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Research Article

PREPARATION AND CHARACTERIZATION OF MOUTH DISSOLVING TABLETS OF INDOMETHACIN USING BANANA PEEL POWDER AS A NATURAL SUPER DISINTEGRANT

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ABSTRACT

Mouth dissolving tablets are meant for administration to the patients who cannot swallow, such as elderly, stroke victims, bedridden patients, patients affected by renal failure, and the patients who refuse to swallow, such as pediatric, geriatric, and psychiatric patients. The aim of the study is to formulate mouth dissolving tablet of Indomethacin for the pain management of Rheumatoid Arthritis and to improve the efficacy and patient compliance. In the present work, fast dissolving tablets of Indomethacin were prepared by direct compression method using Banana peel powder as natural super disintegrant with a view to enhance patient compliance and to avoid hepatic first pass metabolism and to improve its bioavailability. The prepared formulations of tablets were evaluated for hardness, thickness, friability, drug content uniformity, wetting time, disintegration and in-vitro dissolution studies. Thus, the study leads that *Musa paradisicum (*Banana peel powder*)* releases high amount of drug content which is used as natural super disintegrant.

Keywords: Indomethacin, Mouth dissolving tablets, Banana peel powder, Natural super disintegrant.

INTRODUCTION

A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue. Despite of tremendous innovations in drug delivery, the oral route remains the preferred route for administration of therapeutic agents because of accurate dosage, low-cost therapy, self-medication, non-invasive method and ease of administration leading to high level of patient compliance (Deepak *et al*, 2012). The tablets disintegrate into smaller granules or melt in the mouth from a hard solid structure to a gel-like structure, allowing easy swallowing by the patients. The disintegration time for those tablets varies from a few seconds to more than a minute (Abdul Sayeed *et al*, 2011)**.** ODTs offer dual advantages of solid dosage forms and liquid dosage forms along with special Features which include: Enhanced bioavailability: Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus. Rapid action: Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity. Ease of administration: Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing. Cost effective: Conventional processing and packaging equipment's allow the manufacturing of tablets at low cost (Jagani *et al*, 2011)**.** Fast Dissolving Films**:** It is a new frontier in MDTs that provides a very convenient means of taking medications and supplements. In this technique, a non-aqueous solution is prepared containing water-soluble film forming polymer (pullulan, carboxymethylcellulose (CMC), hydroxypropyl methylcellulose (HPMC), hydroxylethylcellulose, hydroxylpropylcellulose, polyvinyl pyrrolidone, polyvinyl alcohol or sodium alginate, etc.). The dissolution in 5 sec, instant drug delivery and flavored after taste (Vummaneni *et al*, 2011). Super disintegrants**:** Despite increasing interest in controlled release drug delivery systems, the most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract (GIT) still remains the dosage form of choice (Kiran *et al*, 2011) Disintegrates are substances or mixture of substances added to tablet formulations to promote the

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break-up of the tablet (and capsule "slugs') into smaller fragments in an aqueous environment thereby increasing the available surface area and promoting a more rapid release of the drug substance. An ideal disintegrant should have poor solubility, poor gel formation, good hydration capacity, good compressibility, flow properties and no tendency to form complexes with the drugs (Basawaraj *et al*, 2011).

MATERIALS AND METHODS

Internal Addition

In wet granulation method, the disintegrant is added to other excipients before wetting the powder with the granulating fluid. The disintegrant is incorporated within the granules. In dry granulation method, the disintegrant is added to other excipients before compressing the powder between the rollers (R. Bala *et al*, 2012). In a computer optimized experiment, the study shows the effect of incorporating a disintegrant, croscarmellose sodium, intragranularly, extra granularly or distributed equally between the two phases of a tablet in which a poorly soluble drug constituted at least 92.5% of the formulation. The results analyzed by means of a general quadratic response surface model suggest that tablets with the same total concentration of croscarmellose sodium dissolve at a faster rate when the super disintegrant is included intragranularly (Khinchi *et al*, 2011).

Internal and External Addition

In this method, disintegrant is divided into two portions. One portion is added before granule formation (intra) and the remaining portion is added to granules (extra) while mixing prior to compression. This method can be more effective. Since a compaction process does not involve its exposure to wetting and drying, the intragranular disintegrant tends to retain good disintegration activity (Rao *et al*, 2010).

