IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

# A Review On Formulation And Quality Control Evaluation Of Oral Dosage Form: Tablet

**Nikita Yadav*, Mr. Prashant Kumar Verma, Mrs. Smita Verma**
Department of Pharmacy
Nirmala devi pharmacy college, Nayansand, Gaurabadshahpur, Jaunpur, (U.P)

## ABSTRACT

Tablets are the most widely used dosage form in the pharmaceutical industry, accounting for 70% of all ethical preparations. They are solid dosage forms containing drug substances prepared using compression or moulding methods, and vary in shape and weight. The manufacturing procedure of tablets are easy than other dosage forms.The doctors mostly prescribes it to be administered to the patients because of its quality and higher availability in the market. A tablet contains one or more medicaments with appropriate or desirable excipients. The excipients includes like – binders, lubricants, diluents, disintegrants etc. which are necessary in the preparation of tablets.

In this review article; tablet and its types, excipients, method of preparation and evaluation parameters have been discussed.

Keywords: Tablets, types, API, excipients, disintegration, preparation and evaluation.

## INTRODUCTION:

Solid medicaments, such as powders, pills, cachets, capsules, or tablets, are administered orally as single units. Despite the decline in powders and pills prescribing due to modern formulation requirements, tablets and capsules account for over two-thirds of medicines produced worldwide. Tablets, the most popular form of medication, are solid dosages containing medications with or without excipients, accounting for 70% of total medicines.

Pharmaceutical products undergo physical, chemical, and biological testing under pharmacopoeia standards, with many countries adhering to British Pharmacopoeia. Manufacturing, production, packaging, and testing are key industry phases.

## Benefits:

1. The oral dosage form is the most economical due to its lack of additional processing steps.
2. In all over dosage forms, tablet is more cost effective and convenient to transport.
3. It is more lighter and conservative.
4. The solid dosage form is more convenient and cost- effective to package and handle than liquid dosage form.
5. Large scale manufacturing of tablets is feasible than other dosage forms.
6. Coating techniques can effectively mask unpleasant odors and taste.
7. The enteric coating process allows for the production of a sustained release product.
8. Tablets have longer shelf life, stable composition.

## Drawbacks:

1. Difficult to formulate a drug which has poor wettability and slow dissolution rate.
2. 2. Slow onset of action than parenterals and liquid dosage forms.
3. Some tablets may cause local irritation in GIT mucosa.
4. Moisture containing drugs not suited for the compression.
5. Swallowing can pose a significant challenge for both children and unconscious patients.

## Ideal properties of Tablets:

1. The weight, size and appearance of the tablets should be consistent.
2. The API should be uniformly distributed through all over the tablets.
3. It should have good mechanical strength so that transportation and handling is easier.
4. The tablet should not be too hard.
5. They should be biocompatible.
6. They should be physically, chemically and microbiologically stable during storage.
7. The appearance of tablets should be attractive.

