



# AN USE OF NATURAL DISINTEGRATING AGENT THAT ENHANCE THE DISINTEGRATION OF IR TABLET

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**Abstract :** The present review article consisting the enhancement of disintegration time of immediate release tablet by use of natural excipients who acts as a disintegrants. The IR tablet which has already less Dt and by use of this natural excipients we can increase its Dt. It is done for getting a better relief from disease and less time consume so the patient will feel better. The less Dt can be measured by dissolution test, weight variation test, disintegration test, content uniformity, hardness parameters. And finally, prepared IR tablet including natural disintegrating agent compared with standard tablet.

**IndexTerms -** Tablets,Types, Natural Disintegrants, Dt.

## INTRODUCTION

Tablets are solid pharmaceutical dosage forms formed by compression or molding that may include one or more drugs, excipients, or both. [1]

Types of tablets:

- (A) Tablets ingested orally:
1. Compressed tablet (e.g. Paracetamol tablet)
  2. Multiple compressed tablet
  3. Repeat action tablet
  4. Delayed release tablet (e.g. Enteric coated Bisacodyl tablet)
  5. Sugar coated tablet (e.g. Multivitamin tablet)
  6. Film coated tablet (e.g. Metronidazole tablet)
  7. Chewable tablet (e.g. Antacid tablet)
- (B) Tablets used in oral cavity:
1. Buccal tablet, e.g. Vitamin - c tablet
  2. Sublingual tablet, e.g. Vicks Menthol tablet
  3. Troches or lozenges
  4. Dental cone
- (C) Tablets administered by another route:
1. Implantation tablet
  2. Vaginal tablet e.g. Clotrimazole tablet
- (D) Tablets used to prepare solution:
1. Effervescent tablet e.g. Dispirin tablet (Aspirin)
  2. Dispensing tablet e.g. Enzyme tablet (Digiplex)
  3. Hypodermic tablet
  4. Tablet triturates e.g. Enzyme tablet (Digiplex) [2]

**Preparation method direct compression:**

Direct compression refers to the process of creating tablets by compressing powder blends of active ingredients and appropriate excipients directly, ensuring that they flow uniformly in the die cavity to form a solid tablet. [3, 4]

Wet granulation:

The method consists of several steps including weighing ingredients, mixing, granulation, screening of damp material, drying, lubrication, and tablet compression. The main active ingredient, diluent, and disintegrant are blended and sifted. Binding agent solutions are added to the mixture while stirring, ensuring that the amount is enough to prevent over-wetting of the tablets.

**Dry granulation:**

This method is used for tablet preparation, in case tablet ingredients are highly sensitive to moisture, or unable to withstand elevated temperatures during drying, slugging may be used to form the granules. Dry granulation double compression, usually eliminates various steps, which involves slugging of the powder mass. The active ingredient, diluent and lubricant are blended together, to form the slug. Thus, the compressed slug is passed through the mesh or through the mill, and the remaining lubricant is added to the granulation, blended properly and compressed to form the tablets [5-8]

**IMMEDIATE RELEASE TABLET:**

Immediate release tablets are designed to quickly disintegrate and release their medication without any special rate-controlling features. Their effectiveness is influenced by factors such as disintegration, dissolution, and physiological characteristics. These dosage forms benefit manufacturers by allowing market diversification while providing patients with a convenient option for medication. [9-11]

Essential requirements for immediate release tablet [12] MUCILAGE:

Mucilage is a gelatinous substance found in various plants, consisting of proteins and polysaccharides. It is a long-chain polysaccharide that forms a thick, gluey material

when extracted from nearly all plants and some microorganisms. Mucilage occurs in different plant parts, including epidermic cells of leaves, seed coats, roots, barks, and middle lamella. [13]

Importance of Mucilage in disintegration:

The complex structure of hydrophilic substances allows them to trap water, causing them to swell and form a gel when mixed with water, like mucilage does. [14]

Advantages:

- Biodegradable polymers, primarily carbohydrates made of repeated sugar units, are produced by living organisms and are biocompatible and non-toxic.
- Natural sources are generally cheaper than synthetic ones.
- Mucilage, which can be easily harvested in large quantities from various sources, is beneficial due to environmentally friendly processing. In developing nations, governments promote the cultivation of plants like guar gum and tragacanth
- Natural products also enhance patient tolerance and public acceptance, as they typically pose a lower risk of side effects compared to synthetic alternatives. Most mucilages are derived from food sources.

