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Research Article

Formulation and Evaluation of Fast Disintegrate Tablet of Amlodipine Besylate

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ABSTRACT

Fast disintegrating tablets (FDTs) have revolutionized oral drug delivery by offering rapid disintegration and dissolution in the oral cavity without the need for water, thus enhancing patient compliance and convenience, especially in pediatric, geriatric, and dysphagic populations. Amlodipine Besylate, a widely used calcium channel blocker for hypertension and angina, often encounters challenges related to bitter taste, poor aqueous solubility, and delayed onset of action in conventional dosage forms. Formulating Amlodipine Besylate as an FDT can overcome these issues by enabling faster disintegration, improved palatability, and potentially enhanced bioavailability. This review comprehensively examines various formulation strategies, including the selection of superdisintegrants, binders, fillers, and taste masking techniques, alongside different preparation methods such as direct compression, wet granulation, and sublimation. The evaluation parameters critical for FDTs such as disintegration time, hardness, friability, dissolution profile, and stability are discussed in detail. Additionally, recent advancements like the use of natural superdisintegrants, nanoparticle incorporation, and 3D printing technology are highlighted for their potential to further optimize Amlodipine Besylate FDTs. The article also addresses formulation challenges and future perspectives, emphasizing the role of innovative excipients and technologies in the development of effective, patient-friendly fast disintegrating tablets for cardiovascular therapy.

INTRODUCTION

Oral drug delivery remains the most preferred and convenient route for administering therapeutic agents due to ease of administration, patient compliance, and cost-effectiveness. However, conventional oral dosage forms such as tablets and capsules often pose difficulties for specific patient populations, including pediatric, geriatric, and dysphagic patients, who may struggle with

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swallowing solid dosage forms. This limitation has driven significant research into alternative dosage forms that improve patient compliance and therapeutic efficacy 1. Superdisintegrants like sodium starch glycolate and croscarmellose sodium are used to deliver medications to living things. To get the desired result with the fewest possible side effects, the medication must be taken at work in a specific amount and concentration. Superdisintegrants including sodium starch glycolate, croscarmellose sodium, and crospovidone1 are used in the two fundamental processes for making tablets for oral disintegration. To improve their pore structure, tablets can also be lyophilised and vacuum-dried. For all methods, direct compression is used because it is reliable, efficient, and reasonably priced. Oral administration is a highly prevalent method of administering up to 50–60% of all dose types. Due to their exceptional ease of use, accuracy in Particularly popular are solid dose forms for pain relief, self-medication friendliness, dosage, and above all patient compliance. The most widely used solid dosage forms are capsules and tablets. widely used; nonetheless, swallowing issues are a major disadvantage for some patients. Drinking water is essential to taking an oral dosage form well. When traditional dose forms, such as tablets, are taken without water, people often experience discomfort. [2]

1.1 SYSTEM FOR ORAL DRUG DELIVERY [2-3]

A possible method for achieving a quick onset of action or better bioavailability for medications with a high first-pass metabolism is oral mucosal drug administration. Because a rapidly dissolving medication can enter the systemic circulation immediately through the oral mucosa, there is increasing interest in creating alternate dosage forms, such as oral fast disintegrating tablets. These dosage forms are also practical for older people who have trouble swallowing, youngsters, and situations where potable liquids are not available. But in addition to formulation challenges, the active ingredient's properties must be suitable to guarantee medication dispersion into the systemic circulation following intraoral delivery. The need for lipophilic medications to be stable, soluble, and rapidly dissolved can provide challenges.

With saliva, they have the unique capacity to breakdown and release the drug fast, eliminating the need for water during administration. They also change into a liquid or soft paste that is safe to ingest and doesn't choke a person. These tablets are mostly prepared with super disintegrants such as crosspovidone, sodium starch glycolate, and croscarmellose sodium.

The inclusion of super disintegrants in this formulation helps the pill break down into smaller pieces, which speeds up the beginning of action. In order to mask the bitter taste of the active substance, most rapidly dissolving tablets must include other chemicals. The veiled active component, soluble excipients, and insoluble excipients are subsequently swallowed by the patient's saliva. It has been established that speed causes an increase in the rates of absorption, commencement of action, and dissolution. Certain drugs are absorbed from the mouth, throat, and oesophagus, avoiding the first pass metabolism, as saliva moves down into the stomach. The drug's bioavailability is therefore significantly greater than that of conventional tablet dosing forms.

The primary cause of Fast disintegrate tablet dissolution and disintegration is the action of super disintegrants, which have a high rate of disintegration due to the porous structure of the formulation, which is created by both swelling and water absorption. The ideal concentration of super

disintegrants can be found using the critical disintegrant concentration; below this concentration, the tablet disintegration time is inversely proportional to the concentration of superdisintegrants.

