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FORMULATION AND EVALUATION OF ORODISPERSIBLE TABLET OF AMLODEPINE  
BESILATEE

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### Abstract

Orodispersible tablet are uncoated tablet intended to be placed in the mouth where they disperse rapidly before being swallowed. Orodispersible tablets disintegrate within 3 min when examined by the test for disintegration of tablets and capsules. Orodispersible tablet in which cross povidone (Polyplasdone XL 10), Sodium starch glycolate(SSG), Cross carmellose sodium(Ac-De-Sol), these are the different super disintegrant are used to maintain the release profile of drug.

Dysphasia or difficulty in swallowing is seen to afflict nearly 50% of the general population. This disorder is also associated with number of medical conditions including stroke, Parkinson's disease, AIDS, head and neck radiation therapy and other neurological disorder including cerebral palsy. Recent advances in novel drug delivery system aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for better patient compliance.

**Keywords:** Orodispersible tablet, Optimization study, effect of super disintegrant release profile of drug, method to preparation orodispersible tablet.

### Objective

in the present study an attempt will be made to formulate Orodispersible tablets of Amlodipine Besilate, is 3-Ethyl 5-methyl 2-(2-aminomethoxymethyl) -4- (2- chlorophenyl)- 1,4-dihydro-6-methylpyridine-3,5-dicarboxylate monobenzene sulphonate. Calcium channel blocker used in treatment of hypertension and angin

The present study is planned with the following objectives:

- 1 Preparation of Orodispersible tablets of Amlodipine besilate by direct compression using different concentration of superdisintegrants like croscarmallose sodium (AC-di-sol), sodium starch glycolate (Explotab) and crospovidone (polyplasdone XL).
- 2 Drug-excipients interaction using IR studies.
- 3 Orodispersible tablets of Amlodipine besilate were also prepared by sublimation method using camphor as subliming agent and croscarmellose sodium (Ac-di-sol), sodium starch glycolate (Explotab) and crospovidone (Polyplasdone XL) as superdisintegrants.
- 4 Orodispersible tablets of Amlodipine besilate were evaluated for hardness, friability, weight variation, disintegration time, drug content, water absorption ratio, wetting time.
- 5 Stability study of formulation as per the ICH guidelines.
- 6 Study *in vitro* dissolution of Amlodipine besilate from the formulated Orodispersible tablets.

- **Methods of Preparation of Orodispersible Tablets**

1. Direct compression method.
2. Sublimation method.

**A) Preparation of Orodispersible tablets by direct compression technique:**

**Method:** Orodispersible tablets of Amlodipine besilate were prepared by direct compression method according to the formula given in all the ingredients were passed through 60 mesh sieve separately. The drug and microcrystalline cellulose was 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 Multi Station rotary punch tablet compression machine.

**B) Sublimation method:**

**Method:** Amlodipine besilate tablets were prepared by sublimation technique. The basic principle involved in preparing orodispersible tablets by sublimation technique is inert solid ingredients (E.g. urea, urethane, ammonium carbonate, camphor, naphthalene) were added to other tablet excipients and the blend was compressed into tablet. Removal of volatile material by sublimation generated a porous structure. Compressed tablets containing mannitol and camphor have been prepared by sublimation technique. The tablets dissolve within 10-20 seconds and exhibit

sufficient mechanical strength for practical use. Nine formulations were developed by varying concentration of subliming agent i.e. camphor.

Accurately weighed ingredients were sifted through sieve no.44 and thoroughly mixed for 10 min and magnesium stearate and other ingredients were added to the blend and thoroughly mixed. The tablets were compressed using Multi Station rotary punch tablet compression machine. The compressed tablets were than subjected to sublimation at 80°C for 30 min. The tablets were evaluated for disintegration time and mean tablet weight.

