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Study of the Effect of Natural Superdisintegrant on the Disintegration Time of Aspirin Tablets

	
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ABSTRACT

The basic concept is to incorporate natural super disintegrant which helps tablet to break down quickly. The faster the tablet disintegrates, the faster is therapeutic action is achieved and initiated. These tablets were prepared in such way that the time taken by active pharmaceutical ingredient to disintegrate is less as compared to other tablets. The aspirin tablets were prepared using banana powder as natural super disintegrant. Different concentration of super disintegrant were used in this formulation as 2.5%, 5%, 7.5%, 10%, 12.5%. The tablets were evaluated for weight variation, hardness, dissolution and disintegration time. The dissolution and disintegration time of the tablets formulated was determined. Given study shows that for first three formulations, there is a reduction in disintegration time and shows reverse effect for next two formulations.



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1 Introduction

Oral routes of drug administration have wide acceptance, up to 50–60% of total dosage forms. Solid dosage forms are popular for a variety of reasons, including:

- Ease of administration.
- Good chemical and microbiological stability.
- The lowest cost among all solid dosage forms.
- Self-medication.
- Patient compliance.
- Accurate dosage.

The most popular solid dosage forms are tablets and capsules. One important drawback of these dosage forms for some patients is the difficulty of swallowing. These conventional tablets are intended to be swallowed whole and desired to disintegrate, releasing the medicaments for dissolution and providing therapeutic efficacy rapidly in the gastrointestinal tract. As disintegration plays an important role in the development of solid orals, formulators give special emphasis to the selection of disintegrants and super disintegrants in the dosage system. Disintegrants are substances or mixtures of substances added to the drug formulations that facilitate the dispersion or breakup of tablets into smaller particles for quick dissolution.

1.1 Superdisintegrant:

The term "super-disintegrants" refers to substances which achieve disintegration faster than the substances conventionally used. A tablet or capsule's content breaks up or disintegrates into a smaller particle that dissolves more rapidly than in the absence of such disintegrants. Super-disintegrants are granules used at a low level in the solid dosage form, typically from 1 to 10% of the total weight of a given unit dosage form.

1.2 Selection of Superdisintegrants:

Many factors are considered in the selection of superdisintegrants.

- Percentage of disintegrant present in the formulation.

- Compatibility with other excipients.
- Hardness of tablet.
- Nature of drug substance.
- Mixing and types of addition.
- Inert
- Non –toxic
- Good flow properties
- Requirement of the least quantity
- Good mouth feel

1.3 Dehydrated banana powder (plantain):

Bananas are a highly nutritious fruit and have many medicinal properties beyond their nutritive value. Banana powder is mainly comprised of polysaccharides, ascorbic acid amines, citric acid, etc. The dehydrated banana powder (DBP) is made from bananas, specifically, from the variety called Ethan or Nenthran, which belongs to the family Musaceae. It is a natural and widely used nutritional supplement because it contains multiple essential nutrients, including minerals and vitamins. Fully ripened banana pulp contains 33.6% reducing sugar, 53.2% sugar, 5.52% proteins, 0.68% fats, 0.3% fibres, 2.6% starch, and 4.09% ash. The tablets were evaluated for the precompression parameters such as bulk density, compressibility, angle of repose, etc. and post-compression parameters like hardness, weight variation, friability, disintegration time.



Fig.No.01: Banana Powder

1.4 Aspirin:

Aspirin is also called acetylsalicylic acid, in the class of non-steroidal anti-inflammatory drug (NSAID). It is the first drug in the class of NSAID's. Aspirin contains salicylate which is found in plants of willow tree and myrtle around 4000 years ago. Hippocrates used willow bark for relieving pain and fever.

1.5 Chemical and physical properties of Aspirin:

- Acetyl salicylic acid is a white crystalline solid.
- Acetyl salicylic acid is a weakly acidic substance.
- The maximum stability of aspirin at pH 2-3.
- Aspirin is odorless and has a bitter taste.
- The acetyl salicylic acid is stable in dry air but in contact with moist air, it gets hydrolyzed.

