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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLET OF AMLODIPINE BESYLATE USING DIFFERENT SUPERDISINTEGRANTS CONTAINING SOLID DISPERSION BY DIRECT COMPRESSION METHOD

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ABSTRACT: Amlodipine besylate is a major calcium channel blocker for the treatment of hypertension. Solid dispersion Amlodipine besylate (SD-AB) was prepared by using EC, HPMC, and croscarmellose in different ratios. The development of rapidly disintegrating oral tablets of Amlodipine besylate by direct compression method. The tablets were prepared by using direct compression method and evaluated for weight variations, hardness, friability, wetting time, disintegration time, and dissolution study. Although oral disintegrating tablets are much useful in the cases of the geriatric, pediatric, and traveling patient because of no water required for the administration, therefore, the solid dispersions prepared by a solvent evaporation method using EC, HPMC and croscarmellose carrier can be successfully used for the improvement of dissolution of SD-AB and resulted in a faster onset of action as indicated by *in-vivo* studies.

Keywords: Amlodipine besylate, Superdisintegrants, Dissolution profile, Solid dispersion, Direct compression

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INTRODUCTION: Cardiovascular diseases are increasing rapidly in the developing world. Hypertension is one of the most important modifiable risk factors for cardiovascular disease; it affects approximately one billion people worldwide. Treatment of high blood pressure can reduce cardiovascular mortality and morbidity. Orodispersible tablets are those when put on tongue disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva [1].

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The faster the drug release into solution, the quicker the absorption and onset of clinical effect. The advantages of mouth dissolving dosage forms are increasingly being recognized in both industry and academics. Their growing importance was underlined recently when European Pharmacopoeia adopted the term "orodispersible tablet" as a tablet to be placed in the mouth where it disperses rapidly before swallowing.

The increasing popularity of orally disintegrating dosage forms is in part owing to various factors such as fast disintegration, good mouthfeel, easy to handle, easy to swallow, and effective taste. Amlodipine is slowly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are reached at 6-9 h of post dose [2, 3].

Amlodipine is extensively metabolized in the liver, but there is no significant pre-systemic or first-pass metabolism and is slowly cleared with a terminal elimination half-life of 40-60 h. The volume of distribution is large (21 l/kg), and there is a high degree of protein binding (98%) [4, 5, 6]. Because of less extensive and less variable first pass metabolism, its oral bioavailability is higher (60% - 80%), and more consistent. Thus, an oral dosage form is preferable. Amlodipine besylate can be administered once daily as 10 mg orally in the treatment of hypertension. Geriatric patients may have difficulty in swallowing and chewing the tablets resulting in patient noncompliance and ineffective therapy. To overcome these problems, oral dissolving tablets are a good option. Since they disintegrate and dissolve rapidly in saliva without need for drinking water. The development of a fast dissolving tablet also provides an opportunity for a line extension in the market place[7].

MATERIALS AND METHODS:

Materials: Amlodipine besylate was a gift sample from Cadila Pharm. Sodium starch glycolate (SSG), aspartame; crospovidone (CP) and ethyl cellulose (EC) were obtained from Yarrow Chem. products. Croscarmellose (CCS), talc, lactose, microcrystalline cellulose, HPMC, magnesium stearate, D-mannitol was obtained from Central Drug House, India. All other reagents and solvents used were of analytical grade.

Methods:

Preparation of Solid Dispersions by the Solvent Evaporation Method: Solid dispersions were prepared using the solvent evaporation method, and the formula was mentioned in the below **Table 1**.

TABLE 1: SOLID DISPERSIONS FORMULATION TABLE

Ingredients	SD1 (mg)	SD2 (mg)	SD3 (mg)
Amlodipine besylate	10	10	10
Ethyl cellulose	-	10	10
HPMC	10	10	-
Croscarmellose	10	-	10

One gram of the drug was dissolved in a mixture of methanol and dichloromethane (1:1). Shaking very well was to ensure complete dissolving of the drug in the solvent mixture. A mixture of EC, HPMC, and croscarmellose equivalent to expected ratio poured in the solvent containing the drug. Stirring very well using mechanical stirrer and magnetic stirrer was till complete evaporation of the solvent. Sieving till give homogenous powder bypassed through a 200 µm sieve and retained on a 100 µm sieve. Subsequently, the sieved ground powders were stored at 25 °C in a desiccator in a screw-capped glass vial until use [8].