Sodium Starch Glycolate

Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is recommended to use in tablets prepared by either direct-compression or wet-granulation processes (Malviya R *et al*, 2012). The mechanism by which this action takes place involves rapid absorption of water leading to an enormous increase in volume of granules resulting in rapid and uniform disintegration. The natural re-dried starches swell in water to the extent of 10-20 percent and the modified starches increase in volume by 200-300 percent in water (Ghange *et al*, 2011). Oral tablets are the most widely used dosage form because of its advantage in terms of self-administration, compactness, low cost and ease in manufacturing. The major demerits of conventional tablets include poor patient compliance, low bioavailability and delayed on set of action. Because of these problems, scientists developed innovative drug delivery systems known as 'Oro-dispersible tablets (Bhimi Kumari *et al*, 2017). "A solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly within a matter of seconds when placed upon the tongue advantages of Oro dispersible tablets include administration without water, rapid on set of action and increased bioavailability". They are eco-friendly, capable of multitude of chemical modifications, potentially degradable and compatible due to their natural origin (Sandeep Patel *et al*, 2022).

Natural banana powder

Synonym as plantain (Family Musaceae). It contains retinol (Vitamin A). It also contains pyridoxal (Vitamin B6), which is given for reducing stress. It has rich source carbohydrate and potassium and responsible for more brain functioning (Kusuma *et al*, 2021).

Method of preparation of banana peel powder

Take 6–8 unripe fresh bananas, peel them properly and cut them into small pieces. These pieces were dried under sunlight for 24 h. After that, dried pieces were grinded properly to form a powder. The process of banana powder preparation is eco-friendly (Reecha Madaan *et al*, 2020). Indomethacin also known as a Non-Steroidal Anti-Inflammatory Drug (NSAID) commonly used as a prescription medication to reduce fever, pain, stiffness and swelling from inflammation. Indomethacin is used to relieve moderate to severe pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis (arthritis caused by swelling of the lining of the joints), and ankylosing spondylitis (arthritis that mainly affects the spine). Indomethacin is also used to treat pain in the shoulder caused by bursitis (inflammation of a fluid-filled sac in the shoulder joint) and tendinitis (inflammation of the tissue that connects muscle to bone). Indomethacin immediate-release capsules and suspension (liquid) are also used to treat acute gouty arthritis (attacks of severe joint pain and swelling caused by a build-up of certain substances in the joints). Indomethacin is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation (Abhijit Moon *et al*, 2011).

BCS Classification

Class–II (Low Solubility, High Permeability). Indomethacin is poorly soluble in acidic medium (pH 1.1) and distilled water (pH 6.2). Solubility of indomethacin can be improved by formation of inclusion complexes with α-CD or γ-CD, regardless of molar ratio of the prepared physical mixture. Quantitative biopharmaceutical classification system Papp- apparent permeability and q-Dose/solubility (Yashpal Singh Chauhan *et al*, 2018).

Applications in Pharmaceutical Technology

Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations. It is commonly used in tablets prepared by

either direct-compression or wet-granulation processes. The usual concentration employed in a formulation is between 2% and 8%, with the optimum concentration about 4%, although in many cases 2% sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling. Although the effectiveness of many disintegrants is affected by the presence of hydrophobic excipients such as lubricants, the disintegrate efficiency of sodium starch glycolate is unimpaired. Increasing the tablet compression pressure also appears to have no effect on disintegration time. Sodium starch glycolate has also been investigated for use as a suspending vehicle.

Preparation of standard calibration curve

Weighed accurately about 100 mg of Indomethacin and transferred it into a 100 ml volumetric flask and dissolved in a small quantity of 6.8 pH phosphate buffer solution. Then after the volume was made up with the 6.8 pH phosphate buffer solution to get a concentration of 1000 µg/ml (standard stock-1). From this 1 ml was withdrawn and diluted to 100 ml to get a concentration. Of 10 µg/ml (SS-2). From SS-2 aliquots of 2 ml, 4 ml, 6 ml, 8 ml and 10 ml volumetric flasks. The volume was made up with 6.8 pH phosphate buffer solution to get the final concentration of 2,4,6,8 and 10 µg/ml respectively. When this solution was scanned in the UV range i.e. 200 nm to 400 nm and the λmax was found to be 236 nm for Indomethacin in 6.8 pH phosphate buffer solution as a blank in UV- Visible spectrophotometer. The absorbance (abs) of each concentration was measured at 236 nm.

Preparation of Banana Peel Powder

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Direct Compression Method for Tablet Preparation

20 mg of drug and all excipients except magnesium stearate and talc were weighed accurately and transferred to a clean mortar and pestle. The powder blend was mixed for 5 minutes after which magnesium stearate and talc were added and mixed for a few more minutes to ensure complete mixing. After obtaining a uniform blend, it was passed through sieve no 60. The prepared powder blend was compressed into tablets (Figure 1).