2 Literature Survey

2.1 Arun Raj.R (International Journal of Pharmacy and Pharmaceutical Sciences, Vol 5, Issue 2 ,204-207. 2013): The study showed that banana powder and potato starch have a better disintegrant property than microcrystalline cellulose. It was concluded that banana powder and potato starch were having excellent superdisintegrant property which can be used as natural disintegrant in the tablet formulation.

2.2 M. Jhansi Saranya, E. Suma Devi, BSV. Naresh, CHS. Phani Kumar and and KN. Vidyadhar (International Journal Of Pharmaceutical, Chemical And Biological Sciences 2017, 7(3), 247-252): The banana has great starch content in it, and has good disintegrating ability. Hence, the dried unripe banana powder was chosen to prepare the fast dissolving tablets. Thus, we are able to achieve our objective of preparing fast dissolving tablets of Paracetamol with natural excipients.

2.3 Sujatha Kumari M, Rajesh Kaza, Kishore Babu M, Bhavya P, Nagalakshmi BH, Jyoti T, ArshiyaTahaseen SK (International Journal of Pharmacy and Pharmaceutical Research, December 2019, Vol. 17 (1): 187-210.): In this review article, more emphasis is given on the application and usage of various natural super disintegrants comparing with other disintegrants about available scientific studies. Superdisintegrants are generally used at a low level in the solid dosage form, typically 1-10 % by weight relative to the total weight of the dosage unit.

2.4 Lavika Gandhi and Md. Semimul Akhtar (Journal of Drug Delivery and Therapeutics. 2019; 9(2):507-

513): The comparative studies concluded that the use of Natural Superdisintegrant is more advantageous over the synthetic superdisintegrants in the formulation of Orodispersible Tablets.

2.5 Prashant L Pingale, Sahebrao S Boraste, Sunil V Amrutkar (Journal of medical pharmaceutical and allied sciences, Volume 10 - Issue 3, May-June 2021, Page-2977-2981): After considering the assessment parameters of dissolution study, disintegration time, and wetting time, an excellent batch of fast disintegrating tablets was selected. Batch FB3 of fast disintegrating tablets (containing 12 mg, or 6%, of dehydrated banana powder) were chosen as the best batch because of drug release using dissolution study, disintegration time, and wetting time.

2.6 M. Vinod Kumar (International Journal of Pharma Sciences and Scientific Research, Volume 2 Issue 1, 09-30. April 2016): Both superdisintegrants chosen in the present work were natural hence all the formulations showed better and satisfactory drug release profile. The prepared tablets passed all the quality control evaluation parameters as per IP limits.

2.7 Indian Pharmacopoeia: We have collected the information of Aspirin, from Indian Pharmacopoeia 2014, Volume II, published by Indian Pharmacopoeia Commission Ghaziabad.

2.8 Dr Ashok A Hajare, Sandeep M Honmane: We have collected references about evaluation of tablets from Practical book of Industrial Pharmacy-I, published by Nirali Prakashan.

3 Objective

3.1 To choose the natural super disintegrant and drug for the formulation.

3.2 To formulate combination of natural superdisintegrant and tablet.

3.3 To study the effect of different concentration of natural superdisintegrant.

3.4 To study the evaluation parameters, (Preformulation parameters, hardness, thickness, weight uniformity, disintegration time, dissolution, assay etc.)

