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Formulation And Evaluation Of Mouth Dissolving Tablet Of Amlodipine

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ABSTRACT

The present study focuses on the Formulation and evaluation of mouth-dissolving tablet (MDTs) of Amlodipine, a widely used antihypertensive drug with poor bioavailability due to first-pass metabolism. Mouth-dissolving tablets offer a promising alternative to conventional tablets, particularly for patients with dysphagia, by enhancing convenience, compliance, and rapid drug absorption through pre-gastric absorption.

The MDTs were prepared using Direct-Compression and using various Super-disintegrants to ensure rapid disintegration and dissolution. The formulations were optimized based on pre-compression parameters (angle of repose, bulk density, compressibility index) and post-compression parameters (weight variation, hardness, friability, wetting time, disintegration time, drug content and in vitro dissolution).

The optimized formulation exhibited rapid disintegration (within 30 seconds) and high drug release (>90% within 15 minutes), meeting Pharmacopeial standards. Stability studies coAFirmed the formulation's robustness under varying conditions. In vitro drug release kinetics followed the Korsmeyer-Peppas model, indicating diffusion-controlled release.

This study demonstrates the successful development of Amlodipine MDTs with improved patient compliance, faster onset of action, and enhanced bioavailability, making them a viable alternative to conventional dosage forms.

Keywords: *Amlodipine, Doshion, mouth-Dissolving Tablets, Super-Disintegrants, Direct Compression, Dissolution, Bioavailability.*

1. INTRODUCTION

The oral route of administration is considered as the most widely accepted route. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patients incompliance particularly in case of pediatric and geriatric patients [1]. Thus, a new delivery system known as oral fast dissolving/disintegrating (FDDS)/melt-in-mouth tablets gaining importance. These oral dosage forms dissolve rapidly in saliva and can be swallowed without the need of drinking water [2]. Elimination of bitterness is an important criterion in product formulation of mouth dissolving tablets [3].

Superdisintegrants added in the formulation increase the dissolution characteristics thus increasing the bioavailability of drug [4]. Mouth dissolving tablet disintegrate in mouth and are useful for potent drugs where fast absorption is required. A nasal dose for Amlodipine has not been established. However, based on a daily oral dose of 5 mg and the nasal/oral dose ratio for other antihypertensive, a nasal Amlodipine dose in the range 1 to 5 mg/nostril can be assumed. Therefore, for a liquid formulation, with a 0.1 mi dose volume, a concentration of 10 to 50 mg/ml Amlodipine would be required[5]. This amount is effective in reducing blood pressure by 60-65% within 35-50 hours of administration.[6] In the present study, an attempt has been made to develop mouth-dissolving tablets of Amlodipine by direct compression methods using suitable super-disintegrate agents.

2. MATERIALS AND METHODS

Amlodipine was procured from Ultra Drug Pvt. Ltd. Baddi, India. Dosion was obtained from Gujarat Micro Wax Ltd. Indore, India. Sodium starch glycolate was obtained from Signet Chemical Corp. Mumbai. SuperD33 was obtained from Forum Bioscience, London. Talc and MCC were obtained from S. D. Fine Chemicals, Mumbai. All other ingredients were of analytical grade.

Determination of Analytical Wavelength(λmax): A standard stock solution of Amlodipine was prepared by dissolving accurately weighed 5 mg of Amlodipine in water in a 50 ml volumetric flask and the volume was made up to 50 ml with water to obtain a stock solution of 100 µg/ml. From the standard stock solution, 10 ml was pipetted into 100 ml volumetric flask. The volume was made up to 100 ml with water. The resulting solution containing 10 µg/ml was scanned between 200 and 400 nm.

Drug and Drug-Excipients physical compatibility studies: To study the physical compatibility of various formulation excipients with Amlodipine, solid admixtures were prepared by mixing the drug with excipients separately in the ratio of 1:1 and were filled in 2 ml glass vials and sealed. And they were kept in stability chamber at room temperature and 30±20C/65±5%RH. The samples were withdrawn and analysed for colour change for every 10 days.

3. PHYSICOCHEMICAL CHARACTERIZATION:

Density measurement: Granules density may iAFluence compressibility, tablet porosity, dissolution and other properties. Different types of density calculation were done to characterize the drug and its flow property. Generally two types of density are determined i.e., bulk density and tapped density. The methods followed for calculation of the above two densities are determined by the following ways.

Bulk density: It is a measure used to describe the packing of particles or granules. An accurately weighed quantity of powder, which was previously passed through sieve #40 [USP] and carefully poured bed, was made uniform without disturbing. Then volume measure was called as the bulk volume and the bulk density is calculated by following formula.

Bulk density= weight of powder / Bulk volume

Tapped density: After measuring the bulk volume the same measuring cylinder was set into tap density apparatus. The tap density apparatus was set to300 taps drop per minute and operated for 500 taps. Volume was noted as (Va) and again tapped for750 times and volume was noted as (Vb). If the difference between Va and Vb not greater than 2% then Vb is considered as final tapped volume. The tapped density is calculated by the following formula.