Dissolution Data for the Prepared Solid Dispersions: Dissolution study was performed for all the prepared solid dispersion by using USP-II paddle apparatus. In this 300 ml of saliva phosphate buffer pH, 6.8 was used and maintained temp 37 ± 0.5 ºC with 50 rpm. Then 2 ml of sample was withdrawn at every 5 min up to 15 min. and then it was analyzed by using UV-Visible spectrophotometer at 243 nm, and the values were tabled in below **Table 2**.

TABLE 2: DISSOLUTION DATA FOR THE PREPARED SOLID DISPERSION

Time (min)	% CDR from the prepared solid dispersions		
	SD1	SD2	SD3
0	0 ± 0	0 ± 0	0 ± 0
5	71.9 ± 0.9	62.5 ± 0.4359	74.57 ± 0.3152
10	86.5 ± 0.6557	74.57 ± 1.250	90.73 ± 1.250
15	96.47 ± 0.6429	82.07 ± 1.901	98.7 ± 0.3606

Drug Content: The content of Amlodipine besylate in different solid dispersion was estimated using UV-Visible spectrophotometer. An accurately weighed quantity of solid dispersion (equivalent to 10 mg of Amlodipine besylate) was taken and dissolved in 10ml of methanol. From this solution, 1 ml of solution was diluted to 10 ml and assayed for drug content at 243 nm, and the values were tabled below **Table 3**.

TABLE 3: DRUG CONTENT FOR THE PREPARED SOLID DISPERSIONS

Character	SD1	SD2	SD3
Drug content	98 ± 0.2	86.02 ± 1.709	97.97 ± 0.4509

Preparation of Tablets: Formulation chart for the prepared solid dispersions along with excipients were mentioned in **Table 4**. All the materials were passed through # 100 sieve before mixing. The solid dispersion was properly mixed with disintegrants, and then with the diluent D-mannitol, MCC. The mixture was mixed with aspartame, lactose, talc, and magnesium stearate. Finally, the blend was compressed to formulate tablet using a tablet compression machine with an average weight of 150 mg using a 6 mm flat punch in a rotary tablet press [9, 10].

TABLE 3: COMPOSITION OF TABLET FORMULATIONS (mg)

Ingredients (mg)	Formulations									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Drug solid dispersion	10	10	10	10	10	10	10	10	10	10
Croscarmellose (Ac-Di-Sol)	4	6	8	-	-	-	-	-	-	-
Crospovidone (Polylplasdone)	-	-	-	4	6	8				
Sodium Starch glycol ate (Primogel)	-	-	-	-	-	-	4	6	8	-
Mannitol	100	100	100	100	100	100	100	100	100	100
Magnesium Stearate	30	28	26	30	28	26	30	28	26	30
Microcrystalline Cellulose	1	1	1	1	1	1	1	1	1	2
Talc	1	1	1	1	1	1	1	1	1	1
Lactose	1	1	1	1	1	1	1	1	1	2
EC	1	1	1	1	1	1	1	1	1	1
HPMC	1	1	1	1	1	1	1	1	1	2
Aspartame	1	1	1	1	1	1	1	1	1	2

Evaluation of Pre-compression Parameters (Preformulation Studies): [11, 12, 13]

Bulk Density: Bulk density was determined by pouring the blend into a graduated cylimder. The bulk volume (Vb) and the weight of the blend (M) were determined. The bulk density is expressed in gm/ml and is given by:

$$\text{Bulk density} = M / Vb$$

Where, M = mass of powder taken, Vb = Bulk volume of the powder.

True Density: It tested measuring cylinder was tapped about several times, and later its true volume was measured, and true density was measured by using the following formula,

True density = {Weight of the powder (mg) / True volume of the powder (without void spaces) (ml)}.

