4</sup>Mrs.Mangal S.Gaikwad, <sup>5</sup>Ms.Priti B.Shinde

<sup>1</sup>B.Pharm, <sup>2</sup>B.pharm, <sup>3</sup>Principal, <sup>4</sup>H.O.D, <sup>5</sup>Professor

<sup>1</sup>AAEMF's Delight College of pharmacy, Pimple jagtap road, Koregaon Bhima, Maharashtra 412216,

**Abstract:** The formulation development is important part of pharmaceutical development and essential for therapeutic and commercial success of product by providing quality, safety and efficiency. The various parts of formulation development interact with product development processes like discovery research all the way up to and after market approval. Every drug product demands a tailor-made formulation, due to the difficulty of various pathways potentially affecting product stability, the specific characteristics drug molecule, special patient needs, and even marketing considerations. Formulation development can be approached using various paths, based on a rational design, depending on scientific theories applying these knowledge on thousands of components. In this article review of formulation development, pre-formulation and SOP handling is explained so that its important and procedures can be recognize, admire, understand by all.

### I. 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 a cost-effective alternative. Changing needs of the people can be consider 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 department are work at deferent places so there 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 psychochemical and biopharmaceutical properties gives appropriate formulation and delivery methods



### DEFINITION:

Pharmaceutical formulation development links the discovery of a new drug substance to the successful development of a commercial drug product. 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.

## II. HISTORY

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.

## III. STEPS IN FORMULATIONS

### 1. Identification and characterization of drug:

The identification of 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 which chemicals goes with which and which excipients is suitable for drugs

### 4. Formulation Optimization :

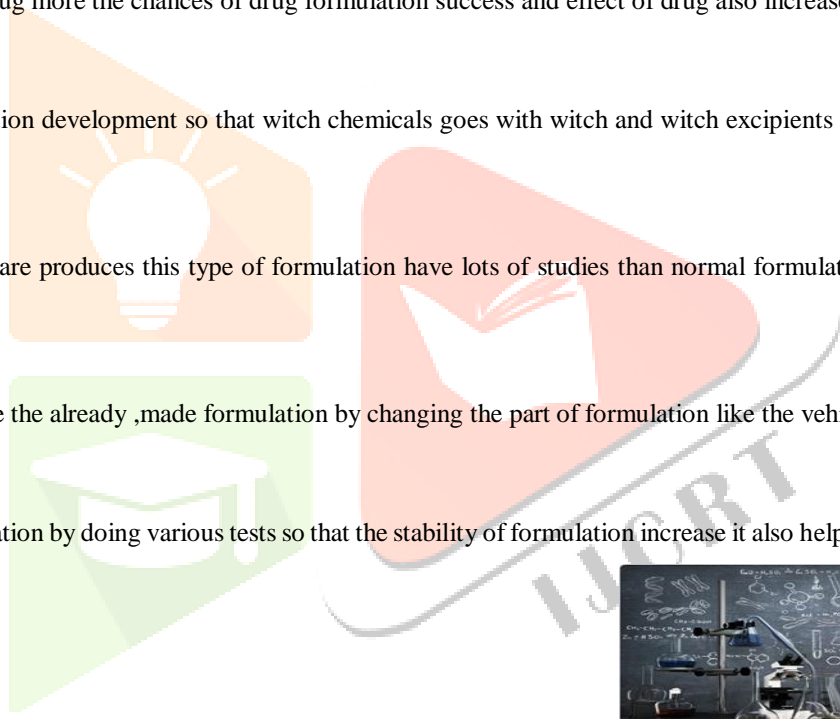
In this stage formulation like vaccine are produces this type of formulation have lots of studies than normal formulation and large amount of the knowledge needed

### 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 improves the shelf life of formulation



## IV. 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 .



## V. PRE-FORMULATION STUDIES:

The concept of pre-formulation is developed around focus industrial pharmaceutical development in which physicochemical properties of the drug substances are established and characterized.

Pre-formulation studies can be defined as Laboratory studies to determine the characteristics of active substance and excipients that may influence formulation and process design and performance. The pre-formulations is a group of studies that emphasize the physicochemical properties of new drug candidate and combination with the excipients that affect drug performance.