Tapped density= Weight of powder /Tapped volume

Flow properties: The flow properties from a material result from many forces. There are many types of forces hat can act between solid particles: frictional forces, surface tension forces, mechanical forces caused by interlocking of particles of irregular shapes, electrostatic forces and cohesive or vander vaals forces. These forces can affect granule properties such as particle size, particle size distribution, particle shape, surface texture or roughness, residual surface energy and surface area.

Compressibility index: Pharmaceutical powders are broadly classified into free flowing and cohesive. Powders are more often compressed into tablets using a pressure of 5kg/cm^2. This is called compression or compaction. During this process the porosity of the powder changes. The compression properties of most drugs are very poor. Therefore compression vehicles such as lactose, calcium phosphate and microcrystalline cellulose are included in tablet formulations. Normally low dose drugs (<50mg) are prepared by direct compression. Tablet materials should be plastic that is capable of undergoing permanent deformation yet exhibit brittleness. Percentage compressibility also known as Carr's consolidation index is indirectly related to the relative flow rate, cohesiveness and particle size. It is a simple, fast and popular method for predicting powder flow characteristics.

Carr's consolidation index = [(Tapped density-Fluff density)/tapped density]*100

Compressibility index can be a measure of the potential strength that a powder could build up in its arch in a hopper and also the ease with which such an arch should be broken.

Angle of repose: The angle of Repose is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

θ= Tan-1 (h/r)

Where 'h' = height of the pile and 'r' = radius of the pile

Values of Θ are rarely less than 200, and values of up to 400 indicate reasonably flow potential. Above 500, however, the powder flows only with great difficulty. In general, the angle of repose increased with decreasing particle size. The addition of talk in low concentration decreases the repose angle, but in higher concentration it increases the angle.

Hausner's ratio: It is the ratio of bulk volume or tapped density to bulk density. Hausner's ratio is an important character to determine the flow property of powder and granules. This can be calculated by the formula

Hausner 's ratio=Tapped density/Bulk density

Particle size distribution: Particle size distribution is a very important in process technique of final blend after blending. It is an important parameter to determine the amount of fines as well as particle with larger particle size in final blend. It also helps in keeping a check over uniformity of distribution of blend over various sizes while carrying out consecutive batches.

Particle size determination was carried by arranging various sieves of sizes #20, #40, #60, #80, #100, #140, #200 and Pan (for finer particles which passes even #200 sieve) in ascending order (i.e.,#20 sieve lies on top and pan at the bottom). Then the final blend of accurately weighed quantity was placed on the top sieve. And the sieves are placed in vibrosifter and allowed to run at 1.0 amplitude for 10 minutes. After the procedure difference of initial and final weight of sieves were noted to calculate the percentage retention of the blend in various sieves.

4. FORMULATION DEVELOPMENT

Mouth dissolving tablets of AMLODIPINE were prepared by direct compression method according to the formula given in table no 2.3. All the ingredients were passed through 60 mesh sieves separately. The drug and microcrystalline cellulose were mixed by small portion of both each time and blending it to get a uniform mixture kept aside. Then the ingredients were weighed and mixed in geometrical order and tablets were compressed of 8mm sizes flat round punch to get tablet using Rimek Compression Machine.

Table 1: Composition of unit dose of various Formulations Characteristics of final blend

Ingredients (mg)	Formulation								
	AF1	AF2	AF3	AF4	AF5	AF6	AF7	AF8	AF9
Amlodipine	10	10	10	10	10	10	10	10	10
Doshion	5	7.5	10	-	-	-	-	-	-
Sodium starch glycolate	-	-	-	5	7.5	10	-	-	-
Super D33	-	-	-	-	-	-	5	7.5	10
Aspartame	3	3	3	3	3	3	3	3	3
Talc	1	1	1	1	1	1	1	1	1
MCC	32	32	32	32	32	32	32	32	32
Mg stearate	1	1	1	1	1	1	1	1	1
D- Mannitol	48	45.5	43	48	45.5	43	48	45.5	43
Total	100	100	100	100	100	100	100	100	100

DS= Doshion; SSG – Sodium Starch Glycolate; SD33= Super D33; AS-Aspartame

*Average of three determination

5. EVALUATION PARAMETERS

Physical appearance: The physical appearance of a tablet, its visual identity and over all “elegance” is essential for consumer acceptance. Included in this category are tablet sizes, shape, colour, presence or absence of any odour, taste, surface texture, physical flaws and consistency and legibility of any identification marking.

Weight variation: Twenty tablets were selected randomly from the lot and weighed individually to check for weight variation. Each tablet weight was then compared with average weight variation. Each tablet weight was then compared with average weight to ascertain the weight of the tablets within the permissible limits. Not more than two of the individual weights should deviate from the permissible limits. Not more than two of the individual weights should deviate from the average weight by more than 5% for >300mg tablets and none by more than double that percentage.

