ISSN: 2754-5008

Journal of Pharmaceutical Research and Reports

SCIENTIFIC Research and Community

Research Article

Open Access

Comparative Study of Natural & Synthetic Super Disintegrants in Development of Cost-Effective Oro-Dispersible Tablets of Amlodipine Besylate

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ABSTRACT

Background: Fast dissolving tablets or orodispersible tablets dissolve or break down as soon as the patients place it on the tongue or buccal mucosa. This is appropriate drug delivery system where drugs are subject to high first pass metabolism. It enhances bioavailability, decreases the dosing frequency and thus reduces the side effects and also makes the dosage form cost effective. This paper examined polysaccharide extracted in the seeds of Cassia tora as a super disintegrant in the or dispersible tablets. The antihypertensive drug that was selected as a model drug was amlodipine besylate.

Methods: The direct compression method was used to prepare amlodipine besylate tablets with different concentrations (1, 2.5, 5 and 7.5 percent w/w) of isolated C. Tora seed polysaccharide (natural) and sodium starch glycolate (synthetic) as a super disintegrant. Evaluation of tablets was done for various pre- and post-compression parameters. The stability tests were done on optimized formulation F4. The in-vitro release of the drug and disintegration time of the formulation F4 was compared to marketed formulations (conventional tablets).

Results: Fourier transform infrared studies were done to characterize the drug excipient interactions. Formulation F4 with 7.5% polysaccharide exhibited good wetting time, disintegration time in comparison to a formulation made with a synthetic super disintegrant at the same concentration level. Therefore, the batch F4 was optimized formulation.

Conclusion: The current study has shown that C. Tora seed polysaccharide could be a good disintegrant when used in the preparation of or dispersible tablets. Since C. Tora polysaccharide is cheap compared to synthetic super disintegrants, nontoxic, compatible and simple to produce, it can be utilized to replace the existing marketed super disintegrants.

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Received: May 04, 2026; **Accepted:** May 11, 2026; **Published:** May 16, 2026

Keywords: Cassia Tora, Super Disintegrants, Direct Compression, or Dispersible Tablets, Patient Compliance, Sodium Starch Glycolate

Introduction

The mouth dissolving tablets constitute the impulse to give the patient the traditional mode of consuming his/her medication. Due to physiological modification linked with, particularly, elderly and pediatrics are very incapable of swallowing (Dysphasia); instead, it is a typical issue with all age groups patients. Certain dosage forms of fast-dissolving tablets that can be disintegrated, dissolved or suspended in saliva in the mouth leading to easy swallowing may have distinguishable utility to pediatric and elderly population and other patients who require easy dosage forms to swallow. When put on tongue, mouth dissolving tablets dissolves rapidly and rapidly releases the drug which dissolves or disperses in the saliva at pH 6.8 [1]. In recent times, pharmaceutical preparations that are administered to elderly patients have been explored to enhance the compliance to treatment and the quality of life of elderly patients. In saliva (pH 6.8) mouth dissolving tablets can rapidly disintegrate. Mouth dissolving tablets is a good dosage form and a patient-cent red pharmaceutical preparation [2].

These Mouth dissolving tablets have attracted the interest of many researchers. A large number of the elderly patients are not able to swallow pills, capsules, or powder. In order to minimize this issue, such tablets will be designed to dissolve or disintegrate in the mouth without taking water. The crumbly mass can slide down easily along the esophagus thanks to saliva, hence even those who have problems in swallowing or chewing can do it easily. Two kinds of dispersible tablet have to be distinguished: One type of dosage form disintegrates immediately in the mouth to be swallowed without the necessity of administration with water, whereas the other type of tablet formulation can readily be dispersed in water, in order to produce dispersion, easily swallowed by the patient [3]. Mouth dissolving tablets are tablets that quickly dissolve and disintegrate in saliva within a few seconds even in absence of water. Despite massive advancement of fast dissolving drug delivery system or technology oral route is still ideal route of administration of therapeutic reagents due to low cost of therapy,

easy administration, and accurate dose, self-medication, avoidance of pain, and high degree of patient compliance [4]. According to European pharmacopoeia, mouth dissolving tablets are those which disintegrate on tongue before swallowing and it should disperse in less than 3 min. ODTs are commonly known as orally disintegrating tablets, mouth dissolving tablets, fast dissolving tablets, or rapid melt tablets.

