Research Article

Formulation, Development and Evaluation of Amlodipine Besylate orally Disintegrating Tablet Using Soy Polysaccharide as Novel Superdisintegrants

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ABSTRACT

The demand for orally disintegrating tablet (ODT) has been growing during the last decade especially for elderly and children who have swallowing difficulties. The present work emphasis that disintegrating properties of a natural super disintegrant soy polysaccharide and synthetic super disintegrant croscarmellose sodium and effect of their varying concentration on disintegration time and drug release. For the present study Amlodipine besylate, a calcium channel blocker was selected as a model drug. Total nine formulations of Amlodipine besylate containing different concentration of superdisintegrants were prepared by direct compression technique. The prepared tablets were evaluated for various parameters like. weight variation, hardness, friability, invitro dispersion time, invitro disintegration time, drug polymer interaction, drug content, water absorption ratio, wetting time and in-vitro drug release. From the FTIR and DSC study it was observed that no interaction was observed between drug and excipient. The optimized formulation from the study was found to be F6 which contains 8% soy polysaccharide and 5% crosscarmellose sodium. The optimized F6 formulation showed 97.56% drug release in 18 min with disintegration time of 20 ± 1.46 sec. The optimized formulations were kept for stability study at $40^0 \pm 2^0$c / 75 ± 5 % RH as per ICH guideline for a period of one month. The prepared optimized formulation was found to be stable during this period. To study the kinetics of in vitro drug release, data was applied to kinetics models such as zero order, first order, Higuchi and Korsmeyer- pappas. The release was found to be quasi-fickanian type, The enhanced disintegration of the tablet was might be due to combined effect of swelling and wicking properties of soy polysaccharide and crosscarmellose sodium.

Keywords: Orally disintegrating tablets, Amlodipine besylate, Croscarmellose sodium.

INTRODUCTION

Oral dosage form is the most widely used route for drug therapy. But conventional dosage forms like tablet, capsules, sachets are pills bears certain drawbacks like difficulty of swallowing to paediatric and geriatric patients, need of water for drug administration and adverse interaction of drug along the GI tract. Also slower onset of action of drug and inconvenience caused to the patient suffering from nausea and vomiting. To overcome all these problem there is a need to develop an alternative delivery system that can be orodispersible tablet (ODT). An orodispersible tablet is a solid dosage form that contains medicinal substance which disperse and disintegrates rapidly in saliva within fraction of second when placed over tongue without aid of water.[1,2]

Thus ODT enhance safety and efficacy of drug molecule along with patient compliance. The ODT preparation increases the pregastric absorption of drug and therefore avoids first pass metabolism and gastric degradation and hence enhances the bioavailability of drug .

AmlodipineBesylate is an antihypertensive drug and is widely been used to treat high blood pressure, certain type of coronary heart failure and angina pectoris. It acts as a calcium channel blocking agent. It inhibit the influx of extracellular calcium across the myocardial and vascular smooth muscle cell membrane resulting in dilation of the coronary and systemic artery, decrease in total peripheral

resistance and decrease in blood pressure. Amlodipine besylate is a white crystalline powder with a mol. Wt. of 567.1 It is slightly soluble in water and sparingly soluble in ethanol. After oral administration of therapeutic doses, Amlodipine is well absorbed with peak blood level between 6-12 hrs. post dose Absolute bioavailability of Amlodipine besylate has been estimated to be between 60-80%. It is extensively metabolized (about 90%) and converted to inactive metabolite via hepatic metabolism with 10% of the parent compound and 60% of the metabolic excreted in urine.[3,4]
The aim of the present study is to formulate orodispersible tablet of Amlodepine besylate by direct compression technique using differentConcentration of superdisintegrants like Ac-di-sol and novel superdisintegrants Soy polysaccharide.[5]
The present aim was also to prepare stable and effective formulation of Amlodepine besylate ODT formulation which can give rapid onset of action as compare to conventional dosage form.

Experimental
1) MATERIALS AND METHOD
MATERIALS
Amlodipine Besylate was obtained as a gift sample from Blue Cross. Pvt Ltd., Nashik, India. Croscarmellose sodium (Ac-di-sol) and Soy polysaccharide were obtained as gift sample from JRS Pharma Pvt. Ltd. Mumbai, India. Also Mannitol, Magnesium stearate, Dibasic calcium phosphate, Aspartame, Sodium hydroxide and Methanol were procured from Research-Lab Fine Chemical Industries Mumbai, India. All other excipients and chemicals used were of analytical grade (AR).

Preformulation study of the drug
Organoleptic properties
The sample of Amlodipine Besylate was studied for organoleptic properties such as colour, odour and appearance.