## CLASSIFICATION OF TABLETS:

(A). Tablets consumed orally

(B). Tablets used through buccal cavity

(C). Tablets used in the preparation of solutions

(D). Tablets administered through another route

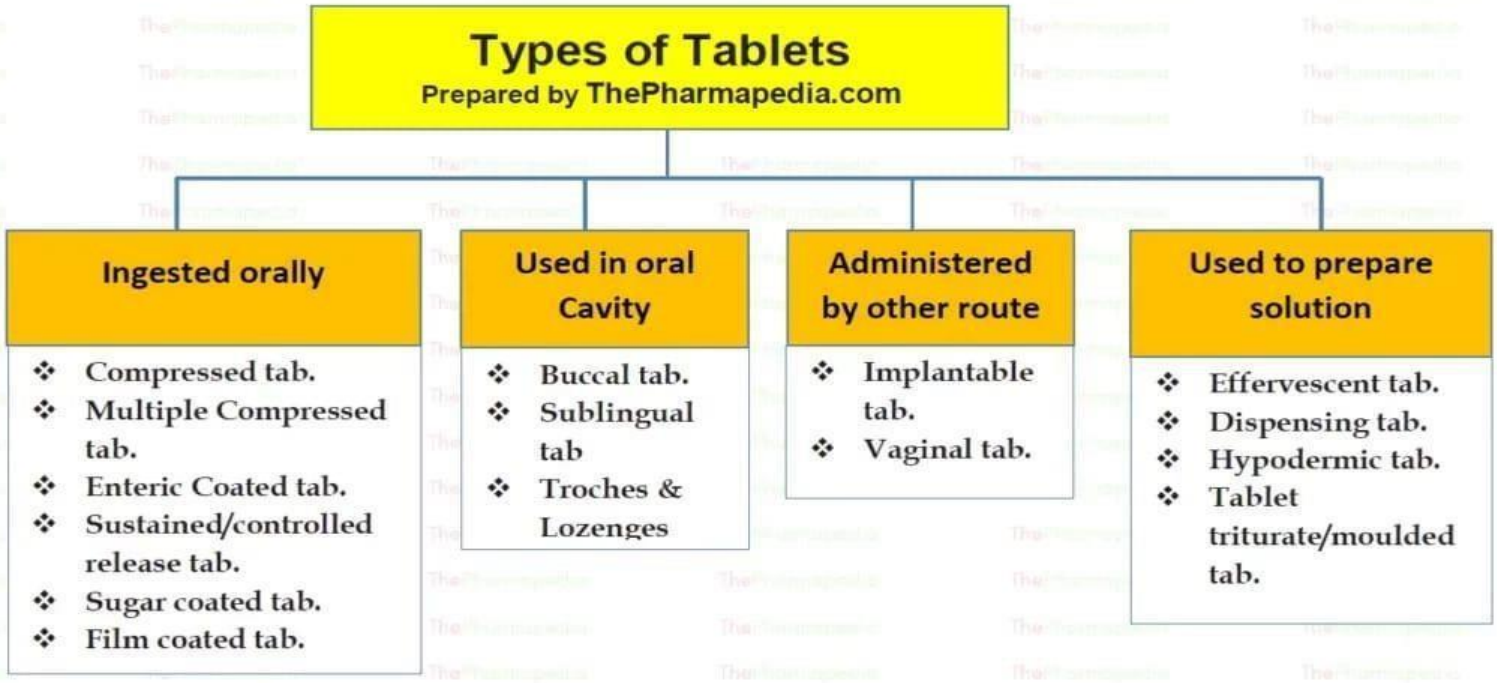


Fig.1. Classification of tablets

THE FORMULATION OF TABLETS INVOLVES THE USE OF VARIOUS EXCIPIENTS:

An excipients are also called as pharmaceutical aids, which are pharmacologically inactive ingredients mixed with API (active pharmaceutical ingredients) to formulate the medicines. Following excipients are used:

1. Diluents
2. Binders
3. Lubricants
4. Glidants
5. Anti- adherants
6. Disintegrants
7. Colouring agents
8. Flavouring agents
9. Sweetening agents
10. Absorbents

| Functional role | Examples | Description and functionality |
|---|---|---|
| Filler | • Microcrystalline cellulose (MCC)<br>• Lactose monohydrate or anhydrous<br>• Mannitol<br>• Sorbitol | • Add bulk to the dosage form<br>• May contribute to dissolution and disintegration characteristics |
| Binder | • Polyvinylpyrrolidone (PVP)<br>• Hydroxypropyl cellulose (HPC)<br>• Starch | • Bind the powder ingredients to form granules for processing |
| Disintegrant | • Croscarmellose sodium (CCS)<br>• Crospovidone (xPVP)<br>• Sodium starch glycolate (SSG)<br>• Starch | • Disintegration of the tablet to granules and powders on coming in contact with water |
| Glidant | • Colloidal silicon dioxide | • Aid the flow of granules/blend |
| Lubricant | • Magnesium stearate<br>• Stearic acid<br>• Sodium stearyl fumarate | • Aid the flow of granules/blend and ejection of tablets in the tablet press |
| Coating material | • Polymers such as hydroxypropyl methyl cellulose (HPMC), ethyl cellulose (EC), polyvinyl alcohol (PVA)<br>• plasticizer (e.g., polyethylene glycol)<br>• opacifier (e.g., titanium dioxide)<br>• glidant (e.g., talc)<br>• colorant (e.g., iron oxide red and/or yellow) | • Provide a physical barrier coating on the surface of the compressed core tablets |
| Coloring agent | • Iron oxide red and/or yellow<br>• FD&C Blue #6 | • Visual appeal of color |
| Stabilizer | • Antioxidants such as ascorbic acid, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), α-tocopherol | • Stabilization of the drug in the dosage form from stresses such as oxidation |
| Sweetener | • Aspartame, saccharin sodium, sucralose, acesulfame potassium | • Sweetening to overcome drug taste and/or improve palatability for some types of tablets |
| Flavoring agent | • Proprietary flavors (orange, pineapple, etc.) | • Flavoring to overcome drug taste and/or improve palatability for some types of tablets |

Fig.2. Excipients used in tablet formulation

**Diluent:** Diluents are fillers utilized to enhance tablet bulk, improve cohesion, facilitate direct compression manufacturing, or promote flow when drug dosage is insufficient.