4 Plan of Work

4.1 Literature survey.

4.2 Selection of suitable drugs and excipients.

4.3 Selection of suitable superdisintegrant.

4.4 To study pre-formulation parameters of banana powder.

4.5 Preparation of aspirin tablets using natural superdisintegrant.

4.6 Evaluation of tablets

4.6.1 Weight variation

4.6.2 Hardness

4.6.3 Thickness

4.6.4 Disintegration

4.6.5 Assay

4.6.6 Dissolution

4.6.7 Result and analysis.

4.6.8 Conclusion.

5 Experimental Design & Formula

Table No. 1: Formula For Preparation of Aspirin tablet

Ingredient mg/Tablet	Role	Formulation				
		F1(2.5%)	F2(5%)	F3(7.5%)	F4(10%)	F5(12.5%)
Aspirin	API	150mg	150mg	150mg	150mg	150mg
Citric Acid	Solubilizer	15mg	15mg	15mg	15mg	15mg
Calcium Carbonate	Solubilizer	50mg	50mg	50mg	50mg	50mg
10% PVP in alcohol	Binder	10%	10%	10%	10%	10%
Magnesium Stearate	Lubricant	1mg	1mg	1mg	1mg	1mg
Talc	Glidant	1mg	1mg	1mg	1mg	1mg
Banana Powder	Disintegrant	6mg	12mg	18mg	24mg	30mg

6 Methods And Material

6.1 Material

6.1.1 **Chemicals:** Aspirin, Citric acid, Calcium carbonate, 10%PVP in Alcohol, magnesium stearate, Talc, Banana powder.

6.1.2 **Apparatus:** Mortar and pestle, beaker, sieves, tablet punching Machine, hot air oven, Tablet disintegration test machine etc.

6.2 ASPIRIN

6.2.1 Structural Formula:

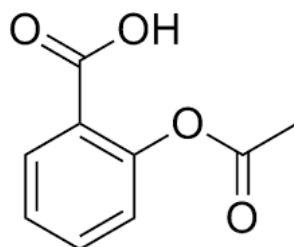


Fig. No. 2 Structure of Aspirin

6.2.2 **Molecular Formula:** C₉H₈O₄

6.2.3 **Molecular Weight:** 180.16

6.2.4 **Chemical Names:** 2-(Acetyloxy) benzoic acid; salicylic acid acetate.

6.2.5 **Description:** Aspirin, an acetyl derivative of salicylic acid, is a Sub crystalline, weakly acidic substance.

Colour: White

Odour: It is odorless but might have a faint odor of acetic Acid.

6.2.6 **Solubility:** Aspirin is slightly soluble in water, Aspirin is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide.

6.2.7 **Density:** 1.4g/cm³

6.2.8 **Melting point:** 136 °C (277 °F)

6.2.9 **Boiling point:** 140 °C (284 °F).

6.2.10 **Uses:** It works by stopping the production of certain natural substances that cause fever, pain, swelling, and blood clots.

6.3 CALCIUM CARBONATE

6.3.1 Structural formula:

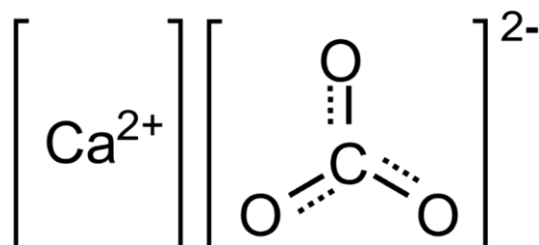


Fig. No. 3 Structure of Calcium carbonate

6.3.2 **Molecular formula:** CaCO_3

6.3.3 **Formula weight:** 100.09

6.3.4 **Chemical names:** Calcium carbonate, carbonic acid calcium salt

6.3.5 **Description:** **Odour:** Odourless

Color: white micro-crystalline powder

6.3.6 **Solubility:** Insoluble in water and ethanol

6.3.7 **Melting point:** 1,339 °C (2,442 °F; 1,612 K) (calcite)

825 °C (1,517 °F; 1,098 K) (aragonite)

6.3.8 **Density:** 2.711 g/cm³

6.3.9 **Boiling point:** decomposes at 899°C

6.3.10 **Uses:** 1.It uses as a dietary supplement when the quantity of calcium in the diet is less