Percentage deviation= [(Tablet weight- Average weight)/tablet weight] ×100

Loss on drying: Loss on drying is an important parameter to determine the moisture intake by blend during processing. Limit on loss on drying is established from the sum of percentage moisture intake values of each excipient used in the process. Percentage moisture in take was determined during in process by using Ohaus Moisture Analyser. In which 1gm of blend was placed after tarring the instrument at 105°C in auto mode.

Friability: Friability test is performed to assess the effect of friction and shocks, which may often cause the tablet to chip, cap or break. Roche friabilator was used for the purpose. This device subjects number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at a distance of 6 inches with each revolution. Pre-weighed sample of tablets were dusted and reweighed. Compressed tablets should not lose more than 1% of their weight.

Percentage friability = $[(w_2-w_1)/w1]\times100$

Where, W1 = Weight of tablets before test; W2= Weight of tablets after test

Thickness: The thickness was measured by using vernier calliper and values were tabulated. Ten tablets of each batch were measured. Average and standard deviation was calculated.

Hardness: The hardness of tablet is an indication of its strength. Measuring the force required to break the tablet across tests it. The force is measured in kg and the hardness of about 3-5 kg/cm^2 is considered to be satisfactory for uncoated tablets. Hardness of 10 tablets from each formulation is determined by Erweka hardness tester.

Disintegration test: Breaking of tablets into smaller particles or granules is known as disintegration and time taken for breaking of tablets in a suitable medium is called disintegration time (DT). This test is not applicable to modified-release tablets and tablets for use in the mouth. For those tablets for which the dissolution test is included in the individual monograph, the test for disintegration is not required. It is determined by USP apparatus (Electro lab Disintegration Tester). It consists of 6 glass tube each 3 inches long, open at top and has 10 mesh screens at the bottom end of basket rack. One tablet is placed in each tube and placed in a one litre beaker of water, simulated gastric fluid or simulated intestinal fluid at 37 ± 2oC. It moves up and down through a distances of 5 to 6 cm at 28 to 32 cpm.

Content uniformity: Uniformity of contend is a pharmaceutical analysis parameter for the quality control of tablets or capsules. Multiple capsules or tablets are selected at random and a suitable analytical method is applied to assay the individual content of the active ingredient in each tablet or capsule.

Stability Studies: The optimized formulation of MDTs is subjected to stability study as per ICH guidelines to assess their stability with respect to their physical appearance and release characteristics.

Table 2: Dissolution parameters

Apparatus	USP Apparatus 2 (paddle)
RPM	50 RPM
Dissolution medium	pH 6.8 Phosphate buffer, 500 mL
Time	10, 20 and 30 minutes
Sample collection volume	10 mL
Temperature	37.0±0.5°C

Drug release kinetics: Various models were tested for explaining the kinetics of drug release. To investigate the mechanism of drug release rate kinetics from the dosage form, the obtained data were fitted with zero-order, first-order, Higuchi and Korsmeyer – Peppas release model.

6. RESULTS AND DISCUSSION

Determination of analytical wavelength (λmax) of AMLODIPINE: By using UV-Spectrophotometer Amlodipine drug solution in water was scanned between the range of 200-400 nm using water as the blank and a sharp peak was observed at nm which reports that the analytical wavelength is 238 nm. The value found was lies in the range 238 specified in official monograph and it has shown in Fig 1.

Calibration Curve Of AMLODIPINE: The absorbances of solution of AMLODIPINE in pH 6.8 buffer solution at 238 nm have been taken and it was found that the solutions show linearity in absorbance at a concentration of 0-25 µg/ml and obey beer-lamberts law. The values are illustrated in Fig 2.

Physical compatibility studies of drug and excipients: Physical compatibility study of drug and excipients is necessary for the stable and effective solid dosage form which is performed on visual basis. The study reveals that the drug, polymer and other excipients were physically compatible with one another as there was no change in physical description.

Chemical compatibility studies by FTIR: The IR spectral analysis of the Amlodipine, polymer and other excipients was carried out by using KBr pellet method and the spectra were shown from Fig 3 to Fig 5. All the characteristic peaks appear for the pure Amlodipine and its physical mixture indicating no interaction between Amlodipine and excipients.