The reagents used to transform active pharmaceutical ingredients are known to be converted into pharmaceutical dosage form as excipients [5]. Excipients from natural sources have a benefit over synthetic excipients in that they are locally available, non-polluting, biocompatible and inexpensive as com-compared to foreign synthetic goods. Herbs are renewable materials of sustaining stocks of less expensive pharmaceutical products [6-13].

Super disintegrants are an important component that is used in the manufacture of fast disintegrating tablets in a direct compression process. Disintegrants are the substances or combination of substances used in drug formulation that assist in the disintegration of the tablet content into smaller particles which dissolve faster than tablets without disintegrants. Croscarmelose, crospovidone, and sodium starch glycolate (SSG) (representing the crosslinked cellulose, crosslinked polymer and a crosslinked starch, respectively) are examples of the most frequently used synthetic origin super disintegrants [14,15]. ODTs have been formulated using various natural origin substances including karaya, modified starch and agar. The natural origin substances are relatively cheaper and some of the desired properties include; abundantly available, nonirritating and nontoxic in nature.16 They have various advantages over the synthetic super disintegrants, including ease of isolation, local availability and biocompatibility.

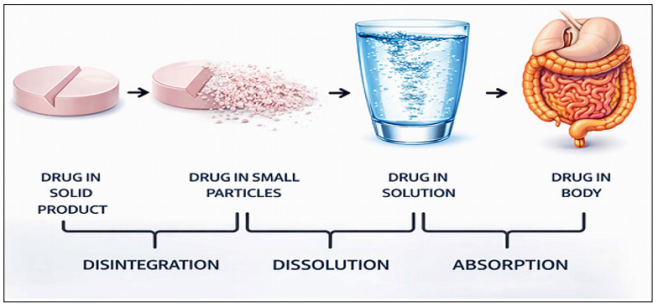

Figure 1: Disintegration of Tablet

Selection Criteria for Super disintegrants

Despite the fact that the rate of disintegration is mostly influenced by they may also have an influence on the hardness of the tablet, super disintegrants. When used in high doses, it has a mouthfeel and friability. For ideal factors to, there are a few formulations when choosing super disintegrants that involves:

- In the mouth/oral when the tablet comes in contact with saliva, disintegrate quickly.
- Be small enough to yield less friable pills.
- Gives patients pleasant mouth feels to accomplish this.
- Small particle size is desired.
- Flow is significant since it enhances the total blend flow characteristics [17,18].

Ideal Properties of Super Disintegrants

Very high Compressibility and Flow Characteristics.

Compressible powders between 12-16 percent are taken into consideration of good flow powders. In comparison to other much more so super disintegrants, crospovidone compressible [19,20].

Insufficiency in Solubility

Disintegration rate of tablets and mechanism can be affected by the solubility of the essential component in a tablet composition. More so water-soluble compounds probably to dissolve rather than disintegrate, and, insoluble ingredients tend to produce fast dissolving tablets [21].

Not Enough Ability to Make Gel

Gels may slow down disintegration because the medicine has to go through the gel layer before it can get into the body. In tablet making, primo gel is employed as a super disintegrant at a concentration of 4–6% [22].

The Ability to Retain Water

Drugs and other excipients that don't like water and may attach to disintegrate surfaces change how effectively these disintegrates operate and how much water they can store.

Adding quick-dissolving substances that can contain a lot of water is said to assist with this issue, which makes the process go quicker [23].

Complexation

Cationic medication actives may form complexes with anionic disintegrants such croscarmellose sodium and primo gel, which can slow down the dissolving process. Crosspointe, a non-ionic polymer, does not interact with cationic medication actives to impede drug release.

The impact of super disintegrating agents such as croscarmellose sodium, primo gel, and polycladose XL on the dissolution kinetics of various cationic drugs with varying water solubility indicates that polycladose XL exhibited a more rapid dissolution rate for the model cationic drugs, irrespective of their aqueous solubilities [24,25].