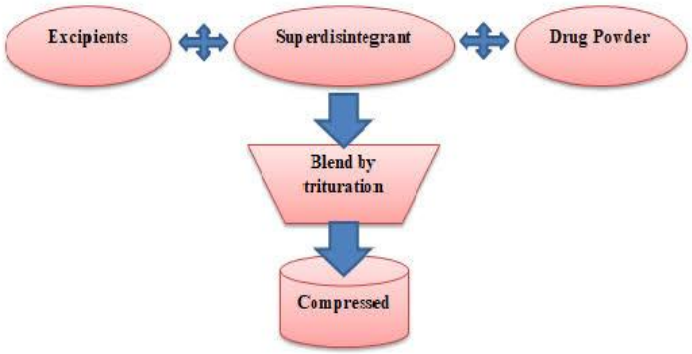


Figure 1. Direct Compression Method for Tablet Preparation.

Table 1. Formulation Table.

S.No	Ingredients (%w/w)	F-1(mg)	F-2(mg)	F-3(mg)	F-4(mg)
1	Indomethacin	20	20	20	20
2	Banana peel powder	35	40	—	—
3	Sodium Starch Glycolate	—	—	35	40
4	Micro Crystalline Cellulose	100	100	100	100

5	D-Sorbitol	10	10	10	10
6	Mannitol	75	70	75	70
7	Magnesium Stearate	4	4	4	4
8	Talc	6	6	6	6
	Total (mg)	250	250	250	250

Calibration curve of Indomethacin in 6.8 pH Phosphate buffer

The calibration curve of Indomethacin was prepared in 6.8 pH Phosphate buffer shows the absorbance at (λ max) 236 nm and shows the calibration curve with regression coefficient of 0.999. The y=mx+c value is y=0.0856x + 0.0839.

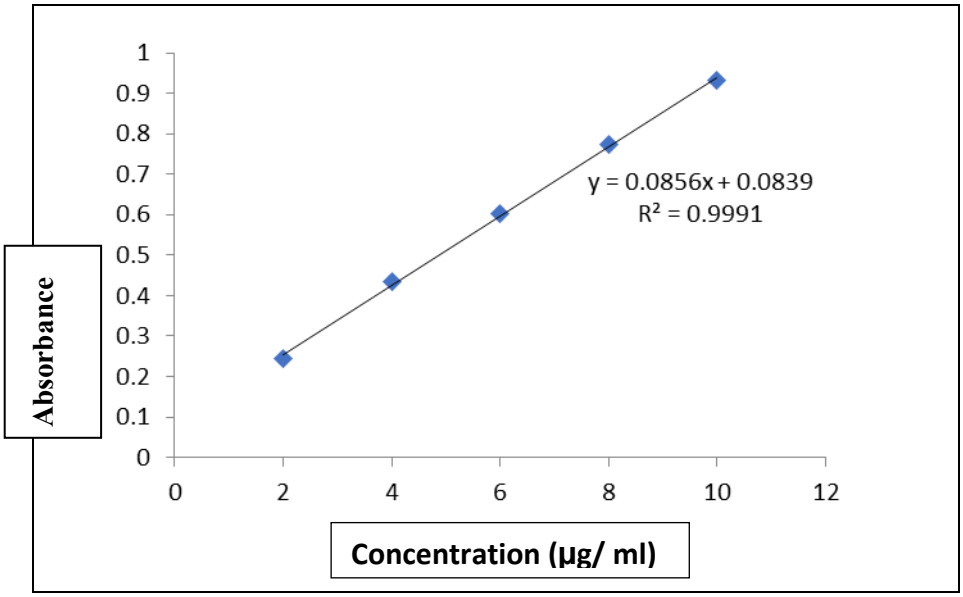


Figure 1. Standard graph of Indomethacin in pH 6.8.

Powder blend of Indomethacin tablet was evaluated for various physicochemical parameters. Bulk density, tapped density, angle of repose and powder flow studies of the different formulations were studied.

Table 2. Flow properties of tablet blend.