**Farmulation of orodispersible table:-**

**Table: Formulation of Amlodipine besilate orodispersible tablets prepared by direct compression method (1-tablet).**

Ingredient (mg)	Formulation code								
	DCC <sub>1</sub>	DCC <sub>2</sub>	DCC <sub>3</sub>	DCS <sub>1</sub>	DCS <sub>2</sub>	DCS <sub>3</sub>	DCP <sub>1</sub>	DCP <sub>2</sub>	DCP <sub>3</sub>
Amlodipine besilate	10	10	10	10	10	10	10	10	10
MCC	80	80	80	80	80	80	80	80	80
Mannitol	41.3	38.3	35.3	41.3	38.3	35.3	41.3	38.3	35.3
CCS	6	9	12	-	-	-	-	-	-
SSG	-	-	-	6	9	12	-	-	-
CP	-	-	-	-	-	-	6	9	12
Aspartame	10	10	10	10	10	10	10	10	10
Mixed fruit flavor	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1
Magnesium Sterate	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70
Total weight	150	150	150	150	150	150	150	150	150

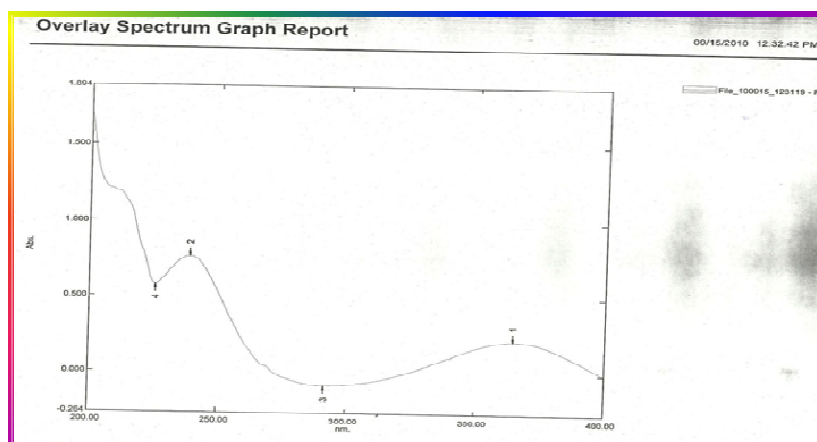
**Table: Formulation of Amlodipine besilate orodispersible tablets prepared by sublimation method (1-tablet)**

Ingredient (mg)	Formulation code								
	SBC <sub>1</sub>	SBC <sub>2</sub>	SBC <sub>3</sub>	SBS <sub>1</sub>	SBS <sub>2</sub>	SBS <sub>3</sub>	SBP <sub>1</sub>	SBP <sub>2</sub>	SBP <sub>3</sub>
Amlodipine besilate	10	10	10	10	10	10	10	10	10
MCC	80	80	80	80	80	80	80	80	80
Mannitol	26.3	23.3	20.3	26.3	23.3	20.3	26.3	23.3	20.3
CCS	6	9	12	-	-	-	-	-	-
SSG	-	-	-	6	9	12	-	-	-
CP	-	-	-	-	-	-	6	9	12
Camphor	15	15	15	15	15	15	15	15	15
Aspartame	10	10	10	10	10	10	10	10	10
Mixed fruit flavor	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1
Magnesium Sterate	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70
Total weight	150	150	150	150	150	150	150	150	150

**Result and discussions**

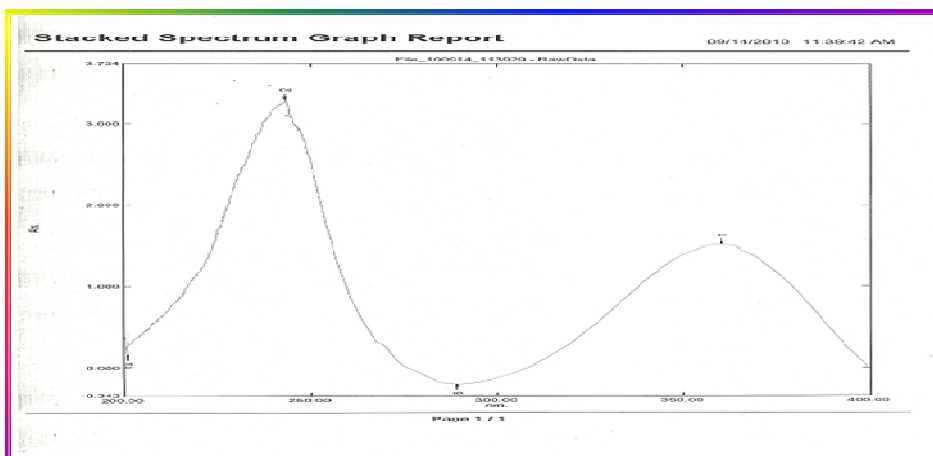
**Results for determination of  $\lambda_{max}$  of Amlodipine besilate:**