Carr's Index (Compressibility Index): It was determined by using the above-determined bulk density and true densities using the following formula,

Carr's index (%) = {(Tapped density-bulk density) / Tapped density} × 100.

Hausner's Ratio: It was also determined by using the above tapped and bulk density values using the following formula,

Hausner's ratio = {Tapped density / Bulk density}

The Angle of Repose: Angle of repose (θ) was determined using the funnel method. The blend test sample powder was passed through a funnel that can be elevated perpendicularly until a maximum pinecone height (h) was obtained. The radius of the pile (r) was measured, and the angle of repose was calculated.

$$(\theta) = \tan\text{-}1(h/r)$$

Evaluation of Post-compression Parameters: [14, 15]

Thickness: It was measured by using Digital Vernier Calipers. Ten tablets from prepared formulation randomly taken and thickness was measured.

Weight Variation: By following USP monographs, it was calculated. In these 20 tablets from each formulation randomly taken and their total average weight was calculated, and then the individual tablet weight was calculated by comparing with the average weight.

Hardness: Hardness was calculated by using Pfizer hardness tester.

Friability Test: By following USP monograph, this test was calculated. It was measured by using Roche Friability. In this 20 tablets from each formulation was randomly taken and weighed and then placed all those 20 tablets in the plastic chamber of the Roche Friability and then it was attached to a motor for rotating with a speed of 25 rpm for 4 min, and then after 4 min all the 20 tablets weight was determined and friability was calculated.

Disintegration Time / Dispersion Time: This was determined by using glass beaker containing 6 ml of saliva buffer pH 6.8. Firstly 6 tablets from each formulation were randomly taken and dispersion time was calculated.

Drug Content: This was tested by taking 10 mg equivalent of Amlodipine besylate was taken from all formulation, and then it was dissolved in 10 ml of methanol. The form that 1 ml was pipetted out

and it was made up to 10 ml using methanol, and then its absorbance was calculated using UV-Visible spectrophotometer at 243 nm of wavelength.

Wetting Time: Wetting time of the tablets was dignified using a piece of tissue paper (12 cm × 10.75 cm) folded twice, placed in a small Petri dish having a diameter of 6.5 cm and containing 6 ml of Saliva buffer (pH 6.8). A tablet was placed on the double folded tissue paper, and the time for the complete wetting was measured.

Water Absorption Ratio: It was tested by using double folded tissue paper, and the petri dish contains 6 ml of saliva buffer pH 6.8. Firstly randomly taken tablets to form the all formulations weight was calculated it was denoted as Wb, and then the tablets were allowed to place on the tissue paper. After completely wet of the tablet weight was calculated, and it was denoted as Wa. And by using the following formula water absorption ratio (R) was measured.

$$R = 100 \times \{(Wa - Wb) / Wb\}$$

Where, Wb = Weight of tablet before absorption, Wa = Weight of tablet after absorption.

TABLE 4: PRECOMPRESSION PARAMETERS

Formulations code	Bulk density ± S.D*	Tapped density ± S.D*	Angle of Repose ± S.D*	Hausner's ratio ± S.D*	Carr's index ± S.D*
F_1	0.379 ± 0.007	0.443 ± 0.004	39.82 ± 0.280	1.169 ± 0.032	14.42 ± 2.370
F_2	0.392 ± 0.004	0.465 ± 0.004	32 ± 0.095	1.186 ± 0.019	15.67 ± 1.380
F_3	0.368 ± 0.002	0.413 ± 0.003	32.53 ± 0.110	1.122 ± 0.012	10.89 ± 1.025
F_4	0.266 ± 0.08	0.443 ± 0.004	32.06 ± 0.051	1.406 ± 0.017	28.85 ± 0.867
F_5	0.371 ± 0.003	0.442 ± 0.005	30.18 ± 0.264	1.192 ± 0.024	16.1 ± 1.685
F_6	0.370 ± 0.25	0.394 ± 0.006	32.42 ± 0.03	1.066 ± 0.020	6.146 ± 1.806
F_7	0.392 ± 0.003	0.442 ± 0.006	32.51 ± 0.036	1.129 ± 0.014	11.44 ± 1.113
F_8	0.368 ± 0.002	0.431 ± 0.003	31.88 ± 0.448	1.172 ± 0.003	14.68 ± 0.235
F_9	0.376 ± 0.007	0.456 ± 0.006	32.12 ± 0.12	1.212 ± 0.04	17.44 ± 2.827
F_{10}	0.396 ± 0.002	0.439 ± 0.003	31.46 ± 0.04	1.652 ± 0.027	14.6 ± 0.045