It should contains following characteristics:

1. Diluents do not cause any toxic effect.
2. They should be readily available in an bearable grade.
3. Inexpensive.
4. They should be physiologically unreactive.
5. They should have physical and chemical stability and can be combined with the drugs.

6. They should not causes any type of impurities.

7. They should not vary the bioavailability of drug.

8. They should have appropriate compatibility with container.

**2. Binders:** To enhance cohesive compacts, binders which are mostly derived from natural sources, such as starch or cellulose derivatives is added during wet granulation or when tablets compressed directly.

**3. Glidants:** Glidants are designed to facilitate the movement of granules or powder material by reducing the friction between particles.

**4. Anti–adherents:** Tablet formulations are supplemented with anti-adherents to prevent the substance from adhering to the tablet press walls.

**5. Disintegrates:** The substance was incorporated into a tablet formulation to facilitate its dissolution in the GIT when it comes into contact with water.

**6. Coloring Agents:** A coloring agent sometimes referred to as a colorant, is a substance used to colors the tablets. It serves three functions: The process involves concealing off color medications, identifying the product, and creating a more sophisticated product.

**7. Flavoring Agents:** These are used to mask the unpleasant taste of the formulations. Chewable tablets and mouth- dissolving tablets are ideal for this purpose, and flavor oils can be added to granules at a concentration of 0.5 to 0.75%.

**8. Absorbents:** Tablet formulations with water-adherent materials require absorbents, while hygroscopic materials make the blend wet and challenging to work with during production.

**9. Lubricants:** This additive main aim to reduce the friction between the tablet's wall and the die cavity wall during tablet ejection.

**PREPARATION TECHNIQUE:**

For the preparation of tablets, there are following methods are used:

1) Compression by direct

2) The wet granulation technique

3) The dry granulation technique

## 1) Compression by direct:

Direct compression is an efficient and cost-effective tablet manufacturing technique, but most active ingredients cannot be compressed directly, necessitating blended ingredients.

Direct compression material should possess following characteristics:

- It should have good flow property and compressibility.
- It should be inexpensive.
- It should have ability to disintegrate.
- It must be tasteless and inert.

## 2) The wet Granulation technique:

The most popular tablet granulation technique involves weighing ingredients, mixing, granulation, damp pass screening, drying, lubrication, and tablet compression. It involves sifting the mixture, adding binding agent solutions, and drying the granules. The process is facilitated by tray drying, with fluid bed dryers being a newer option. After drying, granules pass through a screen, and lubricant is supplied as a fine powder for proper filling.

## 3) The dry Granulation technique:

Tablet preparation involves slugging for moisture-sensitive ingredients, which is eliminated by dry granulation or double compression. The remaining lubricant is added, mixed, and compressed to create tablets after passing through a mesh or mill.