**A)  $\lambda_{max}$  of Amlodipine besilate in methanol:**



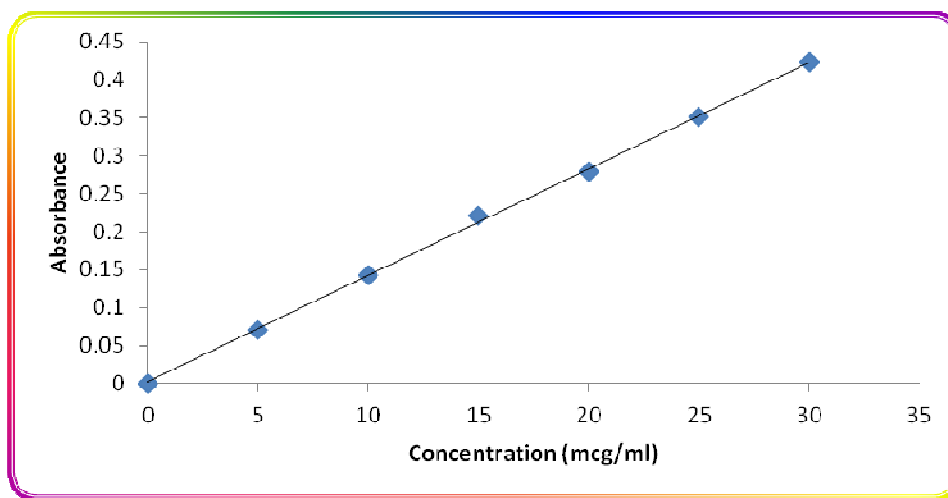
**Fig: Absorption of Amlodipine besilate in methanol.**

**B)  $\lambda_{max}$  of Amlodipine besilate in phosphate buffer pH 7.4:**



**Fig: Absorption of Amlodipine besilate in phosphate buffer pH Standard calibration curve of Amlodipine besilate in methanol solution at  $\lambda_{max}$  237.5 nm**

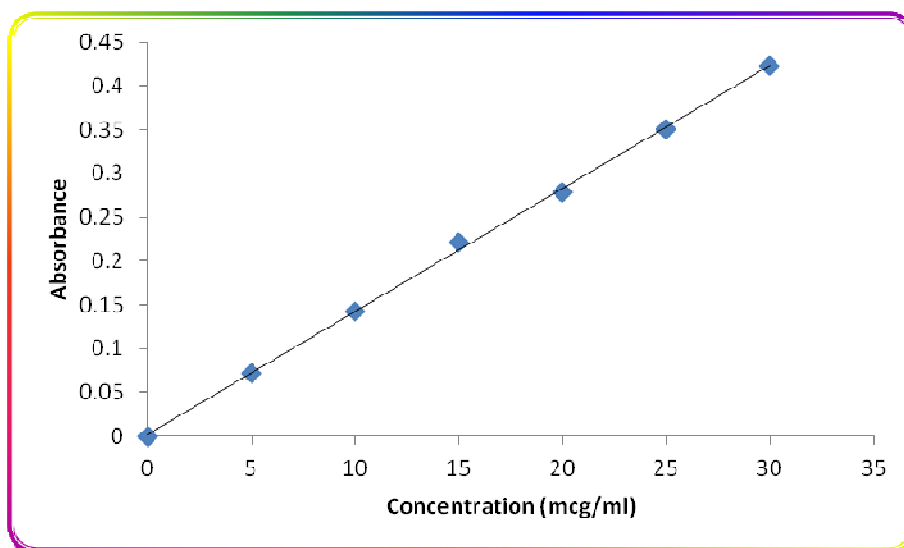
Sl. No.	Concentration (mcg/ml)	Absorbance
1.	00	0.000
2.	05	0.090
3.	10	0.187
4.	15	0.265
5.	20	0.366
6.	25	0.448
7.	30	0.549



**Fig: Standard calibration curve of Amlodipine besilate in methanol solutions at  $\lambda_{max}$  237.5 nm**

**Table 13: Standard calibration curve of Amlodipine besilate in phosphate buffer pH 7.4 solution at  $\lambda_{max}$  237.5 nm**

Sl. No.	Concentration (mcg/ml)	Absorbance
1.	00	0.000
2.	05	0.071
3.	10	0.143
4.	15	0.221
5.	20	0.279
6.	25	0.351
7.	30	0.423



**Fig : Standard calibration curve of Amlodipine besilate in phosphate buffer pH 7.4 solutions at  $\lambda_{max}$  237.5 nm.**