TABLE 5: EVALUATION PARAMETERS FOR THE PREPARED TABLETS CHARACTERISTICS

Characteristics	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}
Colour	White	White	White	White	White	White	White	White	White	White
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Taste	Acrid	Acrid	Acrid	Acrid	Acrid	Acrid	Acrid	Acrid	Acrid	Acrid
Shape	Flat	Flat	Flat	Flat	Flat	Flat	Flat	Flat	Flat	Flat

TABLE 6A: EVALUATION PARAMETERS FOR THE PREPARED TABLETS

Evaluation parameters	F1	F2	F3	F4	F5
Hardness S.D* (kg/cm^2) (N=20)	3.56 ± 0.115	3.6 ± 0.2	3.56 ± 0.28	3.76 ± 0.25	3.63 ± 0.15
Friability± S.D*(%) (N=20)	0.65 ± 0.03	0.65 ± 0.03	0.62 ± 0.03	0.63 ± 0.02	0.03 ± 0.02
Thickness ± S.D*(mm) (N=20)	3.46 ± 0.11	3.48 ± 0.02	3.52 ± 0.02	3.51 ± 0.05	3.47 ± 0.14
Weight variation ± S.D* (mm) (N=20)	150.1 ± 0.11	150.2 ± 0.01	150.3 ± 0.43	151.5 ± 1.28	154.7 ± 2.51
Drug content ± S.D* (N=20)	99.13 ± 0.32	98 ± 1	99.0 ± 0.05	96.9 ± 0.65	95.8 ± 0.76
Wetting time ± S.D* (Sec.) (N=6)	12 ± 2	11 ± 1	10.6 ± 1.15	20 ± 2	22 ± 2
Water absorption Ratio ± S.D*	19.33 ± 1.52	15.67 ± 0.57	14.33 ± 0.57	32 ± 2	35 ± 1
Dispersion time ± S.D* (Sec) (N=6)	5.33 ± 0.57	5.33 ± 0.57	4.66 ± 0.57	9.66 ± 2.08	9.33 ± 1.15

TABLE 6B: EVALUATION PARAMETERS FOR THE PREPARED TABLETS

Evaluation parameters	F6	F7	F8	F9	F10
Hardness ± S.D* (kg/cm^2) (N=20)	3.86 ± 0.11	3.73 ± 0.20	3.93 ± 0.11	4 ± 2	4.99 ± 0.90
Friability ± S.D*(%) (N=20)	0.65 ± 0.03	0.64 ± 0.02	0.58 ± 0.01	0.63 ± 0.02	0.62 ± 0.07
Thickness ± S.D*(mm) (N=20)	3.47 ± 0.14	3.50 ± 0.05	3.52 ± 0.02	3.53 ± 0.11	3.83 ± 0.04
Weight variation ± S.D* (mm) (N=20)	150 ± 0.01	150.4 ± 0.5	149 ± 1	150.3 ± 1.5	150.5 ± 0.2
Drug content ± S.D* (N=20)	97.5 ± 0.5	98.2 ± 0.64	98.63 ± 0.5	99.23 ± 0.5	99.4 ± 0.45
Wetting time ± S.D* (Sec.) (N=6)	22 ± 2	13.67 ± 1.52	14 ± 2	13 ± 1	12.3 ± 0.97
Water absorption ratio ± S.D*	34.33 ± 0.57	20.33 ± 0.57	15.67 ± 0.57	14 ± 0	32 ± 0.42
Dispersion time ± S.D* (Sec) (N=6)	9.33 ± 0.57	6.66 ± 0.57	5.33 ± 0.57	4.66 ± 0.57	8.76 ± 0.22