MATERIALS AND METHODS:

Materials:

Amlodipine besylate was obtained from Hetero Drug Limited, Mumbai. sodium starch glycolate, Croscarmellose (Acdi-sol) (Super disintegrant), Manitol (Sweetening agent), Aerosil (Glidant), Magnesium Stearate (Lubricant) are purchases from Modern Chemical industries-sinnar Crospovidone (Super disintegrant), Microcrystalline cellulose (Binder) are purchases from Research lab fine chem industries, Mumbai.[5]

Methods:

Pre-formulation study

A. Ultra violet spectroscopy:

Determination of Analytical Wavelength (λmax):

In order to create a standard stock solution of Amlodipine Besylate, 10 mg of precisely weighed Amlodipine Besylate was dissolved in 100 ml of water in a 100 ml volumetric flask. The volume was then increased to 100 ml with water to get a stock solution of 100µg/ml. 2.5 millilitres of the standard stock solution were pipetted into a 10-milliliter volumetric flask. Water was added to get the volume up to 10 ml.

Between 200 and 400 nm, the resultant solution, which contained 10µg/ml, was scanned.

B. Drug-excipient compatibility study: FTIR :

Research on drug-excipient compatibility was conducted FTIR measurements. All formulations' FTIR spectra were acquired using a Brunker IR-Spectrophotometer, which has a wavelength range of 4000-400 cm-1.

Preparation of Amlodipine besylate Fast disintegrate tablet by direct compression method:

All materials, with the exception of Aerosil and magnesium stearate, were weighed precisely and mixed uniformly in a mortar and pestle for fifteen minutes. The prepared powder mixture was run through sieve number 60. After passing through filter number 30, Aerosil and magnesium stearate were added and combined for an additional ten minutes. 200 mg of a precisely weighed, uniformly blended powder blend was manually fed into a Cadmach tablet compression machine, which used 8 mm, breakthrough, and flat-faced punches to crush the mixture with consistent compression force and hardness. Nine formulations in all were created.

Experimental Design:

A methodical and scientific way to investigate the connection and interplay between independent and dependent variables is through experimental design. 23 In order to optimise the formulas, a complete factorial design was suggested. A sufficient degree of flexibility is provided by the chosen design to ascertain the primary impacts of both individual variables and factor interactions.

Table 1: Composition of independent variables and their levels for the preparation of Amlodipine besylate Fast disintegrate tablet

Sr. No.	Independent factor	Unit	Low (-1)	High (+1)
1	Croscarmellose sodium	mg	**5**	**20**
2	sodium starch glycolate	mg	**5**	**20**

3	crospovidone	mg	**5**	**20**

Table 2: 2^3 full factorial design for formulation designed using Stat-Ease Design-Expert® soft-ware (Version 8.0.7.1)

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Amlodipine besylate	10	10	10	10	10	**10**	10	10
MCC	95	110	110	125	125	**110**	125	140
Crospovidone	20	20	20	20	5	**5**	5	5
Sodium starch glycolate	20	5	20	5	5	**20**	20	5
Croscarmellose Sodium	20	20	5	5	20	**20**	5	5
Mannitol	25	25	25	25	25	**25**	25	25
Aerosil	5	5	5	5	5	**5**	5	5
Magnesium stearate	5	5	5	5	5	**5**	5	5
Total weight	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**

Three independent variables (factors), concentration of sodium starch glycolate (A), Croscarmellose Sodium (B), and crospovidone were chosen and assessed at two different levels: low (-1) and high (+1) considered as independent factors of disintegration time, and drug release were selected as dependent variables (responses). The range of factor was selected, in order to find out its impact on the responses or dependent variables. Data were analyzed using Design Expert® (version 8.0.7.1) software available from Stat-Ease Inc., Minneapolis, MN. Table 1 provides the details.

EVALUATION:

Pre-Compression Parameters:

1. **Bulk Density (Db) and Tapped Density (Dt):**

After being gently shaken to break up agglomerates, a suitable amount of powder from each formulation was added to a 10 mL measuring cylinder. Following the observation of the initial volume, the cylinder was allowed to descend under its own weight at intervals of two seconds, falling to a hard surface from a height of 2.5 cm. The tapping was kept up until the volume didn't change any more.

The following formula was used to calculate the bulk density (Db) and the tapped bulk density (Dt).[7]

$$Db = \frac{Weight\ of\ Powder}{Volume\ of\ Packing}$$

2. **Carr's Index:**

Carr's compressibility index was used to calculate the powder blend's compressibility index. Evaluating a powder's Db, Dt, and packing down rate is a straightforward test. The following is the Carr index formula.

$$Carr'\ Index = \frac{Weight\ of\ Powder\ X\ 100}{Volume\ of\ Packing}$$

3. **Hausner's Ratio:**

It can be expressed as follows and is found by comparing the bulk density to the tapped density:

$$Hausner\ ratio = \frac{Dt}{Db}$$

Where, Db is the powder's bulk density and Dt is its tapped density.