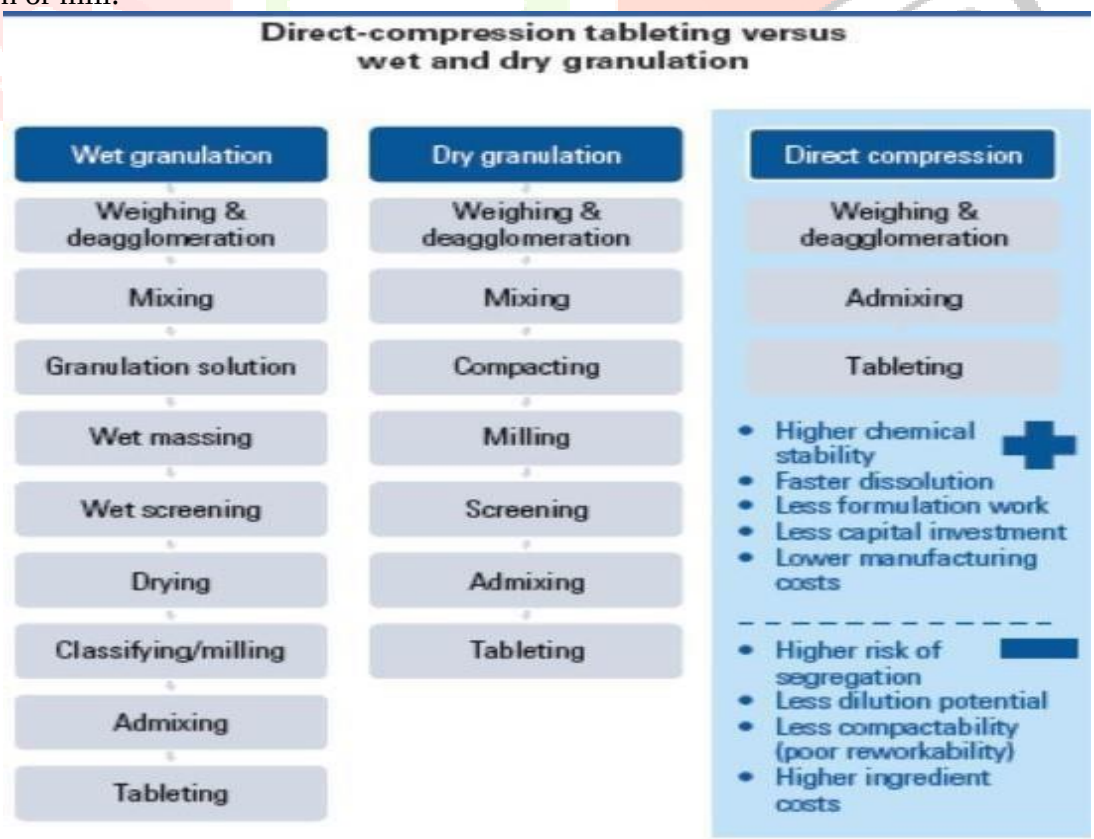


Fig.3. The method involves Direct compression, wet and dry granulation method

## EVALUATION PARAMETERS OF TABLETS:

**1. General Appearance:** The most important factor in tablet acceptance is appearance. Consumer Acceptance is greatly influenced by overall elegance and identify. Characteristics like size, shape, color, odor, taste etc. measured.

**2. Dimensions:** They are controllable and dimensionally described. The only variable is the tablet thickness. A micrometer or another tool can be used to measure the thickness of tablets. The thickness of tablets should be kept within a standard deviation of ± 5%.

**3. Unique identification marking:** These can be used for printing, engraving or embossing. These could be any other symbol associated with the dosage form or the company's identification marks.

**4. Organoleptic properties:** An odor in tablets can indicate stability issues, drug features, additional ingredients, or dosage form, while vitamins and flavoring agents have distinct smells

**5. Hardness:** The force needed to shatter a tablet under diametric compression is known as tablet hardness. The test measures the load needed to crush a tablet, determining the need for pressure adjustments on the tableting machine. Hardness affects disintegration, with too hard tablets causing issues during processing, and too soft ones rejecting the batch.

Fig.4. Lab junction hardness tester


Fig.5.Manual hardness tester

**6. Friability:** In a research center the friability of a tablet is determined by using the roche friabilator. It involves a plastic chamber spinning at 25 rpm, dropping tablets through 6 crawls for 100 upsets. After that we should have to determine the weight difference before and after processing. Tablet loss less than 0.5-1.0% of their weight is acceptable.

Fig.6. Digital Friabilator

**Weight Variation test:** The test involves randomly selecting 20 tablets to determine their average weight and compare to average. If no more than 2 tablets weight exceed from the percentage limit, the tablet passes the test.

**7. Content Uniformity test:** This assay method determines the active ingredient content by calculating the amount in tablets and dividing by the number of tablets taken, ensuring the result aligns with the monograph's range. Choose 30 tablets at random. 10 of these were tested separately. If a tablets have 75% or 85% of the drug content, then the test was pass out, if not then test was failed.

**8. Disintegration Test:** The study involved tablet disintegration and a pharmacopoeial assay using a USP disintegration device and a 6 Paddle Apparatus. The tablets were immersed in simulated gastric fluid (0.1N HCI) and diluted with fresh medium. The absorbances of the filtered samples were determined using a UV Spectroscope at a maximum wavelength of 222 nm. The process involved shaking the contents, adding water, filtering, and adding more NaOH .