### • 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

### • 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 :

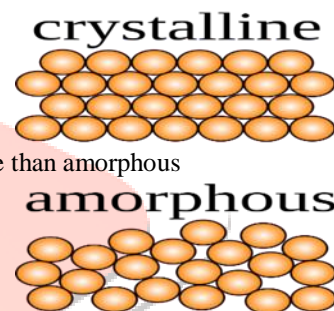
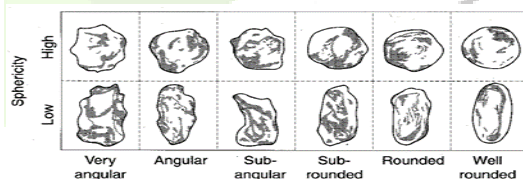
It has repetitive spacing of constituent atoms or molecules in a dimensional array. It is more stable than amorphous.

#### 2. AMORPHOUS:

Does not have any fixed internal shape.

#### 3. PARTICLE SIZE AND SHAPE:

It is one of the most important characteristics that affect the bulk properties of the substance like taste, color, performance, efficiency, solubility, stability, uniformity, and texture. Particle size is obtained by surface area formulae.



### 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

$\Theta$  = ANGLE OF REPOSE, H = HEIGHT OF PILE, R = RADIUS OF PILE

COMPRESSIBILITY INDEX ; CARRS INDEX =

TAPPED DENSITY - POURED DENSITY / TAPPED DENSITY \* 100

#### 5. solubility profile:

It is based on the lipophilicity and hydrophilicity of the drugs. It depends upon  $pK_a$ ,  $pH$ , Partition coefficient  $pK_a + pK_b = pK_w$ ,



## VI. FORMULATION OF CONVENTIONAL OR NOVEL DRUG DELIVERY SYSTEMS

### 1. THE CONVENTIONAL DRUG DELIVERY SYSTEM:



Drug delivery system is the absorption of the drug across a biological membrane, whereas the targeted release system releases the drug in a dosage form. Ex. Tablets Capsules iii. Oral liquids Semisolids like Ointments, creams, lotions . Parenteral etc. Conventional DDSs are classical methods for delivery of a drug into the body. Generally, these systems are used more often when the goal is quickly absorption of a drug; therefore, a quick release of the drug is required. The conventional drug delivery forms include simple oral, topical, inhaled, or injection methods

### FORMULATIONS OF CONVENTIONAL DRUG DELIVERY SYSTEM

[1] **TABLETS:** they are compressed solid dosage form that contain medicaments with or without excipients used to diagnosed or cure the diseases

Ex. compressed tablets, multiple compressed ,repeat action delayed release, sugar coated film coated buccal, sublingual ,troches dental,

- Methods: They made by moulding, compressing ,wet granulation and dry granulation,
- Machines: single station, multi station, tablet compressing machines

[2] **CAPSULES:** it is pharmaceutical dosage forms in which the drug or a mixture of drugs is enclosed in a Gelatine Shell or any other suitable material to form various shapes.

- Type-hard gelation, soft gelatine ,enteric coating ,sustains release ,rectal ,vaginal
- Methods of formulations :punch methods ,volume fill, tamping ,wax fill
- Machines: fully or semi automatic vibration assisted tablet filling Machin 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, meant for oral administration.

- Type: syrups, elixirs, linctus's, mixtures, oral solutions, oral suspensions, emulsions, drops
- METHODS OF FORMULATIONS: FILLERS: mixing ,volumetric methods, diaphragm methods, time flow methods
- Machines: liquid oral plants

[4] **OPHTHALMIC PREPARATIONS:** Ophthalmic preparations are specialized dosage forms designed to be instilled onto the external surface of the eye

- TYPE: anti-angiogenic, miscellaneous, anaesthetics etc.

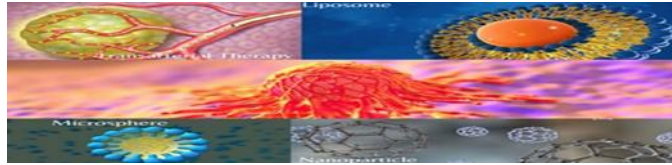
[5] **PARENTALS :** parenteral dosage is a sterile drug product, which is presented in the form of solution, suspension, emulsion, or reconstituted lyophilized powder, suitable for administration by injection.

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

MOF: in sterile environment with proper godliness high risk of death if contamination happen

## 2. 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



### 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:

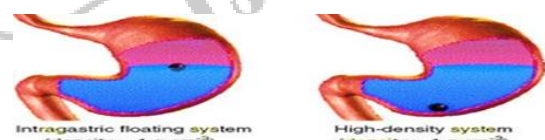
Vesicular drug delivery system is one of the systems that can improve the bioavailability of the drug and the reduction in toxicity by drug targeting to the specific site. Bingham pioneered the biologic origin of vesicular systems in 1965, and hence named them Bingham bodies.

