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GREEN-ENGINEERED AMLODIPINE BESYLATE TABLETS FOR ENHANCED DISSOLUTION PERFORMANCE

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ABSTRACT

Hypertension is a chronic heart disease, and its management is a must by the use of pharmacological agents. A calcium channel blocker in the form of amlodipine besylate is a very popular drug in the management of high blood pressure and angina. However, the traditional pills or tablets may create a problem in swallowing for geriatric, paediatric, and dysphagic patients, and thus may result in adverse effects on patient compliance. A patient-friendly option is available in the form of porous tablets, also known as oro-dispersible tablets, which easily disintegrate in the mouth cavity and do not require the use of water. The purpose of this study is to plan and look into cost-effective porous amlodipine besylate tablets prepared through the direct compression method. Various formulations have been prepared using the commonly used superdisintegrants in varying ratios. Pre-compression and post-compression characteristics, wetting time, in-vitro dissolution, disintegration time, and content uniformity of the produced tablets have all been assessed. This composition led to good physicochemical properties. The optimized composition possessed good properties such as rapid dissolution, uniform distribution of the drug, mechanical strength, and rapid release of the drug. Based on this composition, concluded that the direct compression technique is simple and cost-effective for the preparation of porous amlodipine besylate tablets that may help to increase patient compliance in the treatment of hypertension.

KEYWORDS: Amlodipine besylate, porous tablets, Oro-dispersible tablets, direct compression, super disintegrants, patient compliance.

INTRODUCTION

Oral delivery of drugs offers the best patient compliance particularly when the dosing is required regularly or repeatedly. Oral solid dosage forms in tablet form are an important place in the pharmaceutical forms.[1] Over the last couple of years, the Porous or ODTs are gaining battery amongst various formulations of tablets.

Porous Tablets may be called as "Rapidly/ Fast Disintegrating," "Rapidly/ Fast Dispersing," "Rapidly/ Fast Dissolving," "Fast Melting," and "Orodispersible Tablets.[2-5] The European Pharmacopoeia defines an ODT as an uncoated tablet that dissolves rapidly in the mouth after consumption.[6] Furthermore, according to the European Pharmacopoeia, ODTs should disintegrate using standard disintegration test equipment in less than three minutes.[7]

The U.S. Food and Drug Administration claims, ODTs are solid dosage forms that include an active agent that dissolves in the mouth very quickly when placed on the tongue, typically in a matter of seconds. ODTs were proven to be more precise in dosing than liquid dosage forms, and their invention made them easier to use than traditional tablets, chewable tablets, and liquid dosage forms. Patients who are bedridden, old, mentally sick, children, and dysphagic are all treated with ODT. CCTs are also utilized to treat heart disease, diabetes, cancer, AIDS, and Alzheimer's. Patients who are always ill and need to take medication while traveling, such as those who have trouble locating water, are treated with CCTs.Good drug loading is achieved by rapid degradation of the drug in oral saliva, which takes less than 60 seconds to form an oral suspension. Additionally, when the tablet dissolves in the mouth, the drug can be absorbed through the mucous membranes. Additionally, drug candidates that are absorbed from the stomach after orally disintegrating tablets may have increased oral bioavailability, as reported.[4,8-11] Therefore, ODT was developed to treat high blood pressure and is useful to help hypertensive patients.

Hypertension is a chronic condition, with 1.13 billion cases of hypertension recorded in 2015. A rise in systolic blood pressure above 140 mm Hg is its definition. as well as a diastolic pressure more than 90 mm Hg.[12,13] Management of BP of hypertension patients is a health problem of great concern, affecting the general public. It is also a costly condition. However, if the above lifestyle modifications are inadequate, then the other forms of initial treatment comprise beta blockers, calcium channel blockers, angiotensin receptor blockers, angiotensin enzyme converters, and diuretics.

Amlodipine Besylate is a blocker of calcium channel from a new class of dihydropyridines. Amlodipine is utilized as initial therapy for hypertension and angina pectoris. Amlodipine (AML) is a calcium channel blocker that is ranked as one of the topmost widely used oral antihypertensive drug.[14] It is a simple derivative of dihydropyridine with vasodilatory properties by preventing calcium from penetrating the peripheral blood vessels and coronary artery smooth muscle cells.[15] One of the key factors is the drug's solubility pharmacokinetic properties of a drug, as it affects the rate of absorption of the drug and hence bioavailability. The solubility of AML Besylate salt is more than the free base form of the drug.[16] In addition, various amlodipine tablets are available in different strengths of 2.5, 5, 10mg.