2. It is used as an antacid to relieve stomach upset, heartburn.

6.4 Procedure:

6.4.1 Weigh and pass aspirin powder through a 60# sieve.

6.4.2 In a mortar and pestle, evenly combine the aspirin, citric acid, calcium carbonate, and banana powder.

6.4.3 Make a 10% PVP solution in ethanol and stir until clear.

6.4.4 Drop the PVP solution into the mortar to form a cohesive mass. quantity of PVP solution used for granulation.

6.4.5 Dry granules for 15 minutes at 50 °C.

6.4.6 Separate granules and fine particles with a 22/44 # sieve. Material on a 22 sieve is final granules and on a 44 sieve is fines. Record the weight of the final granules and fines.

6.4.7 Weigh the prepared granules and blend them with the remaining ingredients like magnesium stearate, talc, etc.

6.4.8 The required amounts of granules were weighed and compressed into tablets.

6.4.9 Perform evaluation tests as per project requirements.

6.4.10 Store the prepared tablet in a well-closed and labelled container.

7 Evaluation Test

7.1 Pre-compression Studies

7.1.1 Solubility Test

Solubility tests are tests performed to determine the ability of compounds to dissolve in a solvent, which is usually a liquid.

The solubility of the banana powder in water was determined and the results recorded.

7.1.2 Bulk Density

Bulk density is also called as apparent density or volumetric density is a property of powders granules or any other masses of corpuscular or particulate matter.

A 30g weight of each of the banana powders and to be used as carrier was weighted and poured into a 100ml measuring cylinder and the volume was recorded. The bulk density was then calculated.

$$\text{Bulk Density (BD)} = M / V$$

Where M is mass and V is volume.

7.1.3 Tapped Density

Tapped density is obtained by mechanically tapping a graduated measuring cylinder containing the powder.

A 30g weight of each of the banana powder was weighted and poured into a 100ml measuring cylinder and tapped on a hard surface 30 times from about 2cm height and the volume was recorded.

$$\text{Tapped Density (TD)} = M / V \text{ Where M is mass and V is volume.}$$

7.1.4 Carr's Index

The Carr index is also known as Carr's Compressibility Index. It is an indication of the compressibility of a powder. It is named after the scientist Ralph J. Carr, Jr.

Carr's Index (%) was determined using the following relationship Carr's Index = $(TD - BD / TD) \times 100$

Where TD is Tapped Density, BD is Bulk Density.

Flow Property	Carr's Index
Excellent	0-10
Good	11-15
Fair	16-20
Possible	21-25
Poor	26-31

7.1.5 Hausner's Ratio

The Hausner ratio is a number that is correlated to the flowability of a powder or granular material. It is named after the engineer Henry H. Hausner.

Hausner's ratio was determined using the following relationship Hausner's Ratio = TD / BD

Where TD is Tapped density, BD is Bulk density.

Flow Property	Hausner's Ratio
Excellent	1.00-1.11
Good	1.12-1.18
Fair	1.19-1.25
Possible	1.26-1.34
Poor	1.35-1.45

7.1.6 Angle of Repose

The angle of repose is defined as maximum angle possible between the pile of powder and its horizontal plane.

A 30 g sample was poured into a plugged glass funnel with the tip, 10 cm above the flat surface of the bench. The granules were allowed to flow freely through the orifice of the funnel to form a heap whose height and diameter were determined.

The angle of repose was calculated using the equation below: $\tan \theta = h/r$

Where h = height and r = radius of circular heap.

Flow Property	Angle of Repose ((°)
Excellent	25-30
Good	31-35
Fair-aid not needed	36-40
Passable may hang up	41-45
Poor must agitate, vibrate	46-55
Very poor	56-65
Very-very poor	>66

7.2 Evaluation Test For Aspirin Tablet

7.2.1 Hardness

Tablet hardness refers to the amount of force required to diametrically crush a tablet. It is representative of the tensile strength of a tablet and is determined by the cohesion characteristics of the powder blend. Tablet hardness impacts tablet disintegration, dissolution, and friability. If tablets are too hard, they may not disintegrate within a reasonable period. This can lead to reduced bioavailability and failure to meet the dissolution specification. If they are too soft, then they may not withstand the handling and shipping operations, leading to tablet breakage or chipping (breaking away from edges) and failure during friability testing. The tendency of tablets to chip or break due to tumbling motion is referred to as friability.