### 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 ex Bio adhesive Drug, Expandable Drug, floating Drug, high density drug delivery

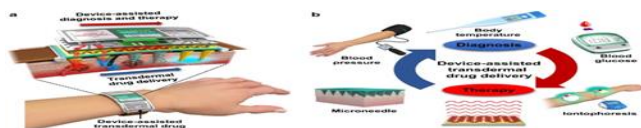
### 5. NOSE BRAIN DRUG DELIVERY SYSTEM:

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 physicochemical 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.



## VII. 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

## 1. SOLID DOSAGE FORM:

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  $37 \pm 0.5$  °C during the test.

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**: 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  $37 \pm 0.5$  °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 form 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,



iii. **Weight variation test**: to find out the uniformity in the weight, 20 tablets average weight is calculated individual weight calculated, comparison is done. Result's 30-N F 25 LIMITS FOR WEIGHT VARIATIONS CASE OF TABLET WEIGHING UP TO  $130 \pm 10\%$ ,  $130/324 \pm 7.5\%$ ,  $324 \text{ mg} \pm 5\%$

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



### iv. Drug uniformity test:

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

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



## 2. LIQUIDE DOSAGE FORM:

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



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



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



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



iv. **PYROGEN TESTING:** pyrogens are metabolic products of the microbes that produce fever with the 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



**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 horseshoe crab gel.



### 3. Semisolid dosage form:

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

**PH MEASUREMENT** : the pH is determined by means of the various methods like used of pH meter electrode measures the pH.



**VISCOSITY MEASUREMENT** : it is measured by instruments called "rheometers" and viscometer



## VIII. 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 an article or the device which contains the pharmaceutical products container may or may not have 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 Dropper. Sachet Packaging Containers. Aluminium foil. Injectables / Vials .Bottles .Cartons. Paper Board. Laminates. 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 lime glass** : 75% silica 15% sodium oxide 10% CALCIUM OXIDE

**Products** :coloured glass ampoules, bottles etc

- **PLASTIC:** they contain one or more polymer together with additives desired shape can be given easily

Materials used : polyethylene, polystyrene, polycarbonate, polyvinyl chloride, polyvinylidene chloride polypropylene etc.

- **METALS** : metals are more versatile of the all products that used

Material used: aluminium, tin,



Products tablets, blisters, collapsible tubes cans, sachets, pouches, 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
- **ADESSIVE LINKS**: they used for labelling adhesion

### 3. EVALUATION TEST FOR PACKAGING MATERIALS :

- **IDENTIFICATION**: appearance of packaging material alone and combination of the product content is checked
- **PHYSICAL TEST**: appearance light absorption, ph., non volatile matter, residue on ignition, heavy metals, 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 TESTS**: 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
- **TESTS AS FOLLOWS**; LEAKAGE TEST, COLLAPSIBILITY, CLARITY, TRANSPARENCY, WATER VAPOUR PERMEABILITY, TEST FOR METALLIC ADDITIVES, NON VOLATILE RESIDUAL, METALLIC ADDITIVES, SURFACE RESISTANCE, HYDRAULIC RESISTANCE, ETCHING, LIGHT TRANSMISSION, OTHERS SOLUBLE, THERMAL SHOCK, INTERNAL BURSTING, PENETRABILITY TEST, FRAGMENTATION, SELF SEALABILITY, EXTRACTIVE, COMPATIBILITY, LIGHT ABSORPTION

### 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

### IX. SOP HANDLING:

#### DEFINITION: SOP HANDLING-

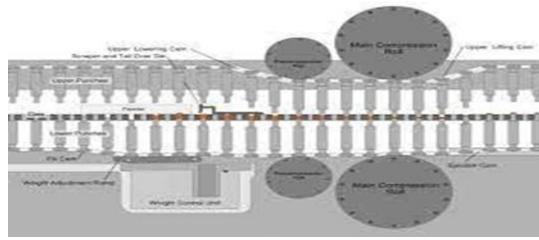
A standard operating procedure (SOP) is a set of instructions given by an organization to help workers to do routine operations. It aims to achieve efficiency, quality uniformity of performance, reducing miscommunication and failure to comply with industry regulations.

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" state that only one procedure is to be used across all units.