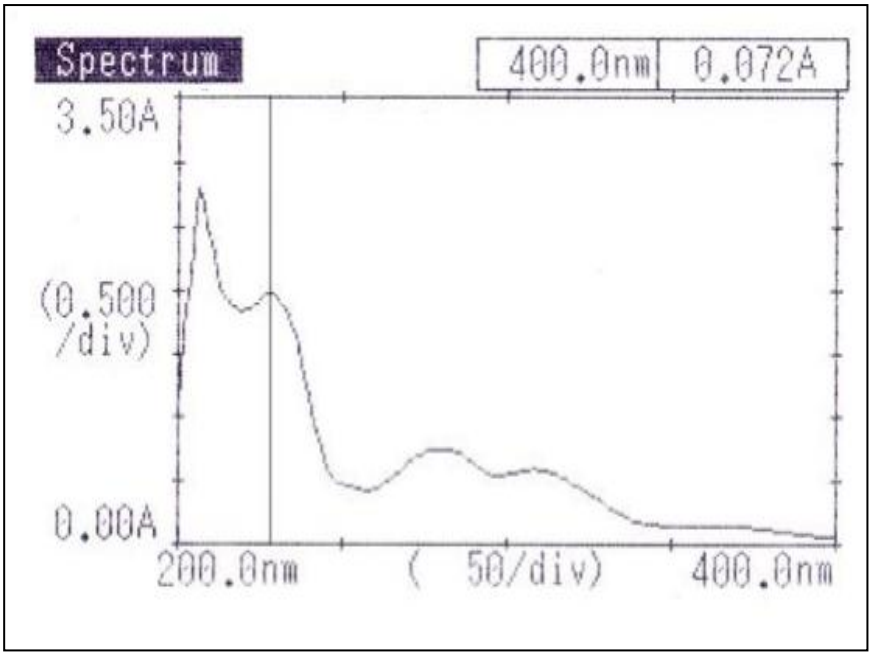

Figure 1: UV Spectra

Table: 3: Concentration of Amlodipine in phosphate buffer pH 6.8

Sr. No.	Conc.	Abs.
1.	0	0.00
2.	5	0.268
3.	10	0.619
4.	15	0.918
5.	20	1.181
6.	25	1.416