Depending on the nature of the active ingredient, Porous Tablets can be prepared at a less costly method using the direct compression. Ideally, active component of the ODTs should be of low-median molecular weight, should be soluble in mouth saliva, and should remain partly lipophilic in the mouth, avoiding complete ionisation.[4,17,18]
Porous tablets are also known under various other names:

- Orally Disintegrating Tablets
- Tablets that Quick-melt or Rapid-melt
- Tablets that dissolve quickly
- Tablets that break down or dissolve in the mouth
- Tablets that Fast Disintegrating

People who travel or have limited access to water also suffer from the same problem. To get good results despite such weaknesses, a new and innovative drug delivery system called "Instant Tablets" or "Orally Dissolving Tablets" that dissolves in the mouth has been created. A novel tablet formulation that can dissolve and disperse in the saliva.[19,20]

Figure 1 shows the different types of new and conventional techniques used to manufacture fast-disintegrating tablets.

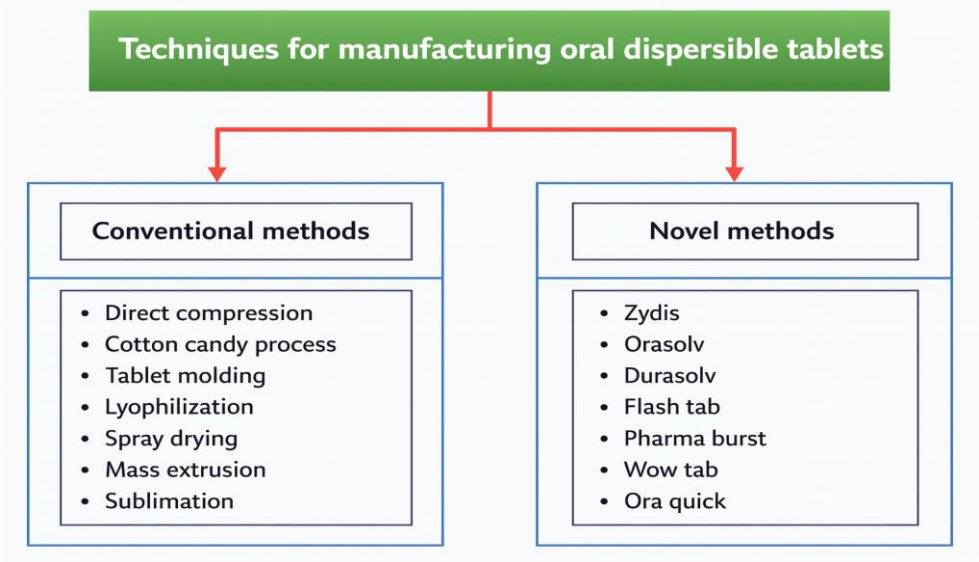

Fig. 1: Different ODTS preparation techniques.

Superdisintegrants: Disintegrants are substances that are typically used to make tablets and capsules that become active when water seeps into the dosage form. The disintegrants' stimulating activity causes the dosage form's shell to disperse into the solution medium. Superdisintegrants require extra caution. One to ten percent of the dose unit's entire weight is made up of superdisintegrants. Superdisintegrants are commonly employed in the same way as Crospovidone (CP), Croscarmellose Sodium (AC-Di-Sol), and Sodium Starch Glycolate (SSG).

Selection of Excipient: The appropriate creation of the oral dispersible tablet serves as the foundation for the excipient selection. Superdisintegrators damage the powder particles from which the granules were generated in addition to turning the pill into granules.[21]

Super Disintegrants: These agents mainly of two types based on availability in the market.

Synthetic Super Disintegrants: These compounds are used in the formulation of oral dispersible tablets, as the disintegration, wetting, etc., properties of these tablets are superior. These drugs are used at low concentrations.[22]

Natural Super Disintegrants: These drugs are of natural nature, easily available, inexpensive, non-irritating, and used as alternatives instead of synthetic drugs, as they are of no use.[23]

Mechanism of Action of Disintegrating Agents: Disintegrating agents assist in the disintegration of tablets through various methods, including water absorption, known as 'wicking'; deformation, also known as 'recovery'; repulsion; and the 'heat of wetting' concept. It has not been possible to account for the disintegrating agents' performance through the application of any single mechanism, but rather through the combined effect of the above-mentioned methods.[24]

2.1 MATERIALS

Cipla Ltd. Pithampur provided the gift sample of amlodipine besylate. Superdisintegrants such crospovidone, croscarmellose sodium, and SSG were selected. Mannitol, aspartame, and magnesium stearate are employed as lubricants, sweeteners, and flavor enhancers, respectively, while microcrystalline cellulose serves as a diluent. All the excipients and chemicals used were of pharmaceutical grade.