***In-vitro* Dissolution Test:** *In-vitro* dissolution studies for all the prepared formulations were carried by randomly picking the tablets from each formulation. This test was carried out using USP type II paddle apparatus at 50rpm using 300ml of Saliva phosphate buffer pH 6.8 as dissolution media, maintained at 37 ± 0.5 ºC. 1 ml aliquots were withdrawn at the specified time intervals, filtered through Whatmann filter paper and absorbance was calculated using UV-Visible spectrophotometer at 243 nm. An equal volume of fresh medium, which was pre-warmed at 37 ± 0.5 ºC, was replaced into the dissolution media after each sampling to maintain the constant volume thought the test [16].

TABLE 7A: DISSOLUTION DATA FOR THE PREPARED TABLETS

	% CDR				
Time (min)	**F1**	**F2**	**F3**	**F4**	**F5**
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
3	56.33 ± 0.5774	55 ± 2	59.67 ± 1.55	41.67 ± 1.528	36.67 ± 1.528
6	67 ± 1	62 ± 2	67 ± 2.646	51 ± 3	46 ± 3
9	76.33 ± 2.309	73.33 ± 4.163	77 ± 6.083	63 ± 3.606	59 ± 4
12	86 ± 3	84 ± 4.583	87 ± 4.933	74.67 ± 4.509	71.67 ± 3.055
15	95 ± 2.646	93 ± 3.606	96.67 ± 3.215	83 ± 2.646	85 ± 4.583

TABLE 7B: DISSOLUTION DATA FOR THE PREPARED TABLETS

	% CDR				
Time (min)	**F6**	**F7**	**F8**	**F9**	**F10**
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
3	38 ± 2.646	53 ± 2	54.33 ± 1.155	59 ± 3.1	62 ± 1.22
6	48.33 ± 4.512	64 ± 3.606	63.33 ± 2.08	67.67 ± 3.055	64 ± 3
9	61.67 ± 3.055	73 ± 1.732	76.33 ± 3.055	78.33 ± 3.055	72.22 ± 2.2
12	73 ± 6	83.67 ± 3.215	86.67 ± 4.933	89 ± 2.646	84 ± 2.602
15	84 ± 4.583	95 ± 2.646	92.67 ± 2.517	97.33 ± 1.528	99.33 ± 2.306

***In-vivo* Studies:** The bioavailability studies for tablets with pure Amlodipine besylate, solid dispersion of Amlodipine besylate, were carried out using male Wistar rats (200-250 g). The animals were maintained in a clean room at a temperature between 20-25 ℃ with 12-h light and dark cycles and controlled relative humidity. The animals were fasted for 12 h before commencement of the study as well as during the study and had access to water *ad libitum*.

The Institutional Animal Ethical Clearance (BU/Pharm/IAEC/a/17/06) was obtained before conducting the studies. They were divided into three groups (two in each group); group I served as a control group whereas other two groups were treated with tablet formulation containing pure drug Amlodipine besylate, and tablet formulation containing solid dispersion of Amlodipine besylate, respectively. Tablets with a dose of 0.04 mg/kg body weight of rats were administered by dispersing in distilled water through oral feeding pipe. Blood samples were collected through the lateral tail vein of rats at 0, 5, 10, 15, 20, 30, 40, 50, and 60 min followed by 3, 8, 12, and 24 h after administration. The blood samples were centrifuged at 10 000 rpm for 10 min. After centrifugation, plasma was transferred into clean, fresh Eppendorf tubes and frozen at –20°C until assayed. The plasma concentration of drug was determined by High-Performance Liquid Chromatography (HPLC).

Stability Studies: The Stability studies indicated that there was no significant change observed for In vitro dissolution studies after three months. Fast-dissolving tablets F3 were found to be stable for 3 months at 40 ºC ± 2 ºC/75% Rh ± 5% Rh [17].

RESULTS AND DISCUSSION:

X-ray Powder Diffractometry Studies (XRPD): X-ray powder diffractometry studies (XRPD) is a powerful technique for the identification of the crystalline solid phase has a unique (XRPD). Every crystalline solid phase has a unique XRPD pattern which can form the basis for its identification [18].