Solubility study
Known excess amount of drug was added to 10 mL of various solvents i.e. 0.1 M HCl (pH 1.2) ,Distilled water (pH 7.0), Phosphate buffer of pH 6.8 and pH 7.4 separately. All samples were sonicated for 30 min at 25^{o}C. Samples were then filtered, suitably diluted and analysed spectrophotometrically at 239 nm.

Drug –Excipients interaction study
DSC Study
The possibility of drug–excipient interaction was further investigated by differential scanning calorimetry. DSC analysis was performed using Mettler Star SW 9.01 DSC-60 (SHIMADZU). DSC of Amlodipine Besylate alone and its combination with Soy polysaccharide and crosscarmellose was taken in the quantity of 1 to 4 mg sample Samples were heated in an aluminum pan at a rate of 10°C / min within a 30 to 300°C temperature range under a nitrogen flow of 10 ml/min. An empty sealed pan was used as a reference.

FTIR Study
To analyze the compatibility of drug with polymers, the infrared spectrum of pure Amlodipine besylate sample and its combination with soy polysaccharide and crosscarmellose was recorded using FTIR spectrophotometer (SHIMADZU 84005). The scanning range was 400 to 4000 cm^{-1}.A change in spectrum pattern of drug due to presence of polymers was investigated to identify any chemical interaction.

Preparation of Amlodipine Besylate orally disintegrating tablet
Orally disintegrating tablets, each containing13.8 mg Amlodipine besylate were prepared by directcompression method. The composition of variousformulations was shown in table 1.Polymercomposition was selected on the basis of trialtaken for the formulated preparation. All theingredients weighed accurately, passed through 60 mesh and mixed in geometric order. Mixing was continued for 10 min to achieve uniform mixing then the mixture was lubricated with magnesium stearate for 5 min. Different polymers were used alone or in combination to formulated orally disintegrating tablet. The lubricated blend was than compressed into a tablet using 8mm standard round shaped punches on 10 station tablet compression machine JM-10 (JAGUAR Co. Pvt. India). Each tablet contains 13.8 mg of Amlodepinebesylate base and total weight of a tablet was 200 mg depending upon polymer concentration. All the tablet formulations were stored in air tight container till further use.

Physical characteristics
Evaluation of powder blends [6,7]
The powder blends were evaluated for flow property (angle of repose), loose bulk density, tapped density, compressibility index and drug content . Angle of repose was determined by fixed funnel method. Loose and tapped density was determined by cylinder method and for Carr's Index (CI) value following equation was used:

Carr's Index = tapped bulk density-loose bulk densityx100/tapped density.
Hausner's ratio was also calculated to define the flow property. A Hausner's value between 1.12 to 1.25 is indication of good flow property.

Evaluation of tablets
The prepared tablets were evaluated for their physical parameters like hardness, thickness, weight variation, friability and drug content. For hardness testing Monsanto hardness tester and for frability Roche friabilator (Campbell Electronics, Mumbai, India) was used to determine the value. Verniercaliper was used to measure the thickness of the tablets. Weight variation was performed as per official method.

Drug Content Estimation
Four tablets were weighted and crushed in a morter. Powder equivalent to 10 mg of drug was taken and dissolved in 100 ml methanol and was sonicated for 15 min.until all the content got dissolved. From this solution 1ml was taken and was diluted to 10 ml with methanol and its absorbance was noted down at 239nm using methanol as a blank.

Wetting Time
The wetting time of the tablets was measured using a very simple process.Five circular tissue papers of 10 cm diameter were placed in a petri dish having a 10 cm diameter. Ten millilitres of water containing a water Soluble dye (eosin) was added to the petri dish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablet was noted as the wetting time.

Water absorption Ratio
A piece of tissue paper folded twice was placed in a small petri dish containing 6 ml of water. A tablet was put on the paper & the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R, was determined using following equation,

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

Where, Wb is weight of tablet before water absorption &Wa is weight of tablet after water absorption.

In vitro dispersion time
Tablet was added to 10 ml of water at steady state of 37±0.5^{0}c, Time required for complete dispersion of a tablet was measured.

In vitro Disintegration Time
Disintegration time for ODTs was determined using USP disintegration apparatus with phosphate buffer of pH 6.8. The volume of medium was 900 ml and temp was 37± 0.5^{0}C. The time in seconds taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured. To comply the test all tablet should disintegrate within 3 minutes.