Determination of melting point: The drug's melting point is ascertained in order to ascertain the purity of the substance under test. Using a melting point apparatus supplied by Lap Hosp, the drug's melting point is ascertained by measuring the drug substance's melting point using the capillary method.[25]

Solubility Analysis: During the analysis of the drug substance's solubility, the most appropriate solvent system that could dissolve the drug was established. A mechanical shaker was employed to carry out the solubility analysis.[26]

Calculating λmax and creating the amlodipine besylate calibration curve: The medication was precisely weighed; that is, 100 mg of the medication was weighed and added to a 100 ml volumetric flask containing a phosphate buffer solution with a pH of 6.8.The solution was made according to the instructions. Ten milliliters of this solution were taken, and it was diluted in another volumetric flask to the necessary concentration. A UV spectrophotometer was used to test the absorbance of the produced solutions between 200 and 400 nm.[27]

Drug-Excipients Interaction Studies: The infrared spectroscopy method provides an in-depth view of the structure of the drug. The graph obtained using the infrared spectroscopy method contains many absorption bands. Compared to the UV method, which contains fewer peaks on its graph, the infrared method provides more details about the drug's structure. A Shimadzu FTIR-8400S spectrometer was employed to carry out the drug-excipients interaction analysis. Using a mortar and pestle in a 1:100 ratio, the medication was reduced to a fine powder. After then, 15 tons of pressure were applied to the powder.[28]

The medication pellet was then extracted by turning the side valve counter clockwise to alleviate the pressure. The sample holder was filled with the medication. Infrared spectroscopy was carried out using a range of 400-2000 cm-1, a resolution of 2 cm-1, and a scanning speed of 2 mm/s.

2.2 METHODS

Using the direct compression method to create porous tablets: Table 1 shows the recipe for dissolving oral amlodipine besylate tablets prepared by the direct compression method. The direct compression approach involves the following steps:

- Sieving of the excipients through a 60-mesh screen is carried out.
- Microcrystalline cellulose and the drug are mixed in small portions and kept for storage.
- The formula is weighed and mixed in the given order.
- During the lubrication step, magnesium stearate is added as the lubricant.
- Finally, the compressed tablets of 6 mm flat and round shapes are produced using Proton Minipress.[29]

Table 1: Formulation Composition of Amlodipine Porous Tablets.

Ingredients in milligrams	F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8
Amlodipine Besylate	10	10	10	10	10	10	10	10
Magnesium stearate	1	1	1	1	1	1	1	1
Mannitol	63	61	63	61	63	61	63	61
Aspartame	6	6	6	6	6	6	6	6
Flavour	2	2	2	2	2	2	2	2
LBG*	-	-	-	-	-	-	8	10
PO*	-	-	-	-	8	10	-	-
MCC*	10	10	10	10	10	10	10	10
CP*	8	10	-	-	-	-	-	-
CCS*	-	-	8	10	-	-	-	-
Total Wt.	100	100	100	100	100	100	100	100

*Abbreviation of all short forms: MCC (Micro-crystalline Cellulose), CCS (Croscaramallose), PO (Plantago Ovate), CP (Crospovidone), LBG (Locust bean gum)

Evaluation of porous tablets: After the preparation of porous tablets, various tests were conducted on the prepared porous tablets to evaluate the changes in the weight, hardness, content homogeneity, friability, wetting time, in vitro release, and in vitro disintegration time studies.

Weight differences: 20 tablets were randomly taken for each formulation. The weights of the tablets were measured individually for each of the 20 tablets of each formulation on a digital scale. Twenty tablets were weighed on average. Each tablet's weight change was computed.[30]

Friability assess: A Roche free biller was used to assess the porous tablets' friability. A crushing drum is filled with a pre-weighed quantity of tablets for this experiment. For four minutes, the machine operates at a speed of 25 ± 1 rpm. This is equivalent to one hundred revolutions. The tablet is dropped six inches with each revolution. Following the experiment, the tablets are weighed again, and the calculation[31] F % = {(Starting weight - Final weight)/Starting weight} * 100 is used to determine the percentage of fracture.