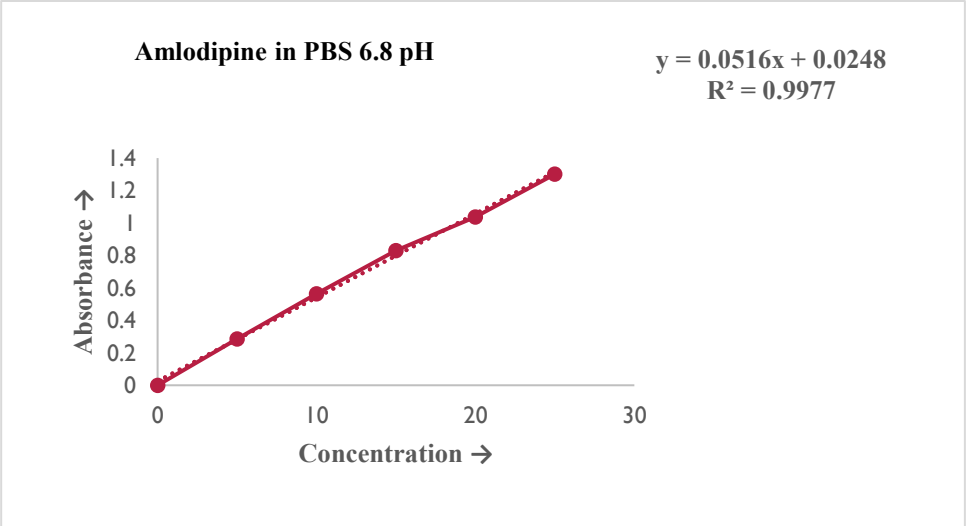

Fig.2: Curve in Phosphate buffer pH 6.8

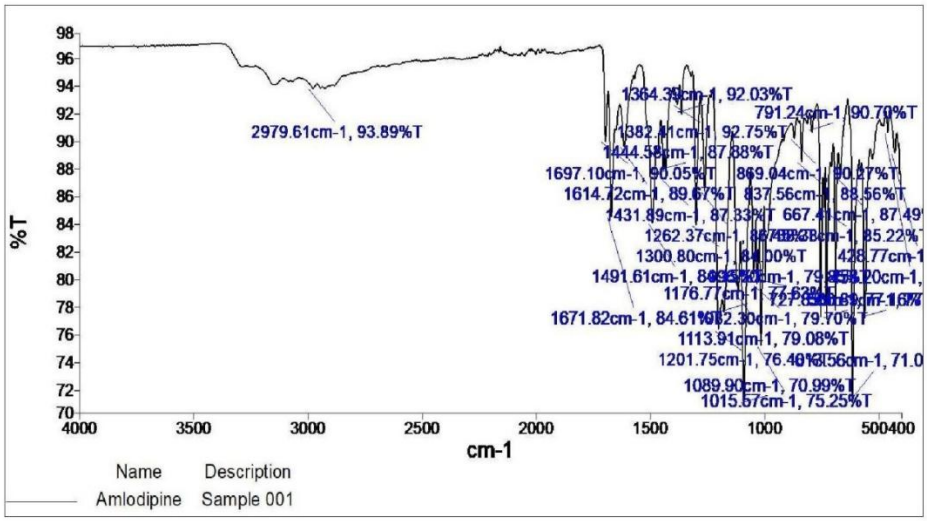

Figure 4: FTIR Spectra of Amlodipine

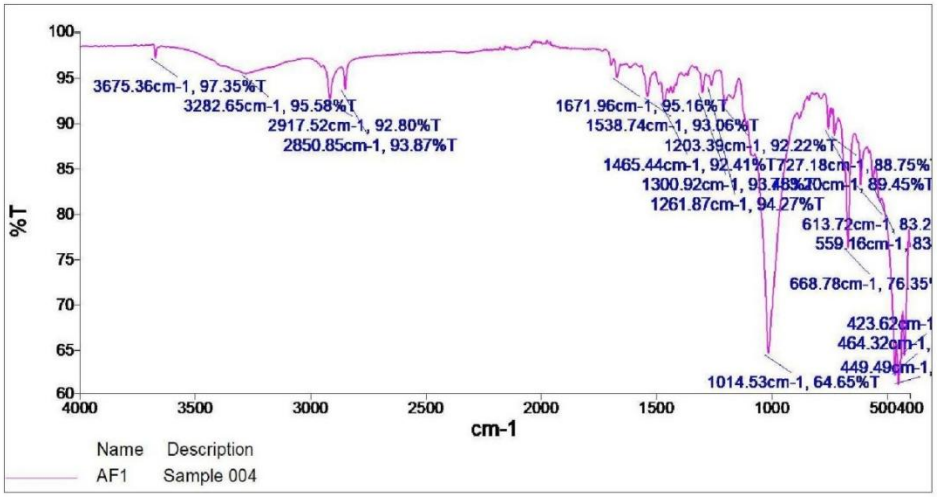

Figure 5: FTIR Spectra of Formulation AF1

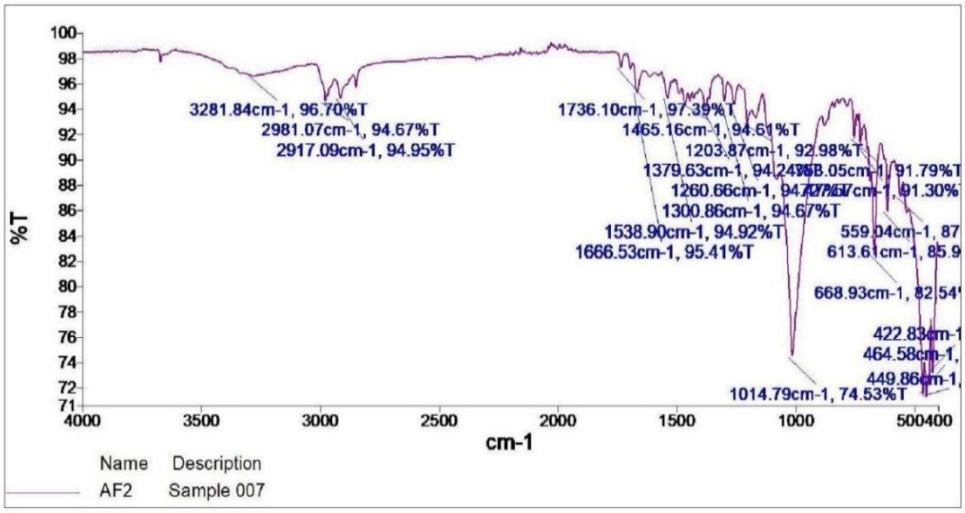

Figure 6: FTIR Spectra of Formulation AF2

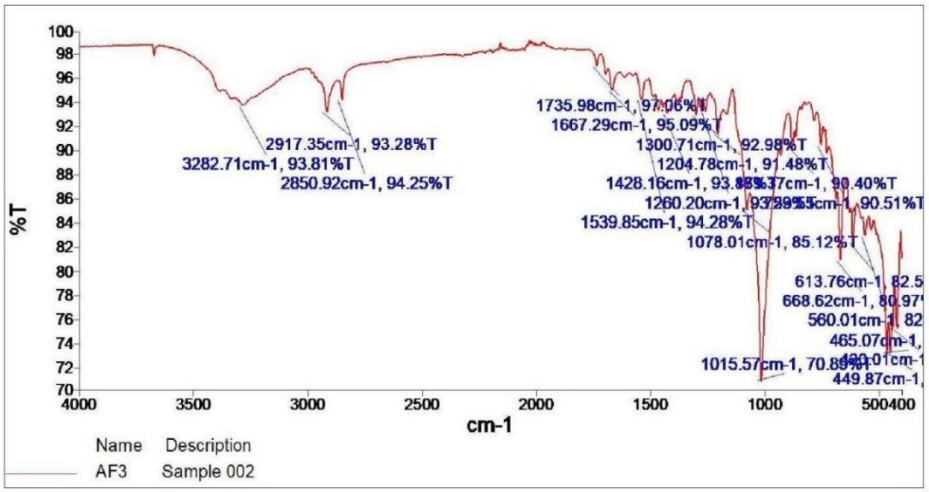

Figure 7: FTIR Spectra of Formulation AF3

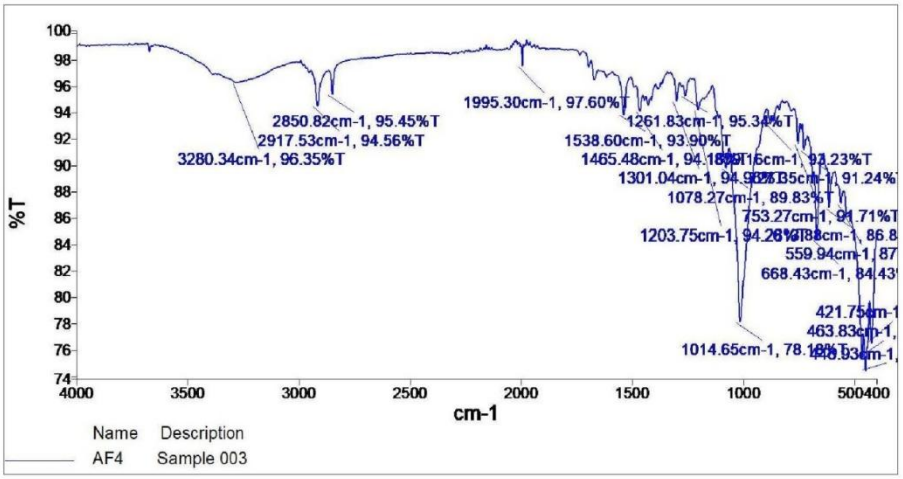

Figure 8: FTIR Spectra of Formulation AF4

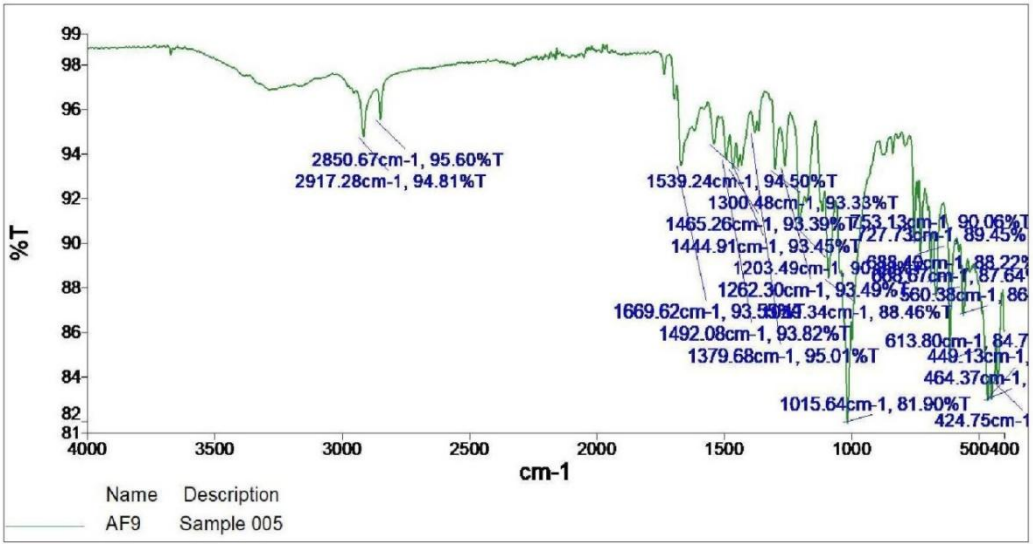

Figure 9: FTIR Spectra of Formulation AF9

7. PRE COMPRESSION STUDIES ON POWDER BLEND

Bulk density: The bulk density of the formulation mixture of drug with different superdisintegrants was measured by graduated cylinder. The bulk density was found in the range from 0.54gm/cm³ - 0.58 gm/cm³. The results are illustrated in Table 4.

Tapped density: The tapped density of the formulation mixture of drug with different superdisintegrants was measured by measuring cylinder. The tapped density was found in the range of 0.56 gm/cm³ - 0.66 gm/cm³.The results are shown in Table 4.

Compressibility index: Compressibility index (Carr's index) indicates the flow property of the granules or the powders. Flow property plays a major role in the dosage forms especially in tablet dosage forms because improper flow of powders or granules may cause weight variation. Values of compressibility index below 15% indicate good flow whereas the values above 15% indicate poor flow property. The compressibility index of various formulation mixture of drug with different super disintegrants was calculated by using bulk density and tapped density results and it was found in the range of 16.45 ± 0.14% to 17.88±0.15 % which reveals that the formulations exhibit good flow property. The results are shown in the Table 4.