4. **Angle of repose:**

The greatest angle that can exist between the surfaces of a powder pile and a horizontal plane is known as the angle of repose. The angle of repose can be used to calculate the frictional force in loose powder or granules using the following equation:

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

Where, r denotes the radius of the pile's base, h is the pile's height, and θ is the angle of repose.

Post-compression parameters:

1. Weight variation:

The average weight of twenty tablets was calculated after they were chosen at random. Subsequently, the weight of each tablet was measured and compared to the average weight.[8]

2. Hardness:

A Monsanto hardness tester was used to calculate the tablet crushing load, which is the force needed to break a tablet by compression in the radial direction.[9]

3. Friability:

The purpose of this test was to evaluate the effects of shock and friction. A pre weighed sample of ten tablets was spun at 25 revolutions per minute for approximately four minutes in the Roche Friabilator. After the tablets were reweighed and dedusted, the friability percentage was computed using the formula. Weight loss from compressed tablets shouldn't exceed 1%.[10]

$$Friability\ \% = \frac{Initial\ wt. - Final\ wt.\ X\ 100}{Initial\ wt.}$$

4. Thickness Test:

Placing the tablet between the two arms of the vernier callipers allowed for the measurement of thickness. A measurement was made of the thickness of five tablets.

5. Disintegration Time Test:

The in-vitro disintegration time was determined using disintegration test apparatus. A tablet was placed into each of the six tubes of the equipment, and one disc was added to each tube. It was determined how many seconds it would take for the pill to disintegrate entirely and leave no appetising lump within the gadget.

6. Content Uniformity:

The percentage of the active ingredient in the tablet was Amlodipine Besylate using the UV Spectrophotometer method with the Amlodipine Besylate Fast Disintegrate tablet in phosphate buffer (pH 6.8), in accordance with the range of Pharmacopoeia. Each batch's five tablets were weighed and ground into a powder. In order to create a stock solution, 20mg of equivalent weight of Amlodipine besylate tablet powder was precisely weighed, dissolved in 100ml of phosphate buffer (pH 6.8) in a 100ml volumetric flask, sonicated for an hour, filtered, appropriately diluted, and tested for drug content at 265nm using a UV-Visible Spectrophotometer.[11]

7. Wetting time of water absorption

The wetting time characteristic of the loose disintegrant powder allows for an evaluation of the intrinsic swelling and wettability of the super disintegrants. The Fast disintegrate tablet wetting time is an important parameter that has to be assessed in order to shed light on the tablet's disintegration properties; a shorter wetting time denotes a quicker tablet breakdown. The wetting time was conducted at room temperature. A piece

of tissue paper that had been folded twice was placed inside a tiny petri dish that had a diameter of 10 cm and contained 6 millilitres of water. While the tablet was resting on the paper, the amount of time it took for water to reach the top surface of the tablet was recorded. To calculate the water absorption ratio, the wet tablet was taken out of the petri dish and weighed. The water absorption ratio (R) was calculated using the following formula.

R=100×Wa- Wb/Wb

8. In vitro Dissolution Studies:

The USP Type II Dissolution test apparatus was used to determine the dissolution profiles of famotidine tablets. The paddle speed was set to 50 rpm. Dissolution took place in 900 millilitres of pH 6.8 phosphate buffer that was kept at 37±5ºC. Five millilitres of the dissolution medium were extracted at 3, 6, 9, 12 and 15 minutes with intervals of three minutes, and filtered through Whatmann filter paper. Using a UV-visible spectrophotometer, the amount of drug dissolved was calculated by measuring the sample's absorbance at 238 nm. To maintain the constant volume throughout the test, an equal volume of fresh medium pre-warmed at 37±5ºC was added to the dissolving medium after each sampling. Disso software was used to calculate the average percentage of drug release after three trials were completed for each batch.[12]

RESULTS AND DISCUSSION:

A. Standard Calibration curve of Omeprazole in 0.1N HCI:

Accurately weighed quantity of Amlodipine Besylate (10 mg) was dissolved in little quantity of distilled water and volume was made up to 100ml with the same (100 µg/ml). Then withdraw 2,4,6,8,10ml from the above solution in to separate 10 ml volumetric flasks and made up the volume to 10ml to produce 2, 4, 6, 8, 10µg/ml respectively. And the absorbances were taken at 2238 nm.

This procedure was performed in triplicate to validate the calibration curve.