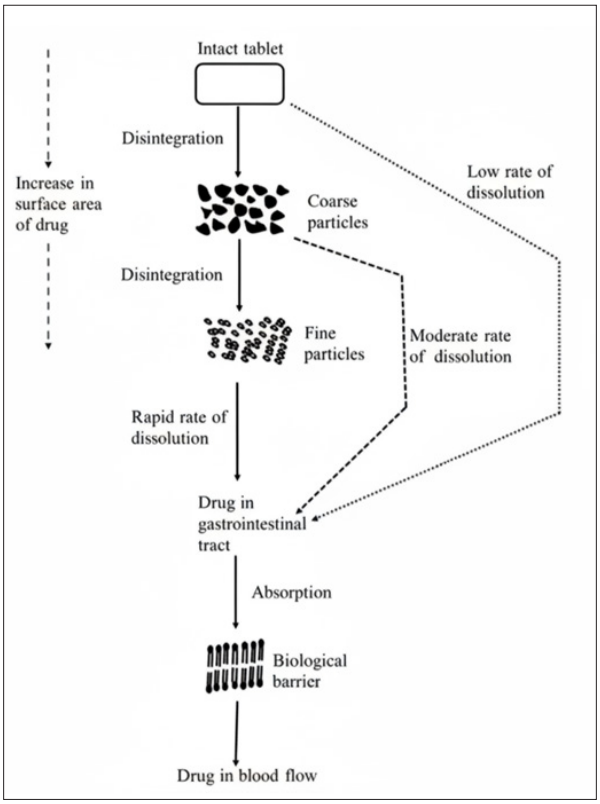

Figure 2: Disintegration Process

Cassia Tora (Family: Leguminosae) is a little shrub that grows every year in India and other tropical nations [26]. Seeds of C. Tora have a lot of anthraquinones and sennosides in them [27,28]. It has been used to cure asthma and make vision better [29]. It protects the liver and reduces inflammation [30]. The seeds of C. Tora produce a kind of gum called "Panwar gum." Chemically, it is a neutral heteropolysaccharide made up of galactose and mannose (galactomannans). The pH of the Panwar gum mucilage is about 7 [31]. A review of the literature showed that the C. Tora polysaccharide has never been employed as a disintegrant before, hence it was chosen for this study. The purpose of this research is to look at a polysaccharide that was taken from the seeds of C. Tora and used as a super disintegrant in ODTs. It also compares its ability to break down with that of synthetic super disintegrants.

The model drug used for the study was Amlodipine besylate, which is an antihypertensive drug belonging to the category of calcium channel blocker. It is a long-acting dihydropyridine calcium channel blocker that selectively inhibits L-type calcium channels in vascular smooth muscle, resulting in peripheral vasodilation and decreased systemic vascular resistance. It is widely used in the management of hypertension, chronic stable angina, and vasospastic angina due to its strong vascular selectivity, minimal negative inotropic effect, and excellent safety profile.

Amlodipine has a long elimination half-life of 30–50 hours, enabling once-daily dosing and improved patient compliance. It is well absorbed orally with high bioavailability (~60–65%) and undergoes extensive hepatic metabolism via CYP3A4 to inactive metabolites. Because of its slow onset and sustained duration of action, amlodipine provides smooth 24-hour blood pressure control without significant reflex tachycardia [32].

Methods

Materials

Amlodipine besylate was obtained from Cipla Ltd., Pithampur, India as a gift sample. Microcrystalline cellulose (MCC PH102), sodium starch glycolate, magnesium stearate, talc, aspartame, and vanilla flavor were obtained from Cure dose Pharma Labs (Indore, India). Cassia Tora seeds were collected from the Maharashtra region (India) in the month of October. The plant material was authenticated at the Blatter herbarium. The specimen sample of the plant is preserved with the Department of Pharmacognosy, IPS Academy College of Pharmacy, Indore, India. All chemicals and reagents used in this study were of analytical grade.

Isolation of Polysaccharide from Cassia Tora Seeds

Cassia Tora seeds were dried in a mixer in order to separate the endosperm and the seed coat. Approximately 100 g of endosperm obtained was moistened in distilled water and stirred 4-5 hours to get a sticky mixture. This solution was then filtered using muslin cloth to eliminate insoluble solution. The gradual addition of 95% ethanol in a 1:1 proportion was done under constant stirring, which precipitated the mucilage (polysaccharide).

The precipitate that was formed was evaporated off in a dish and cleaned up several times with ethanol to purify. It was then dried in an oven with 40- 45 C. The material was dried and powdered then sieved through sieve number 60 and then stored in an airtight container to be used later.