7.2.2 Thickness

The thickness of tablets was determined using Vernier Caliper (Indian Caliper Industries, Ambala, India).

7.2.3 Weight uniformity

Weight Variation Test (U.S.P.), Take 20 tablets and weigh them individually. Calculate the average weight and compare the individual tablet weight to the average. The tablet passes the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

According to IP, there is a weight variation limit.

Average weight of tablet	Deviation%
80 mg or less than	± 10 More
80 mg but less than 250 mg	± 7.5
250 mg or more	± 5

7.2.4 Disintegration

The U.S.P. device to test disintegration uses 6 glass tubes that are 3 long; open at the top and 10 mesh screens at the bottom end. To test for disintegration time, one tablet is placed in each

tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid, or simulated intestinal fluid at 37 ± 20 C such that the tablets remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker on their downward movement. Move the basket containing the tablets up and down through a distance of 5–6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet. According to the test, the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified. If any residue remains, it must have a soft mass.

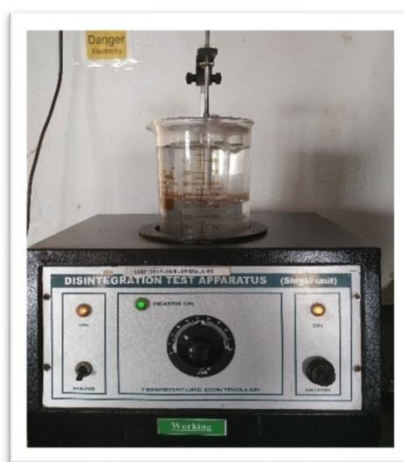


Fig. No. 04: Disintegration of Tablets

7.2.5 Assay

Weigh and powder 20 tablets. Weigh a quantity of the powder containing about 0.5 g of Aspirin, add 30 ml of 0.5 M sodium hydroxide, boil gently for 10 minutes, cool, and titrate the excess of alkali with 0.5 M hydrochloric acid using phenol red solution as indicator. Repeat the operation without the substance under examination. The difference between the titration represents the amount of sodium hydroxide required.

1 ml of 0.5 M sodium hydroxide is equivalent to 0.04504 g of C₉H₈O₄.



Fig. No. 05: Assay of Aspirin Tablet

7.2.6 Dissolution

- 7.2.6.1 Precisely set the dissolution apparatus. (A paddle-type apparatus was used.)
- 7.2.6.2 Pour an adequate amount of water into the vessel.
- 7.2.6.3 Introduce the stated volume of the dissolution medium (0.1 M HCl) into the cylindrical vessel.
- 7.2.6.4 Switch on the power button.
- 7.2.6.5 Preheat the dissolution medium to 36.5-37.5 °C
- 7.2.6.6 Set the speed of rotation at about 50 rpm.
- 7.2.6.7 Introduce the tablet into the cylindrical vessel to sink to the bottom of the vessel before the rotation of the paddle.
- 7.2.6.8 Take samples at the prescribed time.
- 7.2.6.9 Add a volume of dissolution medium equal to the volume of the samples withdrawn.
- 7.2.6.10 Repeat the procedure five times.
- 7.2.6.11 Dilute the sample.
- 7.2.6.12 Measure the absorbance of the blank solution and sample solution with the help of a UV-spectrophotometer.
- 7.2.6.13 Take the readings and draw a graph of time vs. absorption.