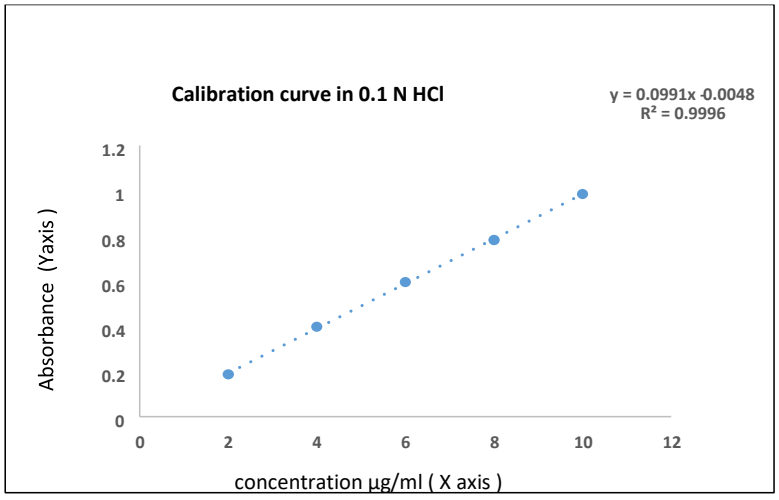


Figure No. 1 : Calibration Curve of Omeprazole in 0.1N HCl

B. Drug- excipient compatibility study:

Fourier Transform Infrared Spectroscopy (FTIR): The FTIR spectra of pure drug and pure drug + excipient was taken and shown in figure 2.

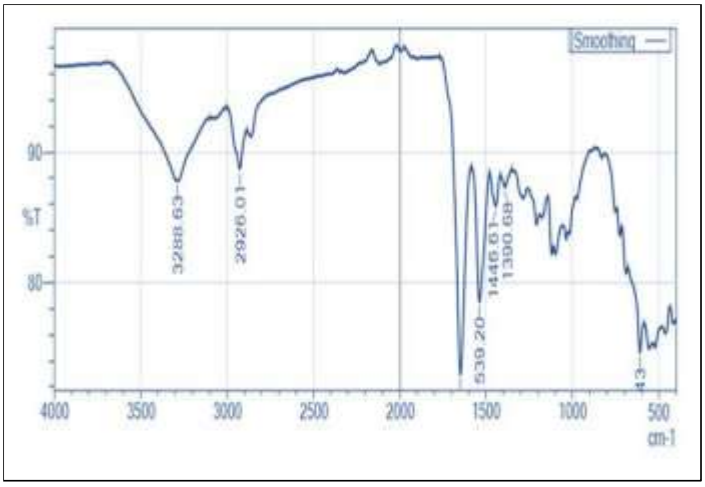


Figure No. 2 : FTIR Spectrum of Pure Omeprazole

When comparing pure drug + excipient to pure drug, these spectra showed no discernible shift or alteration in the absorption peaks. It demonstrates that the medicine and excipients do not significantly interact.

Pre compression evaluation of formulation powder:

All formulations had bulk densities between 0.45 ± 0.008 and 0.47 ± 0.0017 g/ml and tapped densities between 0.46 ± 0.0214 and 0.55 ± 0.0220 g/ml. The powder blend's angle of repose for all formulations fell between 20.8 ±0.2645 and 30.6 ±0.3464; this falls within the outstanding or Good range, indicating the outstanding flowability required for the powder to flow well. All formulations' powder blends had compressibility indices between 11 ± 0.0021 and 14.74 ± 0.0006 percent. which is within the acceptable range indicates that the combination is good or fair and has adequate powder flow and compressibility qualities for a correct powder blend flow. It was discovered that the Hausner's ratio fell between 1.11 ± 0.0020 and 1.20 ± 0.0015. These findings all suggested that the powder.

Table 3: Pre-Compression Parameters for the Formulations

Formulation Code	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner's Ratio	Angle of repose (°)
F1	0.47±0.0013	0.51±0.0230	14.74±0.0006	1.16±0.0012	25.7±0.0645
F2	0.45±0.0008	0.50±0.0098	11.50±0.0003	1.11±0.0020	20.31±0.3055
F3	0.46±0.0013	0.55±0.0064	14.48±0.0070	1.14±0.0018	27.05±0.0725
F4	0.47±0.0017	0.55±0.0218	13.98±0.0018	1.16±0.0021	28.3±0.2081
F5	0.46±0.0013	0.51±0.0108	11.00±0.0021	1.20±0.0015	20.8±0.2645
F6	0.47±0.0015	0.55±0.0220	14.36±0.0016	1.16±0.0016	30.6±0.3464
F7	0.47±0.0103	0.46±0.0214	14.20±0.0016	1.15±0.0057	24.5±0.5932
F8	0.45±0.0043	0.53±0.0215	11.35±0.0020	1.12±0.0115	22.9±0.2081

All values are expressed as mean± SE, n=3.