**Pre-compression parameters of Direct Compression method**

Formulation code	Bulk density* (g/cc)	Tapped density* (g/cc)	Angle of repose* ( ° )	Carr's index* (%)	Hausner's Ratio*
DCC <sub>1</sub>	0.52 ± 0.007	0.63 ± 0.01	29.25 ± 1.56	17 ± 1	1.21 ± 0.03
DCC <sub>2</sub>	0.53 ± 0.007	0.63 ± 0.01	30.02 ± 1.20	15 ± 1.51	1.18 ± 0.04

<b>DCC<sub>3</sub></b>	0.53 ± 0.007	0.64 ± 0.02	30.1 ± 1.70	17 ± 1.20	1.20 ± 0.03
<b>DCS<sub>1</sub></b>	0.55 ± 0.007	0.65 ± 0.01	30.20 ± 0.88	15 ± 2.51	1.18 ± 0.03
<b>DCS<sub>2</sub></b>	0.50 ± 0.007	0.63 ± 0.01	28.43 ± 1.48	20 ± 1.58	1.26 ± 0.03
<b>DCS<sub>3</sub></b>	0.52 ± 0.007	0.63 ± 0.02	30.72 ± 1.22	17 ± 1.55	1.21 ± 0.04
<b>DCP<sub>1</sub></b>	0.51 ± 0.007	0.62 ± 0.38	29.87 ± 1.32	17 ± 1.39	1.21 ± 0.04
<b>DCP<sub>2</sub></b>	0.54 ± 0.007	0.65 ± 0.02	28.04 ± 1.34	16 ± 2.20	1.20 ± 0.03
<b>DCP<sub>3</sub></b>	0.52 ± 0.007	0.62 ± 0.01	26.28 ± 1.26	16 ± 2.01	1.19 ± 0.03