The isolated polysaccharide underwent assessment of diverse physicochemical characteristics, such as solubility, pH (1% w/w aqueous solution), swelling index, loss on drying, ash value, bulk density, tapped density, compressibility index, Hausner ratio and angle of repose, in line with known procedures [33,34].

Formulation of Oro-Dispersible Tablets

ODTs of amlodipine besylate were developed in direct compression method, using isolated polysaccharide and a synthetic super disintegrant at 1%, 2.5%, 5% and 7.5% w/w concentration. A 60-mesh sieve was used to pass all the components of the formulation to guarantee homogenous particle size.

Weighed amounts of each ingredient were properly mixed to develop a homogenous powder mixture. The mixture was then made into 200 mg tablets by pressing the prepared mixture with 9 mm round, flat punches on a one-station rotary tablet press. Table 1 shows the detailed formulation of each formulation.

Table 1: Composition of ODTS

Ingredients in milligrams	F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8
Drug	5	5	5	5	5	5	5	5
Cassia Tora polysaccharide	2	5	10	15	-	-	-	-
Sodium starch glycolate	-	-	-	-	2	5	10	15
Microcrystalline cellulose PH102	186.2	183.2	178.2	173.2	186.2	183.2	178.2	173.2
Aspartame	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
Vanilla	1	1	1	1	1	1	1	1
Talc	2	2	2	2	2	2	2	2
Magnesium stearate	1	1	1	1	1	1	1	1
Total Weight	200	200	200	200	200	200	200	200

Evaluation of Powder Blend (Pre-compression Parameters)

The prepared powder blend was assessed for its flow characteristics, including angle of repose, bulk density, tapped density, Hausner's ratio, and Carr's index.

Angle of Repose

The angle of repose of the powder blend was determined using the fixed funnel method. A known quantity of the powder was accurately weighed and placed into a funnel. The funnel height was adjusted so that its tip just touched the apex of the powder heap formed below. The powder was then allowed to flow freely through the funnel onto a flat surface without any obstruction.

The height and radius of the resulting conical pile were measured, and the angle of repose was calculated using the following equation:

$$\tan\theta = \frac{h}{r}$$

where h represents the height and r represents the radius of the powder cone.

Bulk Density and Tapped Density

A 5 g sample of powder from each formulation was transferred into a 25 mL graduated cylinder. The cylinder was gently tapped to break any lumps or agglomerates, and the initial volume was recorded. It was then allowed to fall freely onto a hard surface from a height of 2.5 cm at intervals of 2 seconds. Tapping was continued until no further change in volume was observed, indicating a constant volume had been reached [35].

The loose bulk density (LBD) and tapped bulk density (TBD) were calculated using the following equations:

$$\text{LBD} = \frac{\text{Weight of powder}}{\text{Initial volume}}$$

$$\text{TBD} = \frac{\text{Weight of powder}}{\text{Tapped volume}}$$

Compressibility Index and Hausner's Ratio

The compressibility of the powder blend was evaluated using Carr's compressibility index, which was calculated from the values of tapped and bulk density. Hausner's ratio was also determined as an additional indicator of flow characteristics. The calculations were performed using the following expressions:

$$\text{Carr's Index (\%)} = \frac{(\text{Tapped Density} - \text{Bulk Density}) \times 100}{\text{Tapped Density}}$$

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Evaluation of Tablets (Post-Compression Parameters)

Tablet Hardness

Tablet hardness is an important parameter that ensures mechanical strength, helping tablets withstand handling, transportation, and storage conditions. The hardness of the tablets was measured using a Monsanto hardness tester and expressed in kg/cm².

Tablet Thickness

The thickness of the tablets was determined using a Vernier caliper by placing each tablet between its two jaws. Measurements were recorded for five tablets, and the average value was calculated.

Weight Variation

For weight variation analysis, twenty tablets from each formulation were randomly selected and weighed individually using a digital balance (Shimadzu Corporation, Japan; Model BL220H). The individual weights were recorded and compared with the average tablet weight to assess uniformity [36].

Friability

Twenty tablets were initially weighed and then placed in a Roche fryolator (USP type, Pharma lab, Ahmedabad, India). The apparatus was operated at 25 rpm for 4 minutes. After completion, the tablets were reweighed, and the percentage weight loss was calculated using the following formula:

$$\text{Friability (\%)} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Drug Content

Ten tablets were accurately weighed and finely powdered. A quantity of powder equivalent to 5 mg of amlodipine was transferred into a 100 mL volumetric flask and extracted using phosphate buffer (pH 6.8). The resulting solution was filtered, and the filtrate was appropriately diluted with the same buffer.