In vitro drug release
In vitro drug release was carried out using USP type II dissolution apparatus containing 900 ml of 0.1 M HCl. The apparatus was operated at 50 rpm at a temperature of 37 ± 0.5°C. 5 ml of aliquot was withdrawn at 3, 6, 9,12, 15 and18 minute intervals. The samples were filtered and concentration in each sample were determined by using UV Spectrophotometer at 239 nm. The analysis were performed in triplicate and average of three determination were mentioned.

Kinetic analysis of release data
The obtained dissolution data was fitted to Zero order, First order, Higuchi,Hixon -Crowell and Korsmeyer- Peppas equations to understand the rate and mechanism of drug release from the prepared formulations. The correlation coefficients values were calculated and used to find the fitness of the data. Zero order equation Q t = Qo + Kot , describe the systems where the drug release rate is independent of concentration of the dissolved substance, where, Qo = initial amount of drug, Qt = cumulative amount of drug release at time t, Ko= zero order release constant, t = time in hrs. First order release equation Log Qt = Log Qo + Kt/2.303 , the drug release rate depends on its concentration, where, Qo = initial amount of drug, Qt = cumulative amount of drug release at time t, K = first order release constant, t = time in hr. Hixon-crowell equation $Mo^{1/3} - Mt^{1/3}=K$, describes the drug release by dissolution and with the changes in surface area and diameter of the particles or tablets. Mo = Initial amount of drug, Mt = Cumulative amount of drug release at time t, K = Hixson-crowell release constant, t = time in h. Higuchi release equation Q=KH t½ or Mt/Mo =K t½ , the Higuchi equation suggests that the drug releases by diffusion mechanism. Q = cumulative amount of drug release at time t, KH = Higuchi constant ,t = time in h Korsmeyer-Peppas: $F = (Mt /M\infty) = K_m t^n$, which described drug release from a polymeric system, Where F=Fraction of drug released at time t, Mt=Amount of drug released at time t, M∞=Total amount of drug in dosage form,

Km= Kineticconstant, n= Diffusion or release exponent, t = time in h.

Stability study

Stability studies were carried out as per ICH Q_1A guidelines. The optimized Amlodepinebesylate tablets were wrapped in aluminium foils and were placed in the environmental stability chamber at $40^0C \pm 2^0C/75\% \pm 5\%$ RH for a period of one month. Sampling was done at a predetermined time intervals of initial, 7^{th}, 14^{th}, 21^{th}, and 28^{th} days. The formulation was analyzed for organoleptic characteristics, hardness, drug content, disintegration time and dissolution profile.

RESULTS AND DISCUSSION

1) Organoleptic properties

The organoleptic properties observed for Amlodipine Besylate is shown in table no. 2

2) Saturation solubility (pH dependent solubility) study

From the table no 3, it was observed that as the pH decreases solubility of amlodipine besylate increases

3) Drug excipients interaction

Differential Scanning Calorimetry (DSC)

Thermal analysis of drugs was carried out using DSC. The DSC curve of Amlodipine besylate profiles a sharp exothermic peak at 204.96^0C corresponding to its melting, and indicating its crystalline nature and purity of sample. The DSC thermogram was shown in figure no 1.

4) FTIR Study

The powdered drug and its mixture were taken separately in a sampler and the spectrum was recorded by scanning in the wavelength region of 4000-400 cm^{-1} using FTIR spectrophotometer. The results are shown in fig. no. 2

From table no.4 and from the FTIR spectra of all sample it was observed that the major peaks of amlodipine besylate, such at peaks at 3294,2985,1674,1496 cm^{-1} was not masked by excipients. Hence, we can conclude that there was no interaction of drug and excipients.

5) Evaluation of powder blend for flow properties

The powder characteristics of drug affect formulation of tablets. The result shown in above table no. 5, indicated that the powder blend has good flow property.

6) Evaluations & Characterization of prepared orally disintegrating tablets.

From table no.6 it was observed that thickness of the tablets for all the formulations was found to between 2.865 mm to 3.085 mm, with the average of 2.959 mm. The maximum standard deviation in thickness was up to 0.063 mm. The hardness of the tablets was found to be in the range 2.67 kg/cm^2. The friability of the tablets for all the formulations was found to be between 0.4985 % and 0.8264 % with average of 0.6469 %. All the formulations pass the test for friability as per IP standards. The average weight of the tablets from all the formulation was found to between 199.58 mg to 203.02 mg.% Drug content for all formulation was found to between 96.11 % and 103.22 %. Thus all tablets comply with IP standards.

Water absorption ratio test can't possible, due to disintegrating of tablet.