Hausner ratio: It is an indirect index of ease of powder flow. Lower Hausner ratio i.e., <1.25 specifies good flow property than the higher Hausner ratio i.e., >1.25. The Hausner ratio of various formulation mixture of drug with different superdisintegrants was calculated by using bulk density and tapped density data. It was found in the range of 1.149 to 1.250 which designates that that the formulation powders having better flow properties. The results are shown in Table 4.

Angle of repose (θ): Angle of repose is direct index of the flow property. The angle of repose of various formulation blends of drug with different superdisintegrants was measured by using funnel method. The range of results is lie in between the 24.23±0.20 - 29.67±0.15, which indicates that the powders having good flow property. The results are illustrated in Table 4.

Particle Size Distribution Particle Size Distribution for final blend of the trial batches were performed and the results are tabulated below.

Table 4: Precompression parameters of Amlodipine Formulations

Form Code	Angle of repose	Compressibility index	Hausner ratio	Bulk Density	Tapped Density
AF1	26.21±0.18	15.68±0.16	1.173±0.03	0.56±0.003	0.63±0.005
AF2	28.24±0.18	16.89±0.15	1.167±0.03	0.54±0.002	0.66±0.001
AF3	27.87±0.15	15.48±0.14	1.223±0.03	0.53±0.003	0.64±0.003
AF4	26.56±0.17	15.68±0.13	1.136±0.05	0.57±0.002	0.58±0.003
AF5	27.34±0.16	16.26±0.16	1.202±0.03	0.55±0.003	0.61±0.005
AF6	24.23±0.20	16.35±0.15	1.154±0.03	0.54±0.003	0.59±0.003
AF7	25.36±0.20	17.98±0.16	1.145±0.03	0.56±0.003	0.62±0.004
AF8	28.94±0.17	17.36±0.16	1.137±0.05	0.54±0.002	0.56±0.005
AF9	29.67±0.15	16.93±0.14	1.145±0.03	0.52±0.004	0.63±0.003

Results are mean of 3 observation ±SD

8. POST-COMPRESSION PARAMETERS

Hardness:

All of the tablets made using both techniques had hardness levels between 2.1±0.02 and 2.5±0.01 kg/cm². Table 5 lists the results of the mean hardness test.

Weight Variation Test:

In every proposed formulation, there was a weight fluctuation within the range of 99 ±5 to 104 ± 5 mg. Table No. 5 displays the results of the mean weight variation test. "Since the average percentage of weight variation was within the pharmacopoeia's limitations, or 7.5%, all of the pills passed the weight variation test".

Thickness:

The average thickness, which varied from 2.31 ±0. 13 mm to 2.45 ±0. 12 mm, was nearly constant throughout all three formulations (n=3). According to the standard deviation values, every formulation fell inside the given range. Table No. 5 displays the tablet thickness data.

Friability Test:

All proposed formulations with friability between 0.34 and 0.76% were determined to be well within the permitted range (<1%). The findings of the friability investigation were tallied in table 6.

Wetting Time

The internal composition of the tablet has a direct bearing on the wetting time. Table No. 6 presents the wetting time results. The direct compression and sublimation methods of Amlodipine preparation yielded wetting times ranging from 42.6 ±1.42 to 48.6 ±1.43 seconds.

Water Absorption Ratio

Formulations with a mere 3% of superdisintegrant exhibit a lower water absorption ratio than formulations with 12% of superdisintegrant; this decrease is also attributed to less swelling property. The formulations prepared using both techniques show wetting times in the range of 60±1.45 to 82±1.15%. It has been noted that as CCS concentrations rise, the water absorption ratio also rises because CCS is produced by the cross-linking process of sodium CMC. The cross-linking process significantly decreased the solubility of sodium CMC in water, allowing the material to expand and absorb water up to 32 times its own weight. Table No. 6 displays the water absorption ratio data.

In-Vitro Disintegration Time

The amount of time needed for uniform dispersion is used to calculate the in vitro disintegration time. All of the formulations showed rapid disintegration within a few minutes. The data pertaining to in-vitro disintegration can be found in Table No. 6. The regulatory standards were satisfied by the in vitro disintegration time of Amlodipine prepared via direct compression, which ranged from 14.12±1.23 to 22.75±2.05 seconds.

Drug Content:

For each of the nine formulations, the drug content homogeneity was tested; the findings are listed in table No. 6. For every batch, three trials were subjected to spectrophotometric analysis. The pills' percentage drug content was determined to be 96.5 ± 6.78 to 99.7 ± 6.33% Amlodipine. The results showed homogeneous mixing because they fell within the range.