The absorbance of the prepared solution was measured at 250 nm using a UV–Visible spectrophotometer (Shimadzu UV-1800 equipped with UV–Probe Version 2.34 software). The drug content was calculated using a previously prepared standard calibration curve [37]. The final result was expressed as the mean percentage drug content obtained from three determinations.

Wetting Time and Water Absorption Ratio (R)

A piece of tissue paper was folded twice and placed in a petri dish (internal diameter of 5 cm) containing 6 mL of water. The tablet was carefully positioned on the surface of the tissue paper. The wetting time was recorded as the duration required for water to reach the upper surface of the tablet and completely wet it [38]. The water absorption ratio (R) was calculated using the following equation:

$$R = 100 \times \frac{(W_a - W_b)}{W_b}$$

where W_b is the tablet weight before water absorption and W_a is the weight after absorption.

In-Vitro Disintegration Time

The disintegration time of the tablets was determined using a standard tablet disintegration test apparatus. Six tablets were placed individually in each tube of the apparatus. The test medium was maintained at a temperature of 37 ± 2 °C, and the time required for complete disintegration of each tablet was recorded.

In-Vitro Dissolution Study

Dissolution studies were carried out using a USP type II (paddle) dissolution apparatus (Electro lab TDT-08L). A volume of 900 mL phosphate buffer (pH 6.8) was used as the dissolution medium, maintained at 37 ± 0.5 °C. The paddle speed was set at 50 rpm.

Samples were withdrawn at intervals of 2 minutes, and drug content was determined by measuring absorbance at 239 nm using a UV spectrophotometer [39]. The drug concentration was calculated using a standard calibration curve and expressed as cumulative percentage drug release.

For comparison, the dissolution study was also performed under identical conditions using a marketed conventional tablet formulation (Valzaar, Torrent Pharmaceuticals Ltd., India).

Drug–Excipient Interaction Study

Compatibility between the drug and excipients was evaluated using Fourier Transform Infrared (FTIR) spectroscopy. Samples analyzed included the pure drug, a physical mixture of drug and polysaccharide (1:1), and the optimized formulation containing all excipients. The spectra were recorded over a range of 500-4000 cm^{-1} using the KBr pellet method.

Table 2: Physicochemical Parameters of Polysaccharide

Parameters	Results
State	Solid
Colour	Light-Brown
pH	7.2-7.5
Solubility	Soluble in hot water forming colloidal solution insoluble in organic solvent
Swelling factor	11.5 mL
Practical yield	18.56% w/w
Total Ash	1.47
Moisture content	1.2%
Total polysaccharide content	72.12% w/w
Angle of repose	29.24◦
Bulk density	0.64g/cm3
Tapped density	0.53g/cm3
Carr's index	17.16
Hausner's ratio	1.20

Results

The polysaccharide extracted from Cassia Tora seeds appeared as a light brown powder with a yield of 18.56% w/w. It was found to be soluble in hot water, forming a colloidal dispersion, while remaining practically insoluble in organic solvents. A 1% w/w aqueous solution exhibited a near-neutral ph. The isolated polysaccharide demonstrated good swelling behavior along with high water absorption capacity. Evaluation of flow properties, including Carr's index and angle of repose, indicated good flowability with moderate compressibility. Additionally, loss on drying and ash values were within acceptable pharmacopoeia limits. The detailed physicochemical properties are presented in Table 2.

Drug–excipient compatibility studies confirmed the absence of any physicochemical interaction between valsartan and the excipients (Fig. 1). All characteristic peaks of valsartan were retained in the spectra. Prominent functional group peaks included aliphatic C–H stretching at 2962.66 cm^{-1}, N–H stretching at 3444.87 cm^{-1}, carboxylic acid stretching at 1732.08 cm^{-1}, C=O stretching at 1600.02 cm^{-1}, and C–N stretching at 1273.02 cm^{-1}, 1205.51 cm^{-1}, and 1064.71 cm^{-1}. The region between 900–600 cm^{-1} corresponded to skeletal vibrations and the presence of an aromatic ring structure. All prepared tablets complied with the weight variation limits specified for uncoated tablets in the United States Pharmacopoeia. Pre-compression studies indicated that the powder blends possessed satisfactory flow properties (Table 3).