From the table no 7 it was observed that in vitro disintegration time for the prepared formulation was range between 14 – 29 sec , and in vitro dispersion time range between 24-48 sec. This results showed that both disintegrates viz. Ac-Di-Sol and soy polysaccharide enhanced the disintegration time and dispersion time of prepared formulation to marked extend. This is probably due to combined effect of wicking and swelling action of both superdisintegrants.

7) % drug release of prepared orally disintegrating tablets

The dissolution rate studies were performed to evaluate the dissolution character of Amlodipine Besylate from the orally disintegrating tablets.Table no 8 shows release profile of all the nine batches. From all the formulation F6 shows faster drug release when compared to other formulations. Hence F6 was considered to be the best formulation based on its release characteristics. By looking to table, We conclude that the F6 formulation was found to be optimized formulation.

The dissolution data of batches F1 to F9 was fitted to Zero order, First order, Higuchi and Korsemayer- peppas models. The n value obtained from the drug release data to the K-peppas equation , indicated that drug release mechanism from these tablet was quasi – fickian diffusion (table no.9)

Stability studies

From above table no.10 and 11 it was observed that the thickness of F6 formulation was found to be in the range of 2.945 – 3.015 mm. Tablet weight in the range of 198.26 – 201.70 mg. Hardness was found to be in the

range of 3-4 kg/cm^2. Content uniformity was found to be in the range of 96.45- 99.15 %. The result for in-vitro Study profile and short-term accelerated stability data obtained for optimized formulation revealed that drug content, thickness, hardness, In-vitro disintegration time and in-vitro dissolution were within the acceptable limit. All results obtained complied with official standards.

CONCLUSION

Based on the studies it was concluded that the tablets prepared were found to be good and free from lamination and capping. Post compressional parameters (hardness, friability, thickness and drug content) were within the acceptable limit.DSC and IR spectroscopic studies indicated that the drug is compatible with all the excipients.F6 formulation was found to be promising and showed In-vitro dispersion time of 24 sec, wetting time of 36 sec and in vitro disintegration time 20 sec which facilitate the faster dispersion in the aqueous media. In-vitro drug release from optimized orally disintegrating tablet of Amlodipine besylate (F6 formulation) was found to be 97.56 % in 18 minute with quasi-fickanian diffusion mechanism of drug release.The disintegration of tablet was might be due to combined effect of wicking and swelling action of both superdisintegrants.The stability study shows that no significant changes in drug content and release profile was observed.Thus we can conclude that formulation is stable, reproducible with good dispersion and disintegration characteristics.

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Table 1: Formulation of orally disintegrating tablet of Amlodipine besylate in nine batches

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Amlodipine Besylate equivalent to 10 mg of Amlodipine.	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
Soy polysaccharide	2	2	2	16	16	16	30	30	30
Croscarmellose sodium	2	6	10	2	6	10	2	6	10
Mannitol	80	80	80	80	80	80	80	80	80
Dibasic calcium phosphate	99.2	95.2	91.2	85.2	81.2	77.2	71.2	67.2	63.2
Aspartame	1	1	1	1	1	1	1	1	1
Magnesium stearate	2	2	2	2	2	2	2	2	2
Total	200	200	200	200	200	200	200	200	200

Table 2: Organoleptic properties of drug

Appearance	Crystalline powder
Colour	White
Odour	Odourless
Melting point	202-204^{o}C

Table 3: Saturation solubility (pH dependent solubility) study

S.No.	Drug	Saturation Solubility (gm/L)			
		0.1 M HCl (pH 1.2)	Phosphate Buffer (pH 6.8)	Water (pH 7.0)	Phosphate Buffer (pH 7.4)
1.	Amlodipine Besylate	0.1503	0.1336	0.1251	0.1135

Table 4: Interpretation of FTIR spectrum of Amlodipine besylate

Peak observed (cm^{-1})	Interpretation
3294.53	N-H stretching
3155.65	C-H stretching, aromatic
2985.91	C-H stretching
1674.27	C=O
1496.81	C=C aromatic
1303.92	C-N
1203.62,1126.47,1095.6	C-O

Table 5: Evaluation of powder blend for flow properties

Batch	Angle of repose (θ) (n=3)	Bulk density (gm/ml) (n=3)	Tapped density (gm/ml) (n=3)	Carr's Index (%) (n=3)	Hausner's Ratio
F1	28.00±0.031	0.544±0.0038	0.652±0.0024	16.56±1.72	1.1985
F2	27.39±0.095	0.553±0.0024	0.639±0.0063	13.45±1.94	1.1555
F3	29.60±0.025	0.503±0.0073	0.608±0.0040	17.26±1.63	1.2087
F4	29.60±0.078	0.520±0.0026	0.625±0.0032	16.80±1.81	1.2019
F5	28.52±0.094	0.475±0.0040	0.576±0.0037	17.53±2.19	1.2126
F6	28.00±0.036	0.511±0.0051	0.600±0.0026	14.83±1.93	1.1741
F7	28.26±0.029	0.552±0.0020	0.623±0.0050	11.39±1.79	1.1286
F8	27.75±0.058	0.516±0.0042	0.594±0.0036	13.13±1.40	1.1511
F9	28.78±0.046	0.470±0.0028	0.555±0.0035	15.31±1.74	1.1808