Post compression evaluation formulation (tablet):

All formulations had weight variations between 202.10±0.1125 and 206±0.161 mg and diameters between 7.65±0.007 and 7.92±0.007 mm. All formulas' tablet thicknesses were determined to be within a satisfactory range, ranging from 2.76±0.009 to 2.99±0.007 mm. The tablets of every formulation had a hardness of 3.0±0.007-

3.5±0.012 kg/cm2, which is either good or within an acceptable range. Friability was determined to be between 0.8±0.6 and 0.9±0.14%. The drug content was measured and found to be within an acceptable range. It was discovered that the drug concentration ranged from 90.27 ± 0.5350 to 99.43 ± 2.0351%w/w (i.e. 99-101% w/w). According to the Indian Pharmacopoeia 2007, the range that was discovered fell within the authorised range.

Table 4: Post-Compression Parameters for the Formulations

Formulation Code	Weight variation (mg)	Diameter (mm)	Thickness (mm)	Hardness (kg/cm^2)	% Friability	Drug content (%)
F1	203.6±0.145	7.72±0.007	2.86±0.010	3.5±0.012	0.9±0.14	90.27±0.5350
F2	204.15±0.125	7.85±0.008	2.96±0.009	3.27±0.011	0.9±0.13	93.26±0.4079
F3	205.15±0.141	7.65±0.007	2.99±0.007	3.35±0.008	0.8±0.11	91.09±0.7794
F4	207.10±0.118	7.82±0.007	2.76±0.009	3.26±0.010	0.9±0.05	95.14±1.1714
F5	205±0.130	7.79±0.007	2.80±0.008	3.10±0.007	0.9±0.007	90.24±0.1401
F6	202.10±0.125	7.82±0.007	2.87±0.006	3.00±0.007	0.9±0.11	99.43±2.0351
F7	205.40±0.130	7.75±008	2.80±008	3.30±0008	0.8±0.06	93.94±1.9813
F8	206±0.116	7.92±007	2.90±006	330±007	0.8±0.09	92.59±0.2523

Disintegration time:

The USP Disintegrate test device was used to evaluate the tablets for in-vitro disintegration time. (VTD-DV Veego Scientific) All eight formulations had in-vitro disintegration times ranging from 16±1.8973 to 31±2.025 seconds. The formulations comprising Crospovidone and Croscarmellose sodium showed the fastest disintegration. Additionally, it was observed that the disintegration time decreased when the content of sodium starch glycollate and croscarmellose sodium rose, followed by sodium starch glycollate and crospovidone. Wetting duration and ratio of water absorption for each of the eight formulations, the wetting time was measured twice. 13±2.3803 to 31±1.7973 seconds are the values.

Crosscarmellose sodium had a quick wetting time, followed by sodium starch glycollate and crosspovidone. Here, too, it was found that the time required for wetting decreased as the disintegrant concentration rose. A crucial criterion for comprehending the ability of disintegrants to enlarge in the presence of a little amount of water is the water absorption ratio, which was computed. It was shown to be between 82.45 ±5.92 and 115.66 ±1.41%. (Table 5) With an increase in the content of sodium croscarmellose, crosspovidone, and sodium starch glycollate, the water absorption ratio (R) rises. Thus, F5 has the maximum water absorption of 115.66%.

Table 5: Post-Compression Parameters for the Formulations

Formulation code	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio (%)
F1	31±2.025	28±3.1863	85.26±0.983
F2	19±1.3142	24±2.0030	95.30±3.982
F3	30±1.7973	16±1.3142	105.40±1.88
F4	19±1.3142	31±1.7973	82.45±5.92
F5	19±1.8963	19±1.3142	92.80±5.10
F6	16±3.2763	13±2.3803	115.66±1.41
F7	18±1.3032	27±2.0020	88.24±6.02
F8	30±1.3142	20±1.3142	89.66±5.40

In Vitro Dissolution Study:

The F8 formulation was used to conduct follow-up drug release research in phosphate buffer PH6.8. For all formulations, the percent cumulative drug release ranged from 71.45±0.1285 to 99.43±2.0351%. The higher the concentration of super disintegrants, the higher the drug release. The maximum drug release, or 99.43%, was seen in the first 15 minutes with F6 formulations.

Table 6: Percentage of Drug Release of Famotidine Formulations ODTs.