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

### EQUIPMENT AND INSTRUMENT HANDLING

#### TABLET COMPRESSION MACHINE-



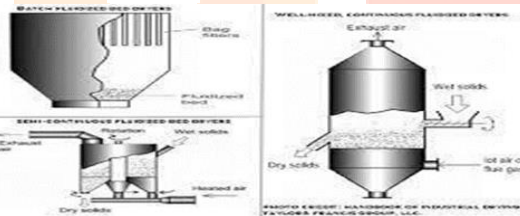
The basic principle of tablet compression machine is hydraulic pressure. This pressure is transmitted without reducing through the static fluid. Any externally applied pressure is transmitted through static fluid to all the directions in the same proportion. It also makes it possible to multiply the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

#### Tablet coater:



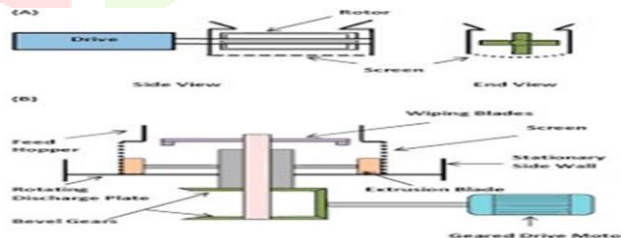
Tablet coating is a process by which dry, outer layer of coating material is given to the surface of a dosage it gives specific benefits over uncoated variety. Coatings applied to various oral dosage forms such as particles, powders, granules, crystals, pellets and [tablets](#)

#### Fluidized bed dryer



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

#### Extruder and Spherometer



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

#### X. 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 efficiany and the new solution of the problems occurring during development cannot be solve one can know that the large amount efforts required with knowledge required for formulation development because “ small mistake big consequences”

**Xi. ACKNOWLEDGMENT:**

Myself and Simran like to express special thanks to respected principal sir Dr. A.M.Shaikh and Head of department Mrs. Mangal S. Gaikwad mam and professor Ms. Priti B. Shinde Mam who inspired us to do this article on such interesting topic and guided thought the information collection.

**REFERENCES**

- [1] Industrial pharmacy i textbook by nirali by dr.ashok hajare page no.1.1to 1.40
- [2] Preformulation Studies: An Integral Part of Formulation Design By Pinak Patel Submitted: July 16th 2018 Reviewed: December 3rd 2018 Published: June 9th 2019 DOI: 10.5772/intechopen .8 2868
- [3] various disintegration test dissolution test usp pharmacopeia stage 4 harmonization official may 1, 2020 ( 701-1 to 703-25)
- [4] PYROGEN TESTING Indian pharmacopeia 2007 volume-1 appendices -1British pharmacopeia 2007 Remington science and practise of pharmacy
- [5] Mundada AS, Meshram DR, Mishra M, Bhalekar MR, Avari JG. Formulation and evaluation of bitterless rapidly disintegrating tablet of Famotidine using ion exchange resins. Int J Pharm Excipients. 2008;7:23–5
- [6] Shirsand SB, Suresh S, Para MS, Swamy PV, Kumar DN. Plantago ovata mucilage in the design of Fast disintegrating tablets. Indian J Pharm Sci. 2009;71:41–5
- [7] Loyd VA, Nicholas GP, Howard CA. Ansel's pharmaceutical dosage forms and drug delivery systems. 8th ed. London: Lippincott Williams and Wilkins; 2005.
- [8] Aulton ME, editor. Pharmaceutics, The science of dosage form design. 2nd ed. Sydney: Churchill livingstone; 2002.
- [9] McMillan A, Young H. The treatment of Pharyngeal Gonorrhoea with a single oral dose of Cefixime. Int J STD AIDS. 2007;18:253–4
- [10] Journal of Pharmaceutical Sciences Volume 74, Issue 1, January 1985, Pages 16-20 Research Articles Pre formulation Studies in a Drug Development Program for Tablet Formulations
- [11] Trevor M. Jones, CHAPTER 1:Preformulation Studies , in Pharmaceutical Formulation: The Science and Technology of Dosage Forms, 2018, pp. 1-41 DOI:
- [12] Sonali S Bharate & Ram A Vishwakarma impact of pre-formulation on drug development Pages 1239-1257 Published online: 27 Mar 2013
- [13] An important approach for novel drug delivery system journal of biometric science polymer edition by hetesh kumar devangen 10.1080/09205063.2020.1825304
- [14] COOPER AND GUNNS DISPENSING FOR PHARMACEUTICAL STUDENTS 12ED (PB 2008)