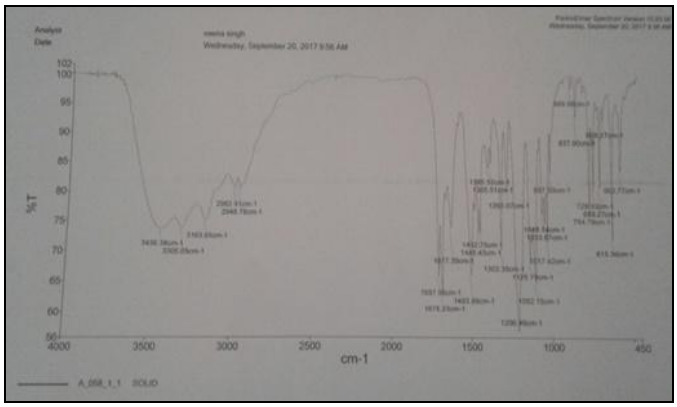

FIG. 1: IR SPECTRA OF AMLODIPINE BESYLATE

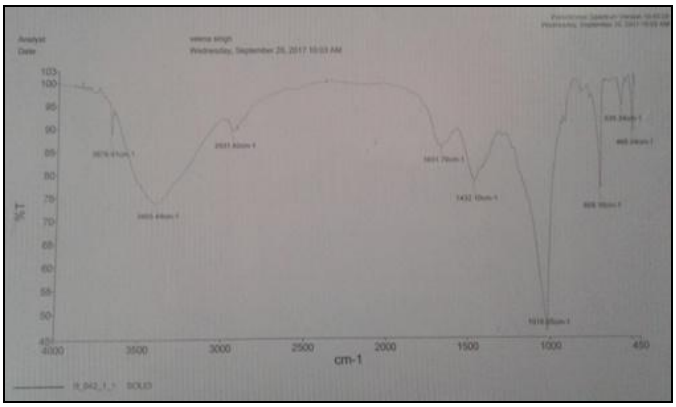

FIG. 2: IR SPECTRA OF AMLODIPINE BESYLATE + POLYMER

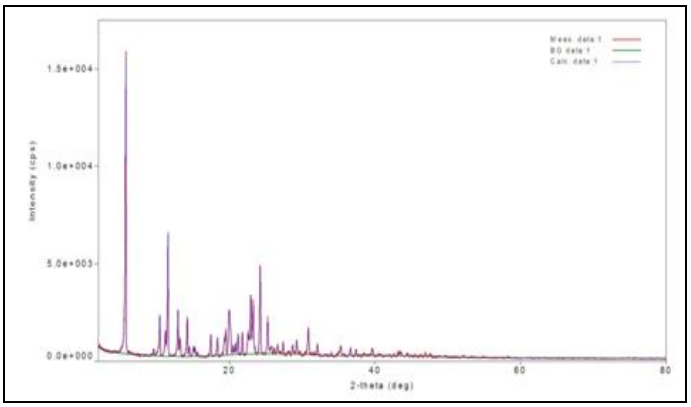

FIG. 3: X-RAY POWDER DIFFRACTOMETRY (XRPD) OF PURE AMLODIPINE BESYLATE

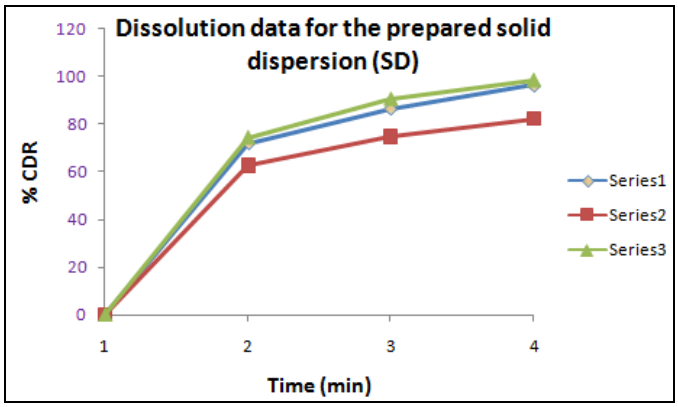

FIG. 4: DISSOLUTION DATA FOR THE PREPARED SOLID DISPERSION

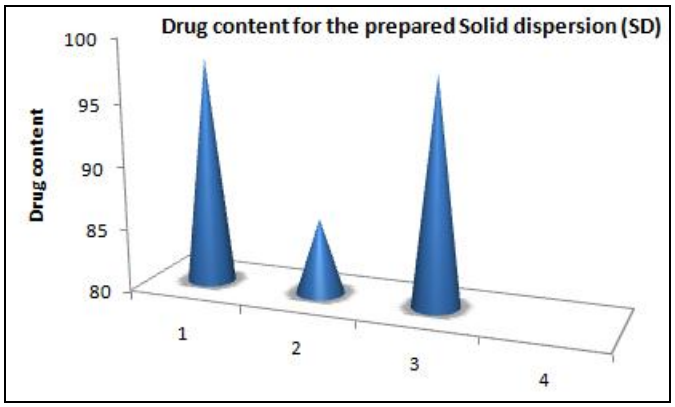

FIG. 5: DRUG CONTENT FOR THE PREPARED SOLID DISPERSION (SD)