Time (min)	Formulation code (Drug Release %)							
	F1	F2	F3	F4	F5	F6	F7	F8
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3	68.25±1.0722	69.9±1.2227	70.45±1.1015	70.37±0.0305	60.5±0.1228	71.45±0.1285	76.55±0.3821	65.25±1.1149
6	70.49±0.1283	75.72±0.0305	72.44±1.3030	78.46±0.1228	75.07±0.1216	81.62±1.1832	81.12±1.4953	79.95±1.2989
9	75.15±1.1829	84.31±0.8357	81.87±0.6992	82.92±1.3308	83.45±0.2523	88.76±0.2663	84.45±1.0001	84.28±0.5881
12	83.27±0.5535	89.29±0.1216	85.93±0.8304	93.74±0.1450	91.41±1.1328	94.61±0.2165	89.91±1.2189	86.44±0.4384
15	90.27±0.5350	93.26±0.4079	91.09±0.7794	95.14±1.1714	90.24±0.1401	99.43±2.0351	93.94±1.9813	92.59±0.2523

All values are expressed as mean± SE, n=3.

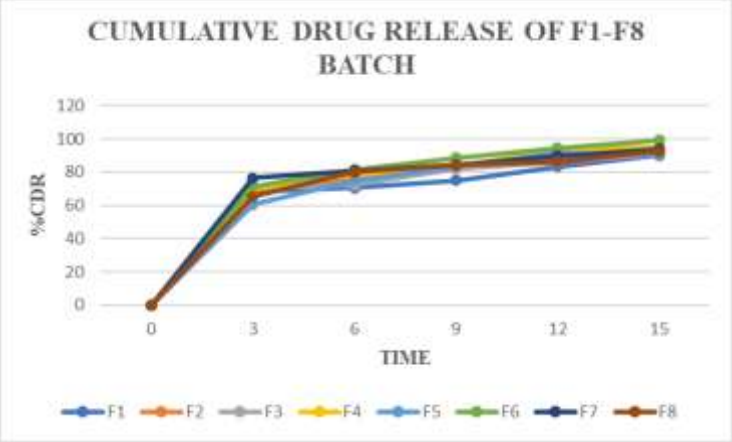


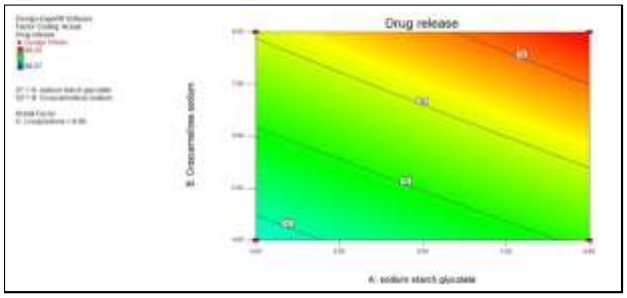
Figure 4: Cumulative % drug release profile of formulation F1-F8.

Analysis of Data:

A polynomial equation was derived to examine the effects of independent variables on the responses, such as the percentage of drug release and the disintegration time, in order to examine the influence of three components using a complete factorial design. Regression equations are used to draw conclusions about the findings after taking into account the magnitude of the coefficient, and the sign of the coefficient shows the type of response. In a polynomial equation, a positive sign indicates that the reaction rises as the value does, whereas a negative sign indicates that the response falls as the value rises.

Effect of independent factors on % drug release (Y1)

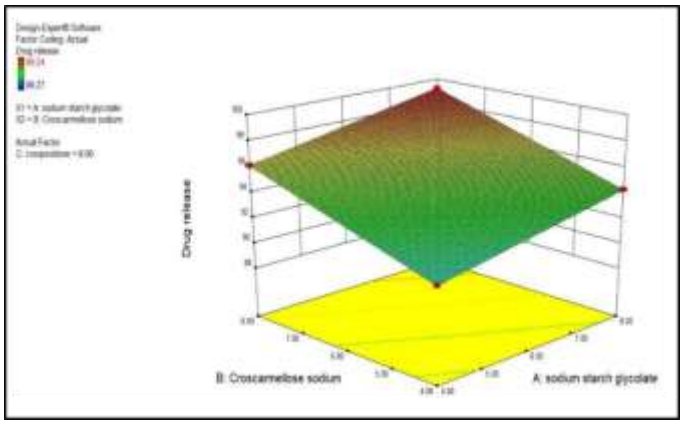
+93.31+1.82*A+1.42*B+1.96*C- 0.21*A* B-0.34*A* C+1.00* B * C+0.28*A*B*C is the drug release. This polynomial equation showed that the independent variables— crospovidone, SSG, and croscarmellose sodium—had a favourable impact on drug release.