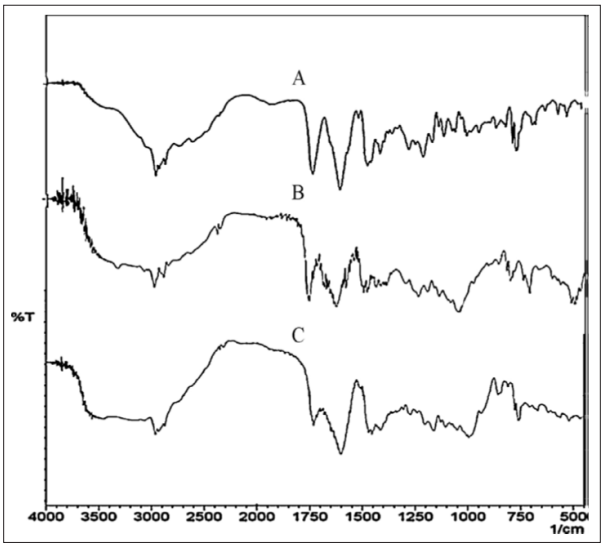

Figure 3: Fourier Transform Infrared Spectrum of (A) Pure Drug, (B) Pure Drug + Polysaccharide, and (C) Optimized Formulation F4

The hardness of the tablets ranged from 4.20 to 4.56 kg/cm^2. Friability values were between 0.49% and 0.79%, remaining below 1%, which indicates adequate mechanical strength. The drug content of all formulations ranged from 98.36% w/w to 100.04% w/w, confirming uniformity.

The results of post-compression evaluation are summarized in Tables 4 and 5. Wetting time and water absorption ratio are key parameters for assessing the swelling ability of super disintegrants in the presence of limited moisture. The wetting time across all formulations varied from 26.2 ± 0.25 seconds to 54.17 ± 0.48 seconds (Table 5).

The in-vitro disintegration times for formulations F1 to F8 are also presented in Table 5. Formulations containing the isolated polysaccharide showed a faster drug release profile compared to those containing sodium starch glycolate (SSG). The dissolution profiles of formulations F1 to F8 are illustrated in Figures 4 and 5.

Stability studies indicated no significant changes in the physical or chemical properties of the tablets. The optimized formulation (F4), containing 7.5% polysaccharide, remained stable under accelerated conditions (40 °C / 75% RH) for a period of 3 months (Table 6).

Table 3: Precompression Parameters of Powder Blend

Batches	Angle of Repose	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Carr's index (%)	Hausner's ratio
F1	30.15 ± 1.21	0.50 ± 0.005	0.646 ± 0.009	22.67 ± 1.40	1.28 ± 0.025
F2	29.20 ± 0.42	0.508 ± 0.002	0.637 ± 0.0098	20.37 ± 1.61	1.24 ± 0.031
F3	28.78 ± 1.29	0.493 ± 0.03	0.654 ± 0.012	24.7 ± 1.66	1.32 ± 0.030
F4	28.03 ± 1.20	0.491 ± 0.015	0.651 ± 0.009	24.54 ± 0.78	1.32 ± 0.015
F5	27.65 ± 1.27	0.522 ± 0.003	0.649 ± 0.008	19.55 ± 1.40	1.23 ± 0.025
F6	26.28 ± 0.91	0.515 ± 0.005	0.635 ± 0.005	18.89 ± 0.39	1.22 ± 0.005x
F7	30.84 ± 0.81	0.547 ± 0.003	0.627 ± 0.004	13.12± 0.005	1.14 ± 0.010
F8	29.20 ± 1.78	0.539 ± 0.003	0.629 ± 0.004	14.39 ± 0.54	1.16 ± 0.005

Results are presented as mean ± SD, n=5.