Table 6: Characterization of prepared orally disintegrating tablets

Batch	Thickness (mm) (n=3)	Hardness (kg/cm^2) (n=3)	% Friability (%)	Average weight (mg) (n=3)	Wetting time (sec) (n=3)
F1	2.905 ±0.018	3.67 ±0.06	0.7236	201.04 ±0.88	44 ±0.68
F2	2.937 ±0.017	2.67 ±0.10	0.5516	200.20 ±0.54	39 ±0.81
F3	2.9 ±0.035	2.83 ±0.06	0.6500	203.02 ±0.84	40 ±0.65
F4	2.876 ±0.026	3.50 ±0.05	0.4985	199.58 ±0.61	39 ±0.42
F5	2.865 ±0.03	3.33 ±0.10	0.7139	202.12 ±0.56	43 ±0.28
F6	2.99 ±0.024	3.33 ±0.10	0.5920	199.88 ±0.74	36 ±0.35
F7	3.012 ±0.024	3.00 ±0.05	0.7173	200.20 ±0.85	51 ±0.71
F8	3.085 ±0.063	3.83 ±0.11	0.5489	199.96 ±1.07	44 ±0.34
F9	3.065 ±0.01	3.33 ±0.06	0.8264	200.00 ±0.64	46 ±0.79

Table 7: Evaluation of prepared orally disintegrating tablets

Batch	In-Vitro Disintegration time (sec) (n=3)	In-Vitro Dispersion time (sec) (n=3)	Drug content (%) (n=3)
F1	16 ±1.18	42 ±1.23	99.16±1.07
F2	14 ±1.63	25 ±1.71	101.08±0.90
F3	24 ±1.78	33 ±1.58	98.88±0.39
F4	17 ±1.69	32 ±1.42	96.94±0.73
F5	23 ±1.15	29 ±1.69	97.50±0.87
F6	20 ±1.46	24 ±1.18	96.11±1.07
F7	18 ±1.32	29 ±1.38	98.05±0.72
F8	29 ±1.12	43 ±1.53	103.22±0.77
F9	23 ±1.52	48 ±1.42	99.44±0.50

Table 8: % drug release of prepared orally disintegrating tablets

Time (min)	F1 (n=3)	F2 (n=3)	F3 (n=3)	F4 (n=3)	F5 (n=3)	F6 (n=3)	F7 (n=3)	F8 (n=3)	F9 (n=3)
0	0	0	0	0	0	0	0	0	0
3	32.63 ±1.18	35.11 ±1.06	35.06 ±0.59	37.22 ±0.25	38.21 ±0.52	39.36 ±0.68	38.17 ±0.89	30.14 ±0.57	36.41 ±0.98
6	43.25 ±0.96	43.34 ±0.72	44.11 ±0.26	46.24 ±0.86	47.89 ±1.09	49.37 ±1.05	48.35 ±1.34	39.02 ±1.09	46.05 ±1.48
9	53.42 ±0.91	68.44 ±0.93	50.00 ±1.69	61.91 ±0.97	70.17 ±1.92	73.08 ±0.91	67.90 ±0.71	51.13 ±1.63	56.68 ±0.49
12	74.03 ±1.06	76.82 ±0.29	67.91 ±1.04	70.94 ±1.13	78.11 ±1.34	80.16 ±1.15	75.23 ±0.23	69.15 ±0.91	70.01 ±0.16
15	84.33 ±1.06	87.12 ±0.11	85.45 ±0.48	86.13 ±1.01	91.62 ±0.56	93.51 ±0.52	89.42 ±0.84	82.07 ±0.48	87.04 ±0.69
18	91.94 ±0.87	94.11 ±0.96	92.73 ±0.16	93.90 ±0.63	96.64 ±0.17	97.56 ±0.81	94.36 ±1.56	90.10 ±0.31	93.35 ±1.31