Disadvantages:

- Microbial contamination can occur in mucilage due to its high moisture content, typically around 10 percent, and its exposure to the environment during development. This issue can be mitigated through careful treatment and preservatives. Additionally, while gums and mucilages often exhibit increased viscosity when in contact with water, storage can lead to a reduction in viscosity due to changes in the composition of the mucilage from monosaccharides to polysaccharides and their derivatives. [15, 16]

**MATERIAL AND METHOD:**

**Material:**

- Diluent: Diluents are fillers that increase the volume of a tablet when the drug dosage alone is insufficient to achieve the desired bulk. e.g. cellulose, dextrin
- Binders: Binders are used to create cohesive compacts for directly compressed tablets. e.g. acacia, gelatine
- lubricants: Lubricants help prevent the adhesion of tablet materials to dies and punches, decrease interparticle friction, and may enhance the flow rate of granulation calcium stearate, sodium lauryl sulphate.
- glidants: Glidants are designed to improve the flow of granules or powder by minimizing friction between particles. e.g. magnesium trisilicate
- Disintegrants: Disintegrants are added to tablets to ensure they break down in water within the gastrointestinal tract sodium starch glycolate.
- colouring agent: Colouring agents serve three main purposes: to mask undesired colours in drugs, aid in product identification, and enhance the product's visual appeal e.g. D&C dyes or lake pigment
- flavouring agent: Flavouring agents, particularly in dry forms like spray-dried beads, are used in chewable tablets to improve taste menthol, vanillin
- Adsorbent: Absorbents are included in tablet formulations when substances with high water affinity are present, as hygroscopic materials can cause the mixture to become wet and hard to manage during production. E.g. Kaolin. [17-20]

**Isolation of mucilage:**

Fresh hibiscus leaves were collected, washed to remove dirt, powdered, soaked in water for 5-6 hours, boiled for 30 minutes, and then left to stand for 1 hour to fully release mucilage into the water. The mucilage was extracted using a multi-layer muslin cloth bag to filter out the marc from the solution. Acetone, three times the volume of the filtrate, was added to precipitate the mucilage, which was then separated and dried in an oven. [21]

**EVALUATION TEST:**

- **General appearance:** The overall appearance of a tablet, including its identity and elegance, is crucial for consumer acceptance and ensuring uniformity across different lots and individual tablets. Controlling appearance involves measuring factors such as size, shape, colour, and the presence or absence of odour and taste.
- **Size & shape:** It is controllable and dimensionally characterized. A tablet's thickness is merely one of several factors. A micrometer or another equipment can be used to measure the thickness of a tablet. Tablet thickness should be kept within a specified value fluctuation of  $\pm 5\%$
- **Organo-oleptic properties:** There must be no mottling and a uniform dispersion of color. To visually compare colors, compare the sample's color to the standard color.
- **Hardness :** Tablets need to be strong enough to endure mechanical shaking during manufacturing, packing, and delivery, as well as resistant to friability. Generally speaking, hardness gauges the tablet crushing strength.
- **Friability:** A Roche friabilator can be used in a lab to test a tablet's friability. This is made up of a plastic chamber that rotates at 25 rpm and drops the tablets into the friabilator six inches away. The friabilator then runs for 100 revolutions. We weigh the tablets once more. Tablets that compress and lose less than 0.5% to 1.0% of their original weight are deemed acceptable.
- **Dissolution test: -**

Apparatus - 1: A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor. The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100 ml flask. The flask is cylindrical with a hemispherical bottom. The flask is maintained at  $37 \pm 0.50^\circ\text{C}$  by a constant temperature bath. The motor is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Apparatus - 2: It is same as apparatus - 1, except the basket is replaced by a paddle. The dosage form is allowed to sink to the bottom of the flask before stirring. For dissolution test U.S.P. specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft, time limit of the test and assay procedure for the test.