Contents of the medicine: Ten milligrams of amlodipine besylate (ABD) were precisely weighed after the medication was broken up into tiny bits. One hundred millilitres of methanol were used to dissolve it. One millilitre of this mother liquor was diluted with ten millilitres of methanol. One millilitre of this solution was diluted once again by adding ten millilitres of methanol. Spectrophotometric analysis of the drug content was performed at 239 nm.[32]

Wetting time: A small Petri dish with folded tissue paper was filled with ten milliliters of water. The time it took for the tablet to get entirely wet was noted when it was placed on tissue paper. The porous nature of the tablet is linked to its behavior throughout this period. This is also connected to superdisintegrants' hydrophilic and swelling properties.[33]

RESULTS AND DISCUSSION

Sensory properties

Color – White or cream.

Taste – Bitter.

Odor – Odorless.

Melting Point: The drug sample's melting point was determined to be 203°C. The melting points of drugs were found using a Lap Hosp digital melting point meter. This apparatus works by finding the average value of three consecutive readings for determining the melting points of drugs. The melting point range for this drug is between 199°C and 202°C.

Partition Coefficient: Partition Coefficient: The shaking flask method was used to determine this drug's partition coefficient. This medication's partition coefficient was determined to be 2.26.

Solubility: Amlodipine besylate was discovered to be soluble in a number of different solvents. The medication was shown to be best soluble at pH 6.8 in phosphate buffer, 0.1 N HCl, and methanol. The drug's solubility results are shown in Table 2.

TABLE 2: SOLUBILITY OF DRUG IN VARIOUS TYPES OF SOLVENTS

Solvents	Solubility
Acetate buffer pH 4.5	Slightly soluble
Distilled water	Slightly soluble
Phosphate buffer pH 6.8	Slightly soluble
0.1 N HCL	Soluble
Methanol	Freely soluble

The λ max is a compound of immense importance in drug development. A UV-Visible spectrum was recorded using a UV-Vis Spectrophotometer (UV 1800, Shimadzu, Japan). Acetate buffer solution (pH 4.5), phosphate buffer solution (pH 6.8), and 0.1 N HCl were the solvents utilized. The range of λ max scanned was from 400 down to 200. The maximum observed wavelength was 239 nm.

In phosphate buffer with a pH of 6.8, λmax was determined at 239.0 nm.
For 0.1 N HCl, λmax is determined to be 238.8 nm.
λmax was determined to be 239.2 nm in acetate buffer at pH 4.5.

FTIR studies of drug-excipient interactions

In order to assess match, we have performed infrared spectra on the drug and some of the excipients. For this purpose, mixtures of AML, excipients, and ODT formulation blends were subjected to infrared spectra. For these experiments, we have employed a Fourier transform infrared spectrophotometer (Shimadzu IR-Affinity 1S, Japan). Scanning was performed between 4000 and 400 cm−1. If new bands appeared, disappeared, or if there was no appearance of characteristic peaks related to the formulation blends, we have suspected incompatibility between the drug and excipients. IR spectra related to drug-excipients mixtures are depicted in Figures 2, 3, and 4.

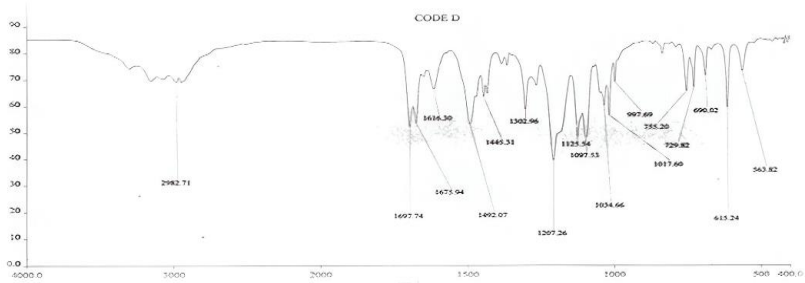

Fig. 2: Amlodipine pure drug FTIR spectrum.

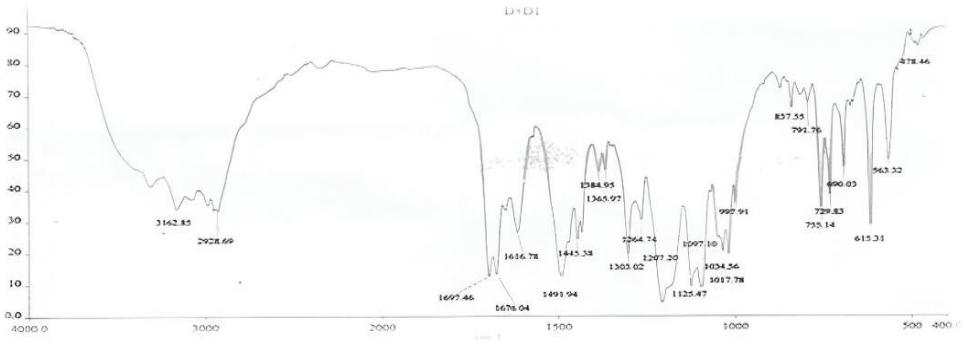

Fig. 3: Amlodipine & Locust bean gum FTIR spectrum.