Table 9: Drug release kinetics of prepared ODT's formulations

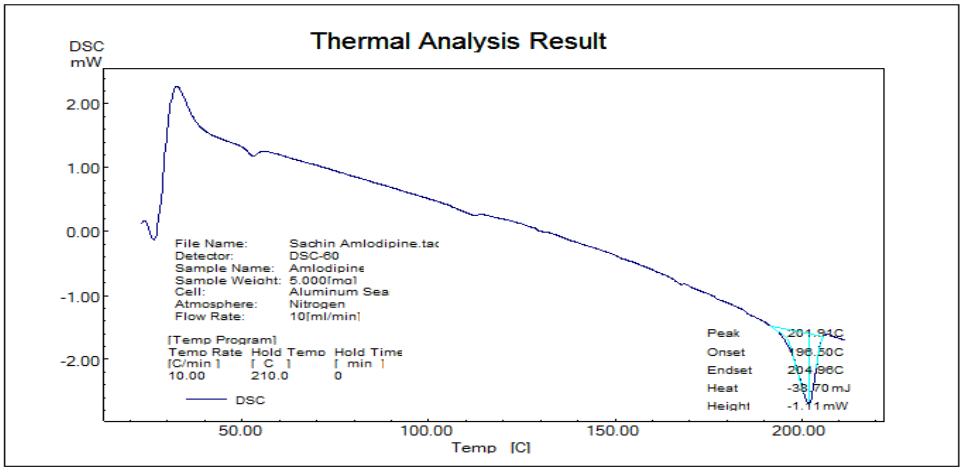
Batch	Zero order Plot	First order Plot	Korsmeyer- Peppas Plot		Release mechanism	Matrix Plot	Hix. Crow Plot
	(R^2)	(R^2)	(R^2)	N		(R^2)	(R^2)
F1	0.5657	0.7817	0.9787	0.4139	Quasi-fickian	0.8974	0.7543
F2	0.6879	0.6487	0.8975	0.5421	Non-fickian	0.9264	0.8412
F3	0.9764	0.8717	0.9155	0.3124	Quasi-fickian	0.9752	0.5498
F4	0.6478	0.6284	0.9561	0.1259	Quasi-fickian	0.9012	0.9814
F5	0.5785	0.7680	0.9365	0.3125	Quasi-fickian	0.8732	0.8452
F6	0.3856	0.6192	0.8465	0.2431	Quasi-fickian	0.8645	0.7654
F7	0.7964	0.7218	0.8922	0.3879	Quasi-fickian	0.8589	0.9851
F8	0.6478	0.5941	0.9823	0.2643	Quasi-fickian	0.9324	0.6884
F9	0.5456	0.6357	0.8643	0.2463	Quasi-fickian	0.9564	0.5936

Table 10: Evaluation of F6 formulation subjected to stability study

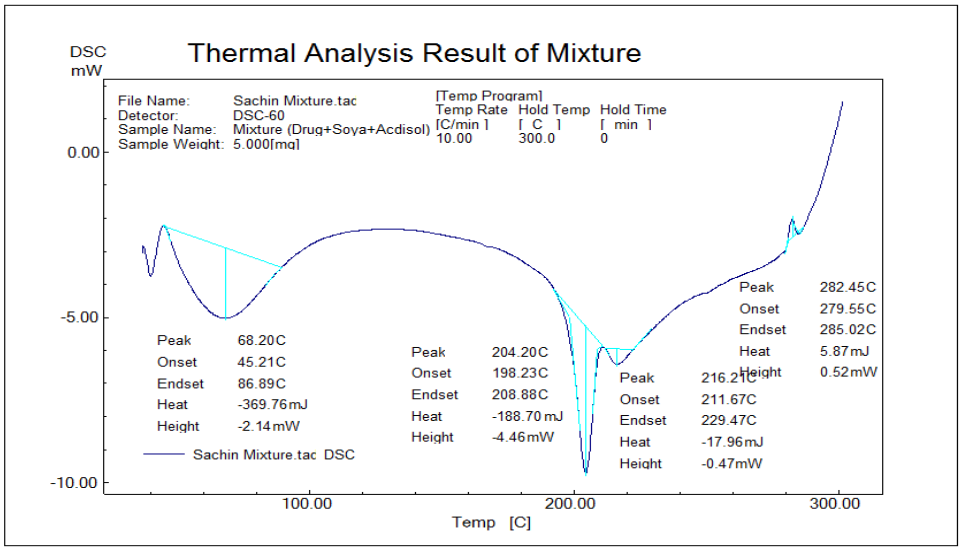
Parameter	7th Days	14th Days	21th Days	28th Days
Appearance	White Color	White Color	White Color	White Color
Thickness (mm)	2.945±0.028	3.015±0.019	2.980±0.017	2.995±0.024
Hardness (Kg/cm^2)	3-4	3-4	3-4	3-4
Tablet weight	201.02±0.63	198.26±0.84	201.70±0.67	200.14±0.78
In-vitro Disintegration time (sec)	31± 1.24	24± 1.62	29± 1.23	21± 1.46
Drug content (%)	98.24± 0.61	99.15± 0.72	96.45± 0.95	96.87± 0.65