- **Disintegration test:**

The USP device for testing disintegration consists of six glass tubes, each 3 inches long, open at the top and fitted with a 10-mesh screen at the bottom. To measure disintegration time, one tablet is placed in each tube, which is then situated in a 1-liter beaker filled with water or simulated gastric or intestinal fluid at a temperature of  $37 \pm 2$  degrees Celsius. The tablets must remain 25 cm below the liquid surface during upward movement and not closer than 25 cm from the bottom during downward movement. The basket with the tablets is moved up and down by 5-6 cm at a frequency of 28 to 32 cycles per minute. To prevent the tablets from floating, perforated plastic discs can be used. The tablets must disintegrate and all particles should pass through the 10-mesh screen within the specified time. Any remaining residue should form a soft mass. The disintegration time for uncoated tablets is 5-30 minutes.

- **Weight variation test:** Weigh 20 tablets individually to calculate the average weight. The tablets pass the USP test if no more than 2 tablets exceed the percentage limit and if no tablet varies by more than twice the percentage limit.
- **Content uniformity test:** Select 30 tablets at random and assay 10 individually. The test is passed if 9 of the 10 tablets contain between 85% and 115% of the labelled drug content, while the 10th tablet may range from 75% to 125%. If these conditions are not satisfied, there 20 tablets are assayed individually, and all must fall within the 85% to 115% range. [22-28]

**RESULT AND CONCLUSION:**

from above study it is concluded that immediate Release tablet having all ready less disintegration time we can reduce Disintegration time more by use of natural disintegrant with Combination of API and other synthetic excipients.

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**REFERENCE:**

- 1 The theory and practice of Industrial Pharmacy, Leon Lachmann, Herbert A.Lieberman, Joseph L. Kanig. Pg. 293-303, Fourth edition.
- 2 Shanu B. Sahu, Harsha R. Shende, Karishma D. Kamde International Journal of Novel Research and Development page no. a440 to a441
- 3 European Pharmacopoeia, 2004; 1: 628.
- 4 L.v.Allen, B.Wang, J.D.Devices,"Rapidly dissolving tablets" US patent No. 2000; 60066, 337.

5 Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig: The theory and Practice of Industrial Pharmacy, Varghese publication house, 3rd edition, 1990, 293-373.

6 Herbert A. Liberman, Martin M. Rieger and Gilbert S. Banker, pharmaceutical dosage forms: Tablets; volume-I

7 Al-Achi A (2019) Tablets: A Brief Overview. Journal of Pharm Practice and Pharmaceutical Science. 2019(1): 49-52

8 Nagashree K. Solid dosage forms: Tablets. Research and Reviews: Journal of Pharmaceutical Analysis.2015

9 Jadhav SB, Mali AD, Rajeghadage SH and Bathe ARS: Formulation and evaluation of immediate release tablets of Imipramine hydrochloride. International Journal of Biomedical and Advance Research 2014; 5(11): 559-65

10 Patel N, Natarajan R and Rajendran NN: Formulation and evaluation of immediate release bilayer tablets of Telmisartan and Hydrochlorothiazide. International Journal of Pharmaceutical Sciences and Nanotechnology2011; 4(3): 1477-82

11 Verma K, Sharma PK, Dudhe R and Patro ASK:Formulation, design and development of Mifepristone immediate release tablet. International Journal of Pharma Sciences and Research 2014; 5(11): 760-69.

12 <https://images.app.goo.gl/NczVqjt7ptWabdaP8>

13 Rangari VD, Pharmacognosy and Phytochemistry, 1st edition, carrier publication, Nashik. 204,(2002)

14 <https://www.sciencedirect.com/topics/agriculturalandbiologicalsciences/mucilage#:~:text=Mucilages,%E2%80%A2&text=These%20are%20highly%20branched%20structures%20composed%20of%20different%20sugars%20and%20acids.&text=They%20are%20hydrophilic%20and%20their,swells%20when%20mixed%20with%20water>

15 Edward MR: Modern Pharmaceutics. Marcel Dekker, New York, 2002: 287- 298.

16 Aslam A and Parrott E: Effect of aging on some physical properties of hydrochlorthiazide tablets. Journal of Pharmaceutical Science 1971; 60: 263-266

17 Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig: The theory and Practice of Industrial Pharmacy, Varghese publication house, 3rd edition, 1990, 293-373.