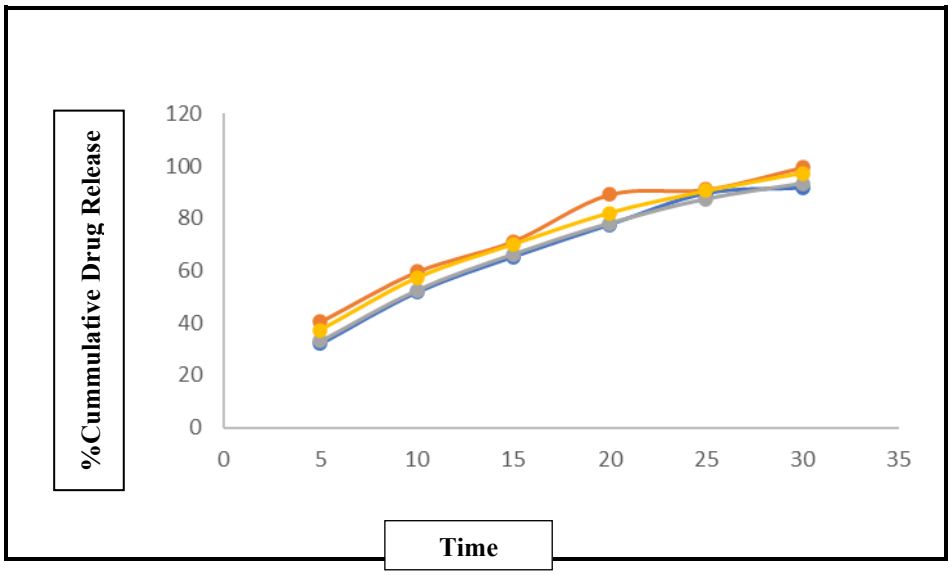
Formulations	Angle of repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's Index	Hausner's ratio
F1	27.94±0.36	0.55±0.67	0.85±0.65	17.53±0.70	1.48±0.87
F2	28.94±0.74	0.57±0.90	0.84±0.78	14.65±0.43	1.48±0.67
F3	27.39±0.56	0.51±0.35	0.81±0.52	15.56±0.52	1.41±0.53
F4	29.94±0.73	0.57±0.21	0.85±0.56	16.46±0.31	1.46±0.19

Table 3. Post Compression Parameters of All Tablets.

Formulations	F1	F2	F3	F4
Hardness(kg/cm2)	3.1±0.86	3.2±0.67	3.2±0.45	3.2±0.34
Thickness(mm)	5.85±1.76	5.84±0.77	5.84±0.34	5.84±0.76
Friability (%)	0.93±0.07	0.83±0.17	0.78±0.22	0.8±0.2
Disintegration(sec)	36 sec	34 sec	37 sec	35 sec
Wetting time(sec)	46 sec	45 sec	43 sec	42 sec
Weight Variation (%)	248±0.17	249±0.07	247±0.16	248±0.15

Table 4. *In vitro* drug release studies of all Formulations.

Time (min)	F1	F2	F3	F4
5	32.1±0.32	40.5±0.36	31.3±0.28	37.4±0.38
10	51.76±0.31	59.3±0.29	50.6±0.32	57.1±0.32
15	65.3±0.87	71.1±0.25	67.3±0.96	70.1±0.31
20	77.5±0.27	89.23±0.15	78.1±0.26	82.1±0.24
25	89.4±0.28	91.1±0.03	87.3±0.31	90.5±0.78
30	91.53±0.59	99.5±0.99	93.33±0.78	97.44±0.43



From the *In Vitro* drug release studies, it was concluded that the increase in the disintegrant Concentration showed better drug release by 30 minutes. Among all the formulations F2 showed better drug release. So F2 formulation was considered as the optimized formulation.

CONCLUSION

The present study was undertaken to formulate mouth dissolving tablet of Indomethacin with a view to deliver the drug in rapid manner in oral cavity. For this study, we have used Banana peel powder and sodium starch glycolate (35%, 40%). Total four formulations are formulated by varying the concentration of these two Super disintegrants. The pre compression parameters such as angle of repose, tapped density, bulk density, Hausner's ratio, compressibility index is within the limit indicating the acceptability of the product formulate into a dosage form. Mouth dissolving tablets are formulated by direct compression method. The prepared tablets were evaluated for post compression parameters such as weight variation, disintegration time, dissolution method, friability, hardness, all the formulation are within the pharmacopoeia limit indicating the acceptability of the product in this dosage form. All the formulations are disintigrated within 30 sec indicating the suitability of the product (orodispersible criteria). Among all the formulations F2 and F4 showed maximum drug release within 30 sec compared to other formulations. F1 and F2 formulation contains Banana peel powder (35%,40%) as a natural super disintegrant and F3 and F4 formulation has contains Sodium starch glycolate (35%, 40%) as a synthetic super disintegrant. By observing these 4 formulations for drug release, Banana peel powder is more suitable for mouth dissolving tablets of Indomethacin tablets compare with Sodium starch glycolate. F2 formulation gave 100% drug release compared to other 3 formulations released within30 minutes. Mouth dissolving tablet is a promising approach with a view of obtaining rapid action of the drug and would be advantageous in comparison to currently available conventional dosage forms. From the data obtained, it is observed from the formulation containing Banana powder in Formulation F2, the Percentage drug release is 99.5 % at the end of 30 min which satisfied all the tablet evaluation parameters for Mouth dissolving tablet Hence looking at all the satisfactory parameters F2 formulation is selected as the optimized formulation.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

FUNDING

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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