Table 4: Post compression Parameters of Oro dispersible Tablets of Amlodipine

Batches	**Angle of Repose**	**Bulk density (g/cm^3)**	**Tapped density (g/cm^3)**	**Carr's index (%)**
F1	2.43 ± 0.11	4.56 ± 0.208	0.68 ± 0.01	200.2 ± 0.63
F2	2.33 ± 0.15	4.40 ± 0.173	0.71 ± 0.01	200.2 ± 0.61
F3	2.46 ± 0.05	4.43 ± 0.11	0.77 ± 0.01	199.7 ± 1.05
F4	2.40 ± 0.12	4.2 ± 0.251	0.79 ± 0.01	200.5 ± 1.35
F5	2.2 ± 0.11	4.33 ± 0.15	0.49 ± 0.015	200.2 ± 0.63
F6	2.23 ± 0.20	4.53 ± 0.05	0.57 ± 0.017	200.2 ± 0.61
F7	2.23 ± 0.057	4.46 ± 0.152	0.58 ± 0.069	199.7 ± 1.05
F8	2.26 ± 0.014	4.3 ± 0.057	0.70 ± 0.015	200.5 ± 1.35

All values are presented as mean ± S D, n=5 a/20 b.

Table 5: Post compression Parameters of Oro dispersible Tablets of Amlodipine

Batches	**In-vitro disintegration time(s) [a]**	**Wetting time (s) [a]**	**Water absorption ratio [a]**	**Drug content [b]**
F1	2.43 ± 0.11	4.56 ± 0.208	0.68 ± 0.01	200.2 ± 0.63
F2	2.33 ± 0.15	4.40 ± 0.173	0.71 ± 0.01	200.2 ± 0.61
F3	2.46 ± 0.05	4.43 ± 0.11	0.77 ± 0.01	199.7 ± 1.05
F4	2.40 ± 0.12	4.2 ± 0.251	0.79 ± 0.01	200.5 ± 1.35
F5	2.2 ± 0.11	4.33 ± 0.15	0.49 ± 0.015	200.2 ± 0.63
F6	2.23 ± 0.20	4.53 ± 0.05	0.57 ± 0.017	200.2 ± 0.61
F7	2.23 ± 0.057	4.46 ± 0.152	0.58 ± 0.069	199.7 ± 1.05
F8	2.26 ± 0.014	4.3 ± 0.057	0.70 ± 0.015	200.5 ± 1.35

All values are presented as mean ± SD, n=6 a/10 b.

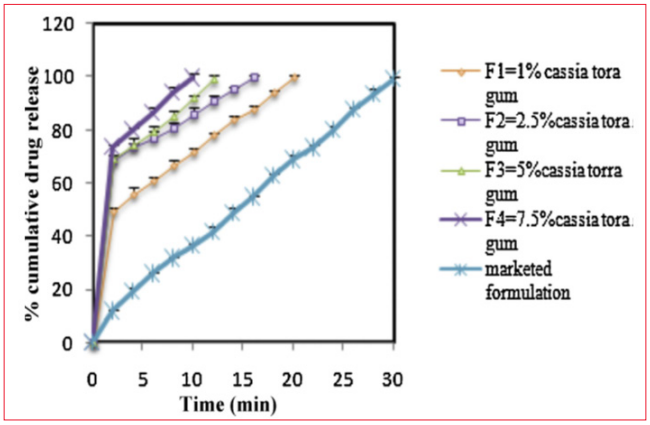

Figure 2: In-vitro Drug Release Profile of Formulations (f1–f4 and Marketed Formulation)

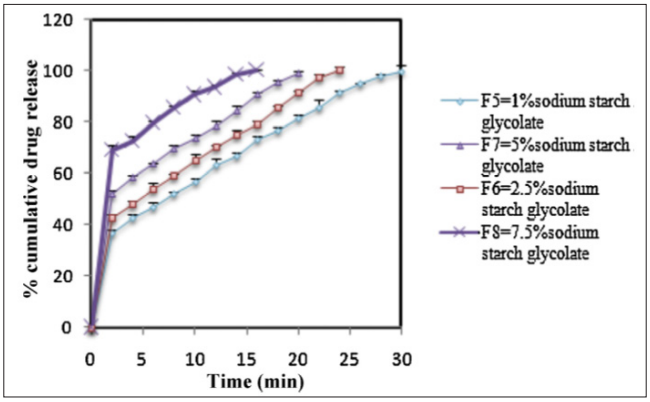

Figure 3: In-Vitro Drug Release Profile of Formulations (f5-f8)

Stability Studies

Stability testing of the tablets was conducted by storing the optimized batch in a stability chamber at 40 ± 2 °C and 75 ± 5% relative humidity for a period of 3 months, in accordance with ICH guidelines. At one-month intervals, the tablets were evaluated for hardness, friability, drug content (assay), disintegration time, and in vitro drug release profile.