18 Herbert A. Liberman, Martin M. Rieger and Gilbert S. Banker, pharmaceutical dosage forms: Tablets; volume-I.

19 Al-Achi A (2019) Tablets: A Brief Overview. Journal of Pharm Practice and Pharmaceutical Science. 2019(1): 49-52

20 Nagashree K. Solid dosage forms: Tablets. Research and Reviews: Journal of Pharmaceutical Analysis.2015.

21 Swati S, Neeharika V and Lakshmi PK. Formulation And evaluation of fast dissolving tablets of freely and Poorly soluble drugs with natural and synthetic Superdisintegrants. Drug invention today, 2011; 3(10): 250-256.

22 Indian Pharmacopoeia, 2010

23 Wang D, Miller R, Zheng J. Comparative population pharmacokineticpharmacodynamic analysis for piroxicam–betacyclodextrin and piroxicam. J Clini Pharmaco 2000 ;( 11):1257–1266.

24 Sharma P, Hamsa V. Formulation and evaluation of buccal mucoadhesive patches of Terbutaline Sulfate, STP Pharma Sci 2001; 11: 275-281

25 Agyilirah GA, Green M, Ducret R. Evaluation of the gastric retention properties of a cross linked polymer coated tablet versus those of a nondisintegrating tablets. Int J Pharma 1991; 75: 241-247.

26 Hoffman F, Pressman JH, Code CF. Controlled entry of orally administered drugs, physiological

Considerations. *Drug Dev Ind Pharma* 1983; 9:1077-1085

- 27 Ichikawa M, Watembla S, Miyake VA. Multiple unit oral floating dosage systems I: Preparation and in-vivo Evaluation of floating and sustained release characteristics. *J Pharma Sci* 1991; 80: 1062-1066.
- 28 Gupta A, Garg S, Khar RK. Measurement of Bioadhesive Strength of Mucoadhesive Buccal Tablet: Design Of an In Vitro Assembly. *Ind Drugs* 1992; 30: 152-154.
- 29 Bhagwati ST, Hiremath SN. Comparative evaluation of disintegrants by formulating cefixime dispersible Tablets, *Ind J Phar Edu Res* 2005; 39: 194-197.
- 30 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
- 31 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.
- 32 Aburahma MH, El-Laithy HM, Hamza YE. Preparation and in vitro/in vivo Characterization of porous Sublingual tablets containing ternary kneaded solid system of Vinpocetine with  $\beta$ - Cyclodextrin and hydroxy Acid. *Sci Pharma* 2010; 78: 363-379
- 33 Kathiresan K, Vijin P, Moorthi C, Manavalan R. Formulation and Evaluation of loratadine Chewable Tablets. *Res J Pharm Bio Chem Sci* 2010; 2: 763-774.
- 34 Jagdale S, Gattani M, Bhavsar D, Kuchekar B, Chabukswar A. Formulation and Evaluation of Chewable Tablets of Levamisole. *Int J Res Pharma Sci* 2010; 1: 282-289.
- 35 Mullarney MP, Hancock BC, Carlson GT, Ladipo DD, Langdon BA. The powder flow and compact Mechanical properties of sucrose and three highintensity sweeteners used in chewable tablets. *Int J Pharma* 2003; 257: 227-236.
- 36 Al-Suwayeh SA, Al-Omran MF, Saleh SI. Bioavailability Assessment of Diclofenac sodium chewable Tablets. *Saudi Pharma J* 2003; 11: 32-36
- 37 Parrot EL. Student experiments in pharmaceutical technology II. FlowabilityOf powders. *Amer J Pharm Educ* 1996; 30: 205
- 38 Carr RL. Evaluating flow properties of powder. *Chem Eng* 1965; 72: 163-168.