Contour plot

3D Response Surface Plot:

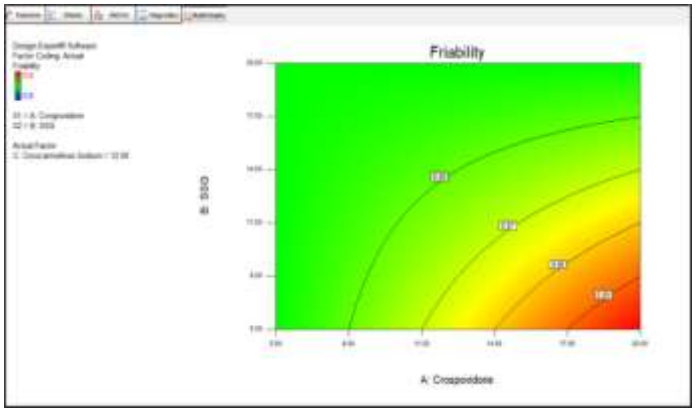
- Curved Y2 (Friability) Effect of SSG, Crospovidone and Croscarmellose Sodium on friability of Amlodipine Besylate in 3D response surface plot confirmed. From the figure response curve of Y2 (% Friability).
- It is observed that as concentration of SSG increases from 5 mg to 20 mg, Croscarmellose Sodium increases from 5 mg to 20 mg and Crospovidone increases from 5 mg to 20 mg drug release increases significantly.



3D Response Surface Plot

Effect of independent factors on friability (Y2)

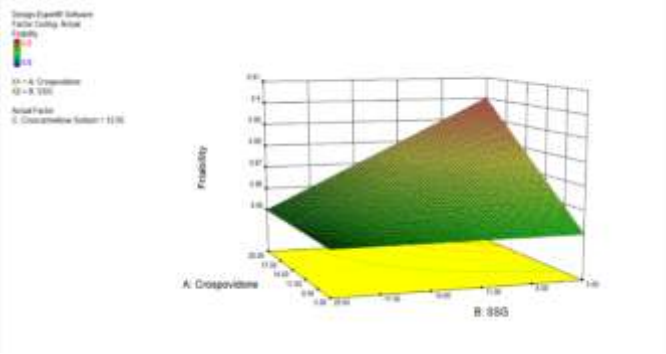
+19.75-3.75* A-0.75* B-2.00*C-1.75%A* B-0.50*A*C-1.50*B* C+2.50 * A*B*C is the friability. The independent variables, crospovidone, SSG, and croscarmellose sodium, were found to have a negative impact on disintegration time based on this polynomial equation.



Contour plot

3D Response Surface Plot

Croscarmellose sodium concentration rises from 5 mg to 20 mg, SSG rises from 5 mg to 20 mg, and Crospovidone rises from 5 mg to 20 mg, according to the Curve of Y2 (Friablity). Figure illustrates the considerable decrease in disintegration time. The statistical model indicates that the eighth run is an optimal formulation. The analysis of the optimised batch's reaction, or drug release rate of 99.24% and disintegration time of 16 seconds.



3D Response Surface Plot

Stability Studies

Research for Fast disintegrate Amlodipine besylate tablet formulation F6, which is optimised at 40°C ± 2°C/75% ± 5% Relative Humidity.

Sr. No	Observation	Before Stability	15 Days	1 Month
1	Appearance	White	White	White
2	Disintegration Time (sec)	16 ± 1.1797	16± 1.532	15± 0.612
3	Drug Content	99.43 ± 0.032	99.02 ± 0.011	98.95± 0.080

Based on the aforementioned findings, it was determined that the tablets' physicochemical features, release characteristics, and disintegration time had not changed significantly.

CONCLUSION

Using a sensory approach and the Direct Compression method, Fast disintegrate Amlodipine besylate tablets may be effectively made using a variety of superdisintegrants, diluents, and taste-inhibiting substances. A preformulation research using FTIR revealed no discernible differences between Amlodipine besylate and the excipients. Formulation F6, which had high concentrations of sodium starch glycolate, croscarmellose sodium, and crosspovidone, showed encouraging results. With its maximum in-vitro drug release, lowest disintegration time, and best water absorption and hydration capacity, this formulation offers rapid beginning of action for hypertension.As a result, the F6 Formulation was found to be optimal. formulating between F1 and F8.

REFERENCES

1. M. Maheswari, K., Kumar Devineni, P., Deekonda, S., Shaik, S., Pravallika Uppala, N., & N. Nalluri, B. (2014). Development and Evaluation of Mouth Dissolving Films of Amlodipine Besylate for Enhanced Therapeutic Efficacy. ncbi.nlm.nih.gov