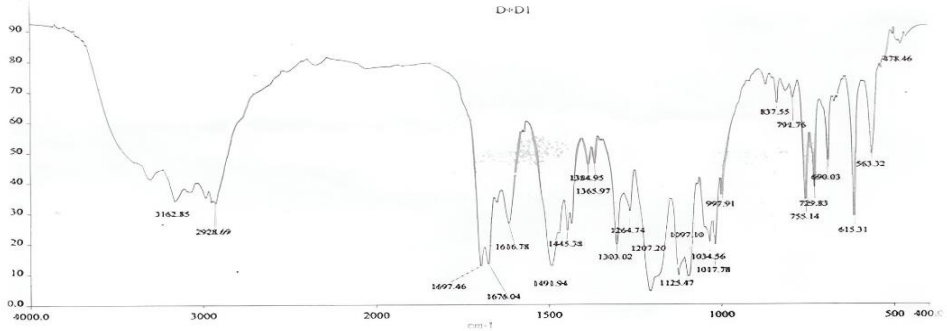

Fig. 4: *Amlodipine* & *Plantago ovata* FTIR spectrum.

Formulation Parameters: In the present study, the quality of the tablet formulation was assessed by testing the formulations in batches. Random samples were taken from the formulations and were visually examined. The tablets were flat, circular, and white. The ingredients were also found to be white. The formulations were found to have very similar values. The tablet thickness varied between 2.9 to 3.1 mm. The variation of weight of formulations remained within the limits of 10%. The formulations were standardized to a total weight of 99.0 to 102.0 mg. The spectrophotometric method proved that the formulations contained 96 to 98% of the drug. There were no variations among the formulations. LBG exhibited quick water absorption and a quick wetting time because of the porous tablets it helped create. This is because it will be in contact with the tongue when placed in the mouthThe amount of time it takes for the pill to dissolve in the mouth is correlated with the wetting time. For the tablets with varying percentages of CP, CHC, LBG, and PO, the following table displays hardness, brittleness, weight change, content homogeneity, wetting time, in vitro disintegration time, and so on.The table demonstrates that the time it takes for a tablet to dissolve in the mouth reduces as the concentration of CP, CHC, LBG, and PO in the tablet rises from 8 to 10%.

Table 3: Post-Compression Parameter Values.

Batches	Weight variation	*In-Vitro* D.T. (sec)	Wetting Time (sec)	Content Uniformity	Hardness (Kg/cm^2)	Friability (%W/W)
F1	Pass	28.11	26.28	96.0 ± 05	2.55	0.56
F2	Pass	24.00	19.42	96.5 ± 16	2.54	0.57
F3	Pass	45.58	43.31	94.75 ± 33	2.33	0.58
F4	Pass	38.46	32.80	94.56 ± 12	2.58	0.58
F5	Pass	25.58	18.71	96.94 ± 39	2.53	0.57
F6	Pass	18.64	15.49	97.27 ± 45	2.54	0.60
F7	Pass	32.17	28.40	95.55 ± 32	2.54	0.71
F8	Pass	25.08	18.49	95.46 ± 11	2.56	0.75

Dissolution Profile: A USP II device was used to test the formed tablets' drug release profile for in vitro drug release. 900 millilitres of pH 6.8 phosphate buffer solution, which mimics the conditions in the mouth, were within the apparatus. The temperature of the solution was kept at 37 ± 0.5°C. The machine's rotational speed was kept constant at 50 rpm. Every five minutes, samples of the solution were collected. Whatman filter paper was used to filter the mixture. The absorbance and concentration of the solution were measured using a UV spectrophotometer. The wavelength was kept constant at 239 nm.

Figure 5 is a plot of %CPDR vs. time for all formulations.

Optimization Study: The optimization criteria were drug content, in vitro drug release, and disintegration time. Based on all criteria, it was determined that the batch F6 was the best batch. The optimized batches were subjected to stability investigations in the further studies of this research.