Table 5: Post Compression Parameters (1)

Formulation Code	Diameter (mm)	Thickness (mm)	Hardness (kg/cm^2)	Weight Variation(mg)
AF1	0.02±0.11	2.46±0.13	2.1±0.02	101 ± 5
AF2	4.03±0.020	2.38±0.15	2.3±0.02	102 ± 5
AF3	3.02±0.011	2.41±0.13	2.5±0.01	103 ± 5
AF4	3.04±0.012	2.32±0.15	2.3±0.02	104 ± 5
AF5	4.04±0.010	2.39±0.15	2.4±0.015	99.6 ± 5
AF6	3.05±0.013	2.42±0.16	2.3±0.02	103 ± 5
AF7	4.04±0.010	2.38±014	2.5±0.05	99 ± 5
AF8	3.02±0.012	2.32 ± 0.012	2.4 ± 0.03	102 ± 5
AF9	3.02 ± 0.010	2.352 ± 0.12	2.3 ± 0.02	101 ± 5

Table 6: Post Compression Parameters (2)

Formulation Code	Friability (%)	Wetting Time* (sec)	Water Absorption Ratio	Disintegration Time (Sec)	Drug Content*(%)
AF1	0.65	44.6±1.32	80±1.43	18.13 ± 1.77	97.9±4.98

AF2	0.76	48.6±1.35	78±1.35	14.13 ± 1.24	99.5±2.54
AF3	0.59	42.7±1.42	75±1.62	13.13 ± 1.57	99.8±6.33
AF4	0.62	45.7±1.43	78±1.43	21.24 ± 2.04	98.9±5.89
AF5	0.73	44.3±1.06	82±1.16	22.76 ± 2.06	96.5±6.78
AF6	0.66	45.6±1.25	73±1.23	19.35 ± 1.79	98.6±5.53
AF7	0.34	48.7±1.43	76±1.22	20.55 ± 2.11	99.6±6.32
AF8	0.53	45.4±1.26	60±1.46	22.11 ± 2.11	98.7±5.66
AF9	0.71	44.2±1.24	68±1.35	17.46 ± 1.63	97.6±6.34

In- Vitro Dissolution Studies:

900 millilitres of phosphate buffer pH 6.8 was used as the dissolving medium in a USP type-II apparatus (USP XXIII dissolving Test Apparatus at 50 rpm) to study the dissolution rate. The dissolution medium was kept at 37±0.5°C in temperature. An aliquot of the medium was taken out and filtered every minute. The UV spectrophotometric method was used to measure the absorbance of the filtered solution at 238 nm, and a standard calibration curve was used to quantify the drug's concentration.

The medicine dissolved more quickly in tablets made using the camphor sublimation approach than in tablets made using other methods once the mode of tablet manufacture was switched to sublimation. This could be because of their lowest hardness and their porous nature, which allows for faster water absorption and, in turn, allows sodium starch glycolate to wick through more easily, resulting in speedier breakdown. Due to the tablets disintegrating quickly, all of the formulations had rapid drug release percentages (85.65±1.65%-99.10±2.92%).

Following a 10-minute duration, the in vitro dissolving investigation of all formulations (AF1-AF9) yields a maximum drug release of 99.10±2.92% for formulation AF3. For every post-compression characteristic, including hardness, friability, weight variation, and drug content, all of the fractionations fell below the bounds.

Here, after 10 minutes, AF3 had better drug release and a shorter disintegration time. Therefore, the optimal formulation was determined to be AF3, which contains doshion as the disintegrant.

Stability Study

To evaluate the long-term stability and integrity of the optimized Amlodipine formulation, designated as AF3, a comprehensive stability study was conducted over a period of 60 days. The study involved exposing the formulation to controlled environmental conditions, specifically 40 ± 2°C/75 ± 5% RH, which are standard accelerated stability conditions. In addition, a parallel study was performed at Room Temperature (RT) to simulate typical storage conditions. Throughout the study, critical quality attributes such as the physical description of the product, the quantitative content of Amlodipine, and its in vitro dissolution profile were meticulously assessed. All evaluations of drug release and other parameters were strictly carried out in accordance with established pharmacopoeial protocols.

Table 7: Description

Storage Condition	Taste	Observation	Inference
RT	Descriptions	No significant changes in appearance or consistency were observed across all batches of the formulation.	The Amlodipine formulation demonstrates good physical stability under ambient conditions.
40 ± 2°C/75 ± 5% RH	Descriptions	No visible signs of degradation, such as discoloration or precipitation, were detected in any of the formulations.	The Amlodipine formulation exhibits compliance with accelerated stability conditions, indicating robustness.

9. CONCLUSION

In the current study various batches were prepared by using super disintegrants like microcrystalline cellulose, doshion, sodium starch glycolate and super D_3 were used to directly compressed mouth dissolving Amlodipine tablets. The study and result revealed that the method of preparation of formulation significantly affect the disintegration time, percentage friability and release of drug. In-vitro dissolution study of all the formulation was carried out for 10 minute and according to results formulation AF2 was found as the best formulation, which should 99.10±2.92% drug release at the end of 10 min.

It is thus concluded that by adopting systemic formulation approach and optimum point can be reached on shortest time with minimum effort and direct compression techniques would be effective alternative approach.

On the basis of experimental data, we can conclude that among all super disintegrants used doshion have given best result.

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