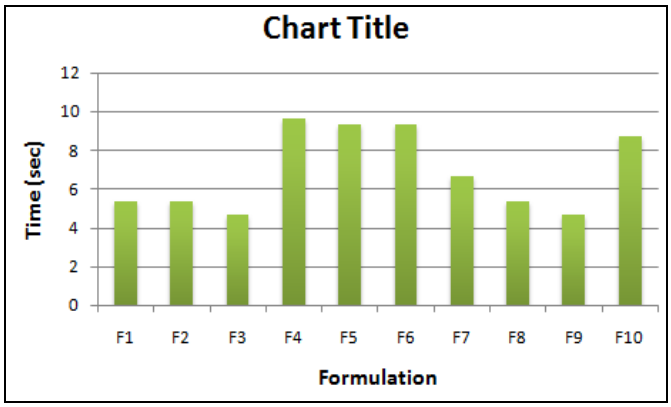

FIG. 6: DISPERSION TIME FOR THE PREPARED TABLETS

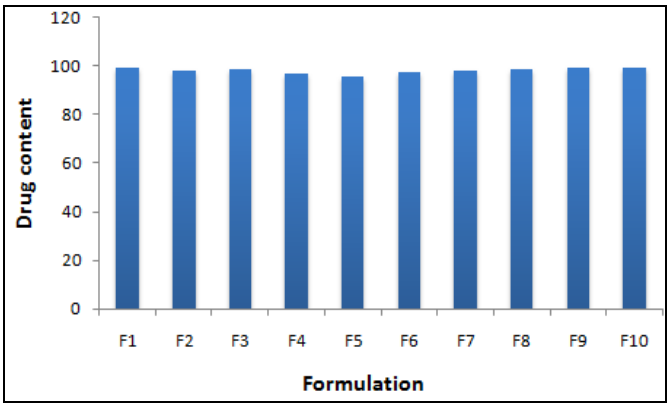

FIG. 7: DRUG CONTENT FOR THE PREPARED TABLETS

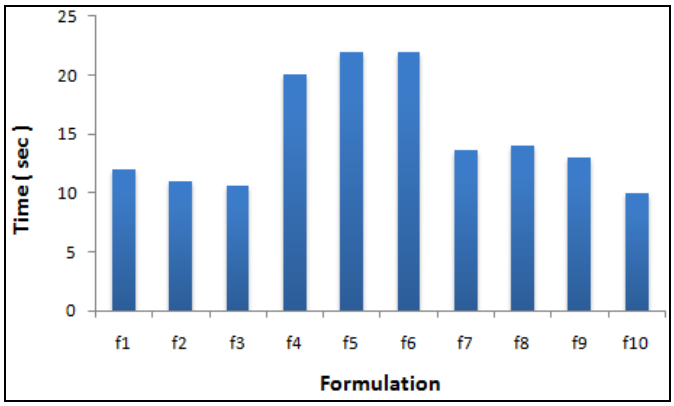

FIG. 8: WETTING TIME FOR THE PREPARED TABLETS

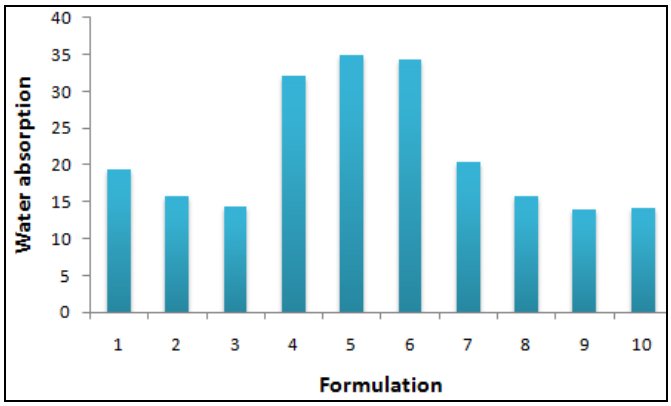

FIG. 9: WATER ABSORPTION RATIO (R)

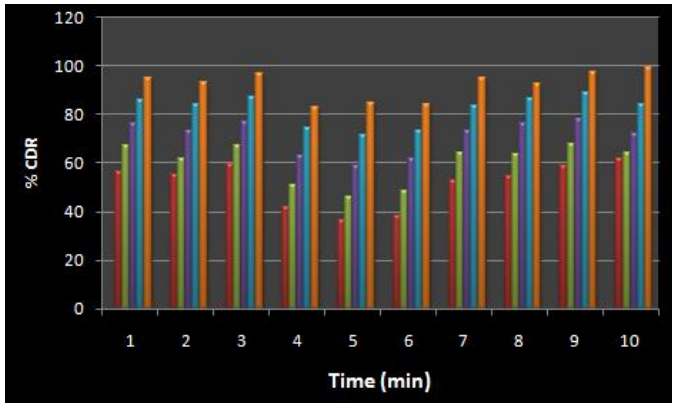

FIG. 10: DISSOLUTION DATA FOR THE PREPARED TABLETS

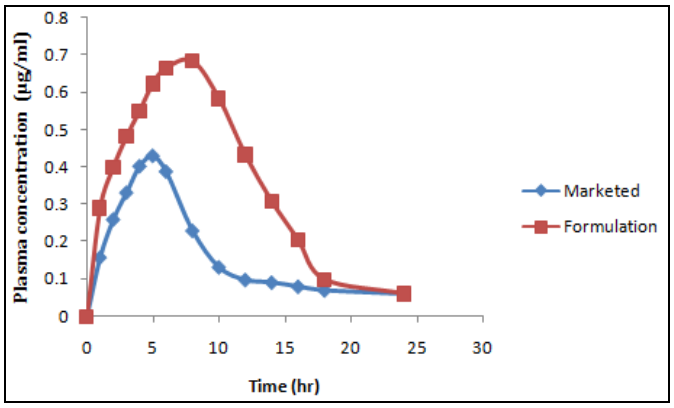

FIG. 11: PLASMA DRUG LEVEL CURVE FOR TABLET CONTAINING PURE AMLODIPINE BESYLATE AND MARKETED FORMULATION IN WISTAR RATS

CONCLUSION: The study showed that the dissolution rate of Amlodipine besylate was enhanced greater extent by a solid dispersion technique using the solvent evaporation method. The F3 batch is having the highest drug release and less disintegration time, which was optimized one. The prepared optimized tablet showed rapid disintegration as well as rapid dissolution as compared to a marketed tablet.

Furthermore, the fast dissolving tablet of Amlodipine besylate was successfully prepared by using different super disintegrants and the usage of this carrier for solid dispersion of Amlodipine besylates like EC, HPMC, and croscarmellose to enhance the dissolution profile. The *in-vivo* studies indicated that the solid dispersion approach could be adopted for the formulation of Amlodipine besylate tablets to achieve a faster onset of action.

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CONFLICT OF INTEREST: Nil

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