Table 11: % Drug release of the optimized formulation subjected to stability study

Time (min)	% release after 7th Day	% release after 14th Day	% release after 21th Day	% release after 28th Day
0	0	0	0	0
3	36.15±0.54	34.26±0.95	39.87±0.78	31.45±0.26
6	46.54±0.68	41.58±0.16	44.57±0.87	42.48±0.88
9	59.45±0.67	56.87±0.64	68.45±0.45	61.21±0.43
12	73.12±0.49	76.45±0.49	71.45±0.61	75.45±1.27
15	80.45±0.91	86.15±1.04	84.97±1.35	88.78±0.19
18	94.15±0.34	96.75±0.57	95.78±0.40	98.78±0.82



(A)



(B)

Fig. 1: DSC thermogram of Amlodipine Besylate (A) and the physical mixture of Amlodipine Besylate and polymers (Soy Polysacharide and crosscarmillose sodium) (B)

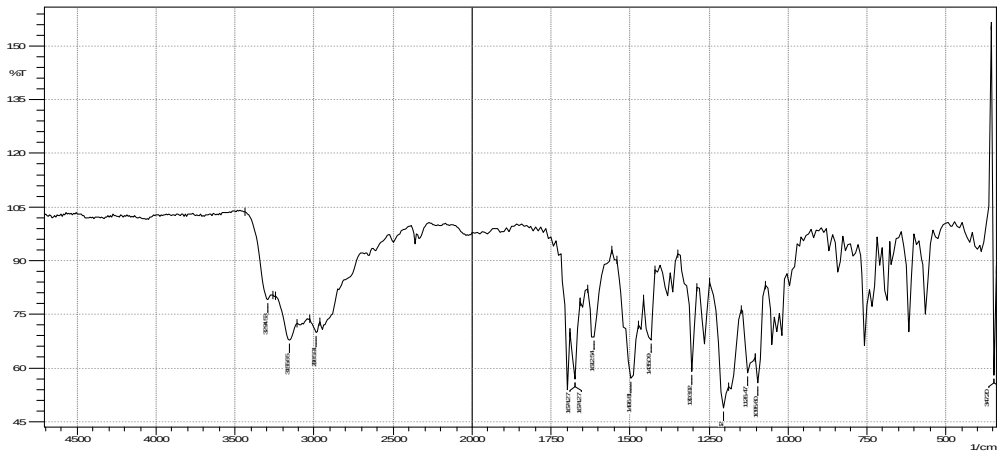


Fig. 2 (A): FITR spectra of pure drug

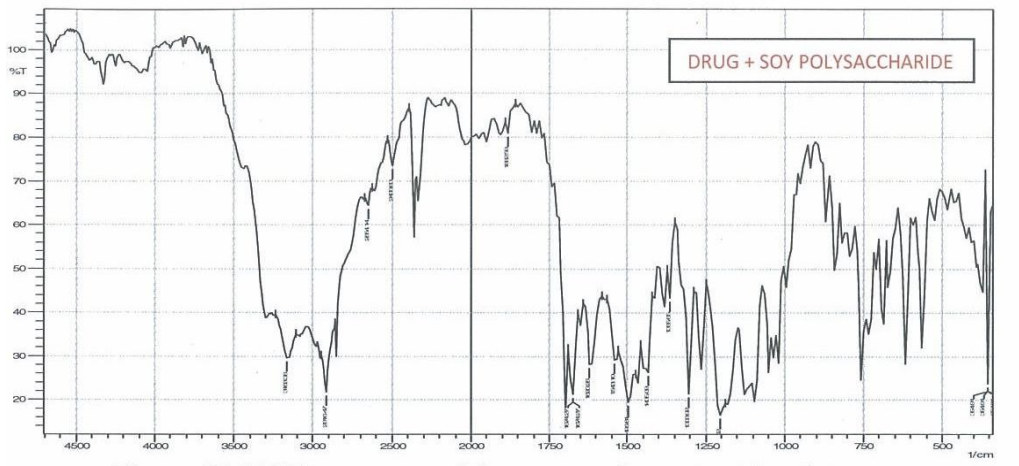


Fig. 2 (B): FTIR spectrum of drug+ soy polysaccharide

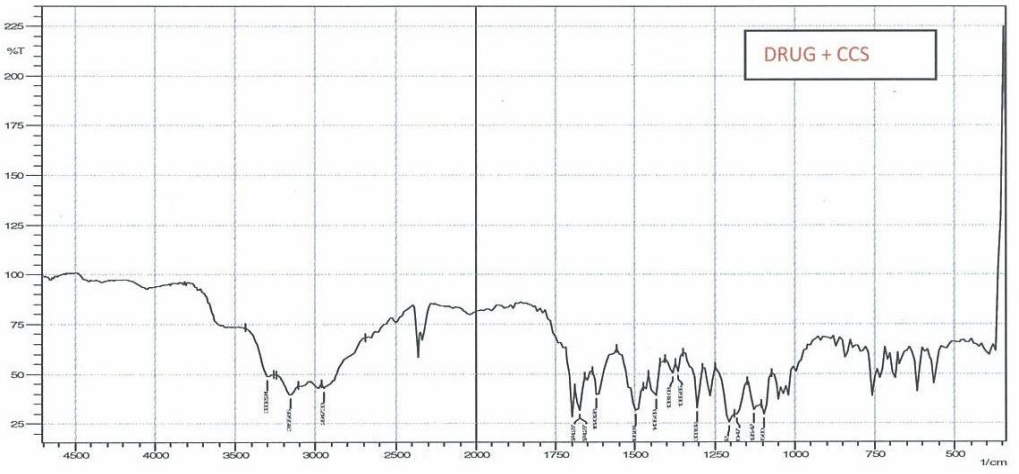


Fig. 2 (C): FTIR spectrum of drug + croscarmallose sodium

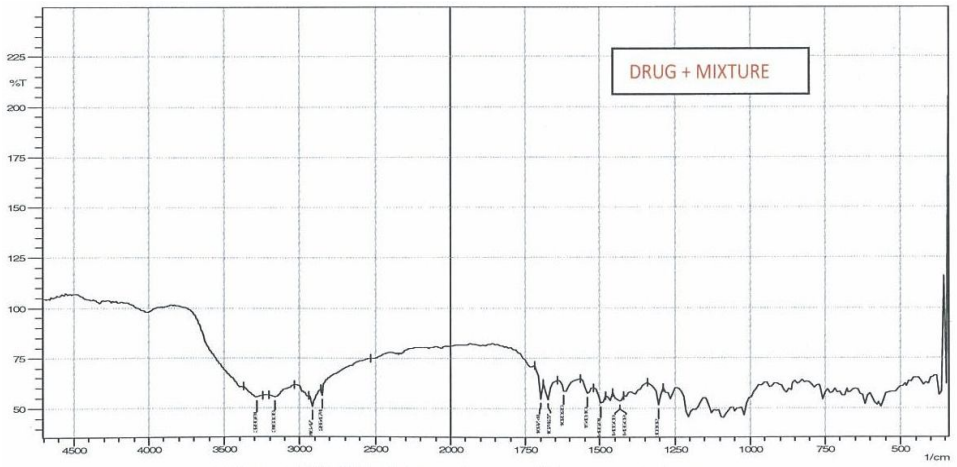


Fig. 2 (D): FTIR spectrum of drug and mixture.
Fig-2 FTIR spectra of pure drug (A), physical mixture of drug and disintegrants(B& C) and drug along with all tablet exipients (D)

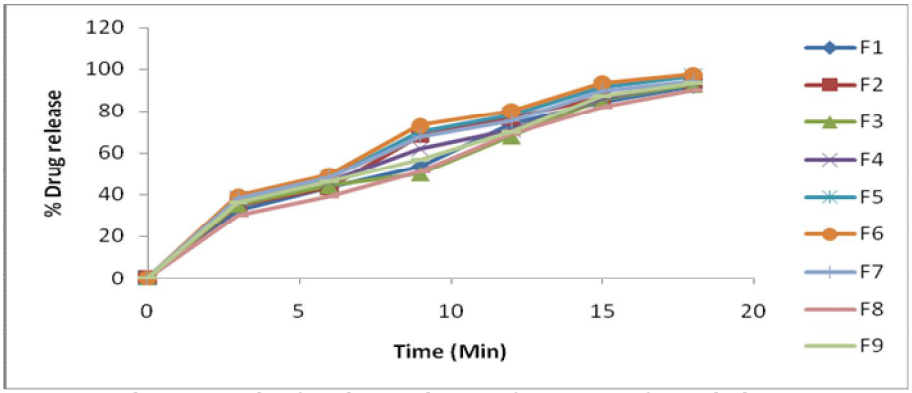


Fig. 3: Graph of % drug release of F 1 to F 9 formulations

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