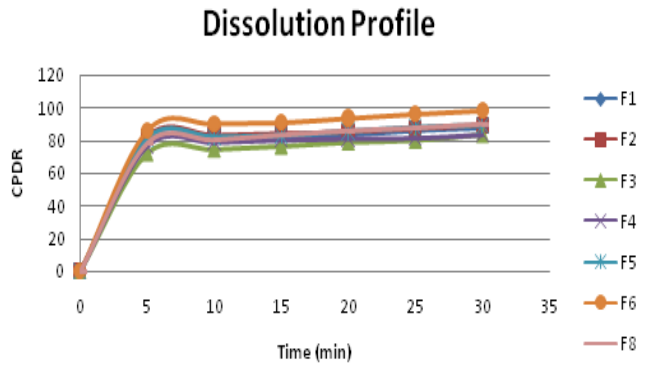

Fig. 5: All batches' drug release profile.

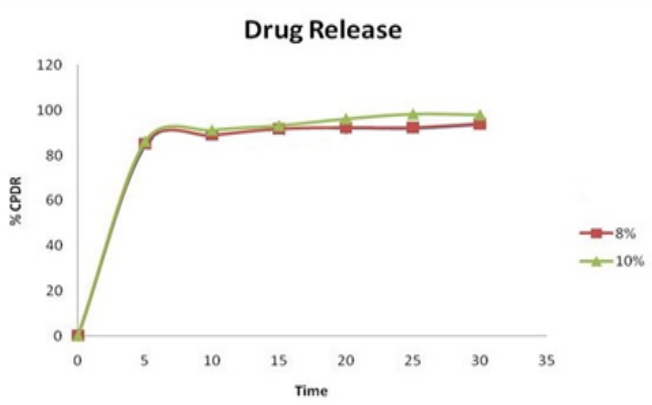

Fig. 6: Locust bean gum batch release profile.

Table 4: F6-Optimized Batch In Phosphate Buffer Solution *In-Vitro* Drug Release.

Formula	Time in minutes	Abs	Conc	%CPDR	CDR
	0	0	0	0	0
	5	0.294	9.573	86.168	8.616
	10	0.311	10.133	91.186	9.118
F6 (10%)	15	0.322	10.355	93.168	9.316
	20	0.333	10.685	96.156	9.615
	25	0.336	10.921	98.324	9.832
	30	0.335	10.886	97.982	9.798

The introduction of batch F6 was done by using a phosphate buffer solution simulating the oral cavity. The pH value of the solution was about 6.8. The results revealed that the F6 tablet released more than 85% of the drug in 5 minutes. It was also revealed that about 98% of the drug was released in 30 minutes. These results were represented in the form of graph (Figure 6). The parameters were listed in Table no 4.

Stability studies: The ICH's recommendations for zones III and IV were followed while determining the improved formulation's stability. The mixture was enclosed in aluminum foil and maintained at 40 ± 2°C and 75 ± 5% relative humidity in a chamber with constant humidity. As indicated in Table 5, after 30 days, stability tests were carried out, during which time appearance, weight change, hardness, disintegration time, content, and medication release were all monitored.

Table 5: Optimized Batch Stability Study Data (F6).

Parameters	F6 1 Day	F6 15 Days	F6 30 Days
Hardness (Kg/cm^2)	2.5	2.5	2.5
Drug content (%)	98.24	98.23	97.88
Weight increase (mg)	100	101.5	103
% Drug released (5 min)	86	85	84
D.T (Sec)	18	18	19

CONCLUSION

Preliminary tests were carried out on amlodipine besylate using FTIR. The compatibility of the drug substance with excipients and superdisintegrants was checked. Two superdisintegrants, synthetic superdisintegrant, and natural superdisintegrant, were used to prepare porous amlodipine besylate tablets by direct compression. Among these, F6, which contains locust bean gum, showed satisfactory results in terms of efficiency and was able to release the drug easily. The choice of the prescription was based on high marks and satisfaction. Stability parameters were checked after 30 days to ensure the stability and retention of the original properties of the drug. The parameters were found to be satisfactory, with over 80% efficiency in releasing the drug within 5 minutes and nearly 98% efficiency in releasing the drug within 30 minutes. The high efficiency of F6 in releasing the drug can be explained by the ability of the superdisintegrant to enhance the solubility of the drug. The hardness of the tablets was constant, and the time taken for the tablets to disintegrate was minimum, possibly because of the synergistic effect of locust bean gum.

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CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest.

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