Fig. No. 06: Dissolution of Tablet

8 Result & Discussion

8.1 Pre-compression Studies

Table No. 2: Pre-compression Studies

Sr.No.	Properties	Result	Flow Property
1	Solubility	Soluble	-
2	Bulk density (g/ml)	0.66	-
3	Tapped density (g/ml)	0.76	-
4	Carr's index (%)	13.15	Good
5	Hausner's ratio	1.15	Good
6	The angle of repose (°)	34.99	Good

8.2 Evaluation Test

Table No. 3: Evaluation Test

Formulation	Hardness (kg/cm ²)	Average Weight Variation (mg)	Assay	% Drug Release	Disintegration Time (sec)
F1	5.50	240±12	93.06 %	72.94	2.38 sec
F2	4.50	241.5±12.075	97.2 %	72.79	1.45 sec
F3	4.50	240.5±12.025	101.7%	74.31	58 sec
F4	5.50	248±12.4	98.1%	72.53	148 sec
F5	5.50	247±12.35	94.4%	71.78	167 sec

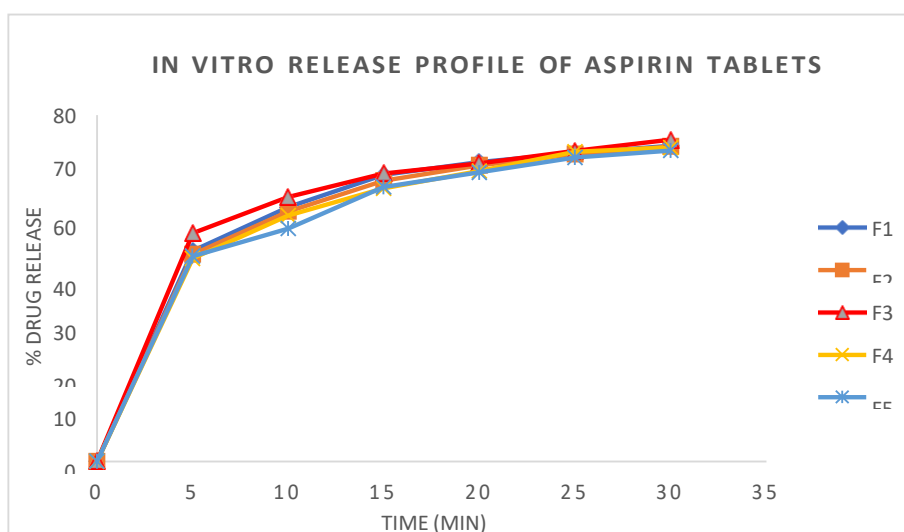


Fig. No.07: In vitro release profile of aspirin tablets

Evaluation tests were performed for all the formulations. Hardness, weight variation, and disintegration time are the parameters which were evaluated. The hardness of all formulations ranged between 4.50 and 5.50 kg/cm², which is well between the given standards as per IP. All tablets passed weight variation tests as deviation was within 5%, which satisfies pharmacopial criteria. The disintegration time for 2.5%, 5%, 7.5%, 10%, and 12.5% is 158 seconds, 105 seconds, 58 seconds, 148 seconds, and 167 seconds, respectively.

9 Conclusion

In the present work, an attempt has been made to develop Aspirin tablets using a natural disintegrant such as banana powder. All the formulations were prepared by the direct compression method and the blend of all the formulations showed good flow properties such as angle of repose, bulk density, and tapped density. The prepared tablets were shown to have good post-compression parameters and they passed all the evaluation tests as per IP limits.

Given study shows with the increase in the concentration of natural superdisintegrant banana powder, there is a reduction in disintegration time and vice versa. For the first three formulations, i.e. 2.5%, 5% and 7.5%, the disintegration time is 158 seconds, 105 seconds and 58 seconds respectively. For 10% and 12.5%, the disintegration time is 148 and 167 seconds, showing the opposite trend. Hence, the study suggests that the natural superdisintegrant can be used in a concentration of up to 10% to achieve fast disintegration.

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