Table 6: Optimized Batch Stability Study Data (F4)

Parameters	1 month	2 months	3 months
Hardness(kg/cm^2)	4.08 ± 0.09	4.22 ± 0.1	4.1 ± 0.12
% Friability	0.76 ± 0.09	0.79 ± 0.03	0.77 ± 0.05
Drug content (%)	99.53 ± 0.45	100.3 ± 0.1	99.95 ± 0.19
Disintegration time(s)	31.84 ± 0.6	30.12 ± 0.9	32.28 ± 0.1
F5	2.2 ± 0.11	4.33 ± 0.15	0.49 ± 0.015
F6	2.23 ± 0.20	4.53 ± 0.05	0.57 ± 0.017
F7	2.23 ± 0.057	4.46 ± 0.152	0.58 ± 0.069
F8	2.26 ± 0.014	4.3 ± 0.057	0.70 ± 0.015

Discussion

It has been reported that the seeds of Cassia tora contain galactomannans.40 Certain galactomannan-based gums, such as locust bean gum and guar gum, have already been explored for their use as super disintegrants [40,41]. Based on this similarity, C. tora gum was investigated for its potential as a supersite grant. The polysaccharide was found to exhibit significant swelling behavior [42].

Therefore, an attempt was made to formulate or dispersible tablets (ODTs) using the polysaccharide isolated from C. Tora seeds to evaluate its effectiveness as a super disintegrating agent. Various mechanisms have been proposed for the action of super disintegrants, including swelling, wicking, deformation, and electrostatic repulsion [43].

Amlodipine ODTs were prepared by the direct compression method using different concentrations of C. Tora gum as a natural super disintegrant, along with sodium starch glycolate (SSG) as a synthetic counterpart at similar concentrations [44]. The selection and quantity of excipients were based on reformulation studies and an extensive literature review. Microcrystalline cellulose was used as a directly compressible diluent, while aspartame served as a sweetening agent and vanilla was added as a flavoring agent [45]. Magnesium stearate was incorporated as a lubricant to enhance flow properties, particularly suitable for the direct compression process [46].

Tablets formulated with the polysaccharide isolated from Cassia Tora exhibited shorter wetting times compared to those containing sodium starch glycolate (SSG). This behavior can be attributed to the faster penetration of water into the porous structure of the tablets. In addition, the water absorption ratio of the polysaccharide-based formulations was higher than that of SSG formulations, and it increased with a rise in the concentration of the super disintegrant.

Due to their superior swelling capacity, formulations containing the natural polysaccharide showed rapid and complete disintegration when compared to those prepared with SSG. The enhanced drug dissolution observed with increasing polysaccharide concentration may be due to its swelling action, which facilitates water entry into the tablet matrix and generates hydrodynamic pressure, leading to faster tablet breakup. In contrast, tablets prepared with SSG disintegrate through rapid water uptake and swelling into smaller particles; however, dissolution is comparatively slower due to the formation of a viscous gel layer around the particles [47].

Among all formulations, batch F4 demonstrated the most rapid drug release and showed better performance than the marketed formulation. The formulation containing 7.5% polysaccharide exhibited significantly faster wetting and disintegration compared to the formulation containing the synthetic super disintegrant at the same concentration. Therefore, batch F4 was identified as the optimized formulation.

In conclusion, the findings of this study suggest that C. Tora seed polysaccharide is a promising natural super disintegrant for the development of or dispersible tablets. It offers advantages such as low cost, non-toxicity, good compatibility, and ease of processing, making it a suitable alternative to synthetic super disintegrants. Furthermore, the developed tablets provide benefits including improved patient compliance, rapid onset of action, enhanced bioavailability, and good stability, making them an effective dosage form for the management of hypertension.

Conflicts of interest

The authors declare that there is no conflict of interests regarding the publication of this article.

Acknowledgment

The authors sincerely express their gratitude to Dr. D.K Jain, Director of IPS Academy College of Pharmacy, Dr. Akash Yadav Principal (Department of Pharmaceutics), IPS Academy College of Pharmacy, Indore, for his continuous support and encouragement throughout the work.

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