Fig.7. Disintegration tester

**The Dissolution test involves the use of two set of apparatus:**

**Apparatus-1:** A wire mesh basket, connected to a motor, houses the adjusting lever in a 100ml dissolving medium flask. The flask is kept in a steady temperature bath at 37±0.50C, and a fluid sample is taken periodically.

**Apparatus-2:** The U.S.P. for a dissolution test uses a paddle instead of a basket, with the dosage form sinking to the bottom of the flask. The test tolerance is expressed as the percentage of dissolved drug.


Fig.8.Dissolution tester

## CONCLUSION:

Tablet pharmaceutical research relies heavily on manufacturing and evaluation of tablets, which have undergone significant changes in recent decades. Advancements in evaluation techniques have been economical and time saving, enhancing researchers scope and ensuring tablets continued relevance in the evolving drug world. Tablet formulation aims to create a simple, cost- effective delivery system provide convenient dosage forms and avoid complexity during regulatory approval processes.

## REFERENCES:


1. The theory and practice of Industrial Pharmacy, Leon Lachmann, Herbert A. Lieberman, Joseph L. Kanig. Pg. 293-303, Fourth edition.
2. Lachmanetal.,1990;Herbertetal.,2006;Kaur,2012;Hymavathietal., 2012.
3. Tejaswietal.,2020;Sharmaetal.,2011.
4. LeonLachman,Herbert A.Lieberman, JosephL.Kanig: The theory and Practice of Industrial Pharmacy, Varghese publication house, 3rd edition, 1990, 293-373.
5. HerbertA.Liberman,MartinM.RiegerandGilbertS.Banker,pharmaceuticaldosageforms:Tablets; volume-I.
6. Al-AchiA(2019)Tablets:ABriefOverview.JournalofPharmPracticeandPharmaceuticalScience. 2019(1): 49-52.
7. NagashreeK.Soliddosageforms:Tablets.ResearchandReviews:JournalofPharmaceuticalAnalysis. 2015.
8. IndianPharmacopoeia,2010.
9. Wang D, Miller R, Zheng J. Comparative population pharmacokinetic-pharmacodynamic analysis for piroxicam–betacyclodextrin and piroxicam. J Clini Pharmaco 2000 ;( 11):1257–1266.
10. Sharma P, Hamsa V. Formulation and evaluation of buccal mucoadhesive patches of Terbutaline Sulfate, STP Pharma Sci 2001; 11: 275-281.
11. Agyilirah GA, Green M, Ducret R. Evaluation of the gastric retention properties of a cross linked polymer coatedtabletversusthoseofanon-disintegratingtablets.Int JPharma1991;75:241-247.
12. Hoffman F, Pressman JH, Code CF. Controlled entry of orally administered drugs, physiological considerations. Drug Dev Ind Pharma 1983; 9:1077-1085
13. IchikawaM,WatemblcS,MiyakeVA.MultipleunitoralfloatingdosagesystemsI:Preparationandin-vivo evaluation of'floatingand sustained release characteristics. J Pharma Sci 1991; 80:l062-1066.
14. Gupta A, GargS, KharRK.Measurementof BioadhesiveStrength ofMucoadhesiveBuccalTablet:De-sign of an In Vitro Assembly. Ind Drugs 1992; 30: 152-154.
15. Bhagwati ST, Hiremath SN. Comparative evaluation of disintegrants by formulating cefixime dispersible tablets, Ind J Phar Edu Res 2005; 39: 194-197.
16. Valenta C, Kast CE, Harich I, Bernkop-Schnurch A. Development and In Vitro Evaluation of a Mucoadhesive Vaginal Delivery System for Progesterone. J Cont Release 2001, 77: 323-332.
17. Yong CS, Jung JH, Rhee JD, Kim CK, Choi HG. Physiological Characterization and Evaluation of Buccal Adhesive Tablets Containing Omeprazole. Drug Dev Ind Pharm 2001, 27: 447-445.
18. Aburahma MH, El-Laithy HM, Hamza YE. Preparation and in vitro/in vivo Characterization of porous sublingualtabletscontainingternarykneadedsolidsystemofVinpocetinewithβ-Cyclodextrinandhydroxy acid. Sci Pharma 2010; 78: 363-379.
19. Kathiresan K, Vijin P, Moorthi C, Manavalan R. Formulation and Evaluation of loratadine Chewabletablets. Res J Pharm Bio Chem Sci 2010; 2: 763-774.
20. Yam KL, Encyclopedia of technology, third edition, A john wiley and sons, 2009; 341-345.