2. Siddiqui N, Garg G, Sharma pk. (2010), Fast dissolving tablets:preparation characterization and evaluation: an overview. International journal of pharmacy science Rev Re; 2:87-96 .
3. Maheshwari, S., Singh, A., Varshney, A. P., & Sharma, A. (2024). Advancing oral drug delivery: The science of fast dissolving tablets (FDTs). Intelligent Pharmacy. sciencedirect.com
4. Bhatt, P., Singh, S., Sharma, S. K., & Rabiu, S. (2021). Development and Characterization of Fast Dissolving Buccal Strip of Frovatriptan Succinate Monoydrate for Buccal Delivery. International Journal of Pharmaceutical Investigation, 11(1). [HTML]
5. Patel TS, Senguptam (2013),Fast dissolving tablet technology. World J pharm sci; 2.485-508.
6. Vinarov, Z., Abdallah, M., Agundez, J. A., Allegaert, K., Basit, A. W., Braeckmans, M., ... & Augustijns, P. (2021). Impact of gastrointestinal tract variability on oral drug absorption and pharmacokinetics: An UNGAP review. European Journal of Pharmaceutical Sciences, 162, 105812. sciencedirect.com
7. Mehta, A. P., Kothari, M. S. S., Chaudhari, M. U. P., & Patil, M. K. S. (2022). Sublingual drug delivery system. International Journal Of All Research Writings, 4(12), 20-29. ijciras.com
8. Momeni, M., Afkanpour, M., Rakhshani, S., Mehrabian, A., & Tabesh, H. (2024). A prediction model based on artificial intelligence techniques for disintegration time and hardness of fast disintegrating tablets in pre-formulation tests. BMC Medical Informatics and Decision Making, 24(1), 88. springer.com
9. Ghourichay, M. P., Kiaie, S. H., Nokhodchi, A., & Javadzadeh, Y. (2021). Formulation and quality control of orally disintegrating tablets (ODTs): recent advances and perspectives. BioMed Research International, 2021(1), 6618934. wiley.com
10. Harish VD,Valli G, Ramya MG(2014), A Review on fast dissolving tablets. International Journal ofuniverals pharmacy and bio sciences, 3:757- 81.
11. Patil SL,Shivshankar MA (2011), formulation and technology of fast disintegrating tablet: a review. Journal of pharmaceutical and biomedical science, 9:1-7.
12. Ayyoubi, S., Cerda, J. R., & Fernández-García…, R. (2021). 3D printed spherical mini-tablets: Geometry versus composition effects in controlling dissolution from personalised solid dosage forms. International Journal of …. strath.ac.uk
13. Khairnar D, Surawase R, Gangurde L, Wagh R, Aher A. A Review on Mouth Dissolving Tablet. Research Journal of Pharmaceutical Dosage Forms and Technology. 2025 May 12;17(2):102-6.
14. Kshirsagar T, Jaiswal N, Chavan G, Zambre K, Ramkrushna S, Dinesh D. Formulation & evaluation of fast dissolving oral film. World J. Pharm. Res. 2021 May 27;10(9):503-61.
15. Ashishmasih, Amar kumar,shivam Singh, Ajay kumartiwari (2012), Fast dissolving tablets: A Review. International Journal of current Pharmaceutic Research-0975-7066.
16. Siddiqui N, Garg G, Sharma pk. (2010), Fast dissolving tablets:preparation characterization and evaluation: an overview. International journal of pharmacy science Rev Re; 2:87-96 .
17. Samineni, R., Chimakurthy, J., & Konidala, S. (2022). Emerging role of biopharmaceutical classification and biopharmaceutical drug disposition system in dosage form development: A systematic review. Turkish

journal of pharmaceutical sciences, 19(6), 706. nih.gov

18. Mehta, A. P., Kothari, M. S. S., Chaudhari, M. U. P., & Patil, M. K. S. (2022). Sublingual drug delivery system. International Journal Of All Research Writings, 4(12), 20-29. ijciras.com
19. Patel TS, Senguptam (2013),Fast dissolving tablet technology. World J pharm sci; 2.485-508.
20. BhowmitDebjit, B. Chiranjib, kantkrishna, pankaj, R. Margretchandira (2009), fast dissolving tablet: An Review Journal of chemical and pharmaceutical Research, 1 (1); 163 – 177.
21. Saptarshidutta, pintukamar(2011), Formulation of fast disintegrating tablets. International Journal of drug formulation & Research, vol-2(1).
22. Tariquekhan, sayyed Novim, siraj Shaikh,Afsarshaikh, Ashishkhairnar, Aejaz Ahmed(2011),An Approach for Rapiddisintegrating tablets A Review. International Journal of pharmaceutical research anddevelopment,(1220- 183)
23. kalindichauhan, Rakeshsolanki, Shivanisharma (2018), A Review on fast dissolving tablet. International Journalof applied pharmaceutics ISSN - 09757058.
24. Kshirsagar, T., Jaiswal, N., Chavan, G., Zambre, K., Ramkrushna, S., & Dinesh, D. (2021). Formulation & evaluation of fast dissolving oral film. World J. Pharm. Res, 10(9), 503-561. researchgate.net.

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