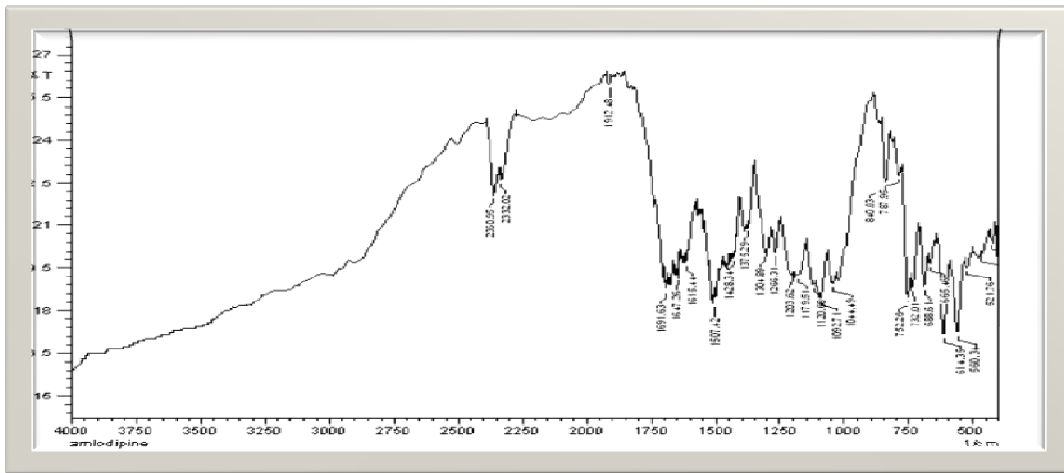
\* Average of three determinations

**Table : Pre-compression parameters of powder blend of sublimation method.**

<b>Formulation</b>	<b>Bulk density* (g/cc)</b>	<b>Tapped Density* (g/cc)</b>	<b>Angle of repose (°)</b>	<b>Carr's Index* (%)</b>	<b>Hausner's Ratio*</b>
<b>SBC<sub>1</sub></b>	0.51 ± 0.007	0.65 ± 0.01	29.25 ± 1.56	17 ± 1	1.30 ± 0.03
<b>SBC<sub>2</sub></b>	0.52 ± 0.007	0.62 ± 0.01	28.02 ± 1.20	16 ± 1.51	1.19 ± 0.04
<b>SBC<sub>3</sub></b>	0.53 ± 0.007	0.61 ± 0.02	29.11 ± 1.70	13 ± 1.20	1.15 ± 0.03
<b>SBS<sub>1</sub></b>	0.53 ± 0.007	0.64 ± 0.01	30.20 ± 0.88	17 ± 2.51	1.14 ± 0.03
<b>SBS<sub>2</sub></b>	0.50 ± 0.007	0.63 ± 0.01	26.43 ± 1.48	20 ± 1.58	1.26 ± 0.03
<b>SBS<sub>3</sub></b>	0.54 ± 0.007	0.65 ± 0.02	27.72 ± 1.22	16 ± 1.55	1.20 ± 0.04
<b>SBP<sub>1</sub></b>	0.52 ± 0.007	0.63 ± 0.38	29.87 ± 1.32	17 ± 1.39	1.21 ± 0.04
<b>SBP<sub>2</sub></b>	0.51 ± 0.007	0.62 ± 0.02	29.04 ± 1.34	17 ± 2.20	1.21 ± 0.03
<b>SBP<sub>3</sub></b>	0.53 ± 0.007	0.63 ± 0.01	30.28 ± 1.26	15 ± 2.01	1.18 ± 0.03

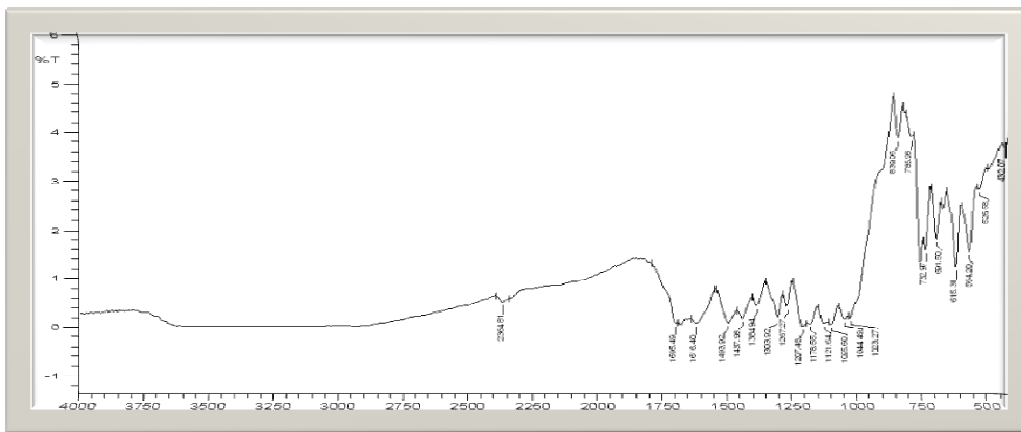
\* Average of three determinations

**RESULTS FOR DRUG POLYMER INTERACTION STUDIES**



**IRStudies:**

**Fig : IR spectra of Amlodipine besilate.**



**Fig : IR spectra of formulation DCC3**

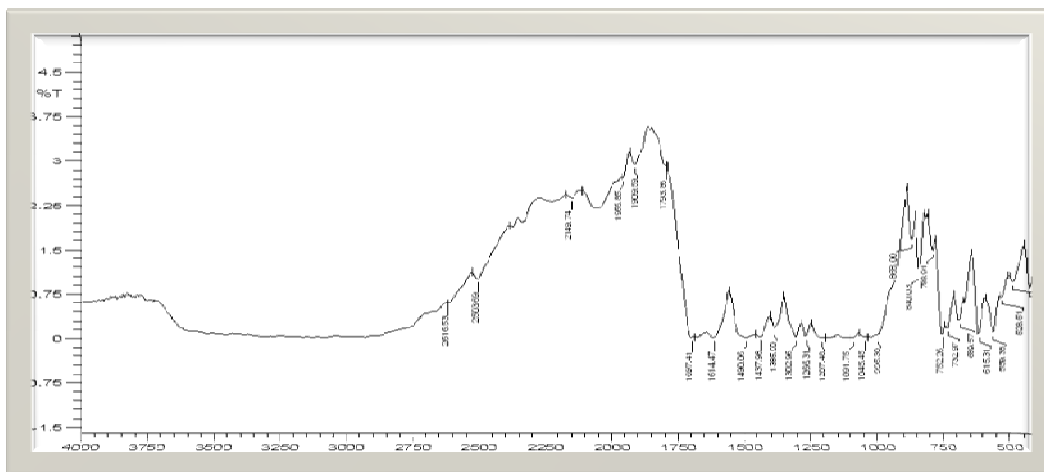


Fig : IR spectra of formulation DCS<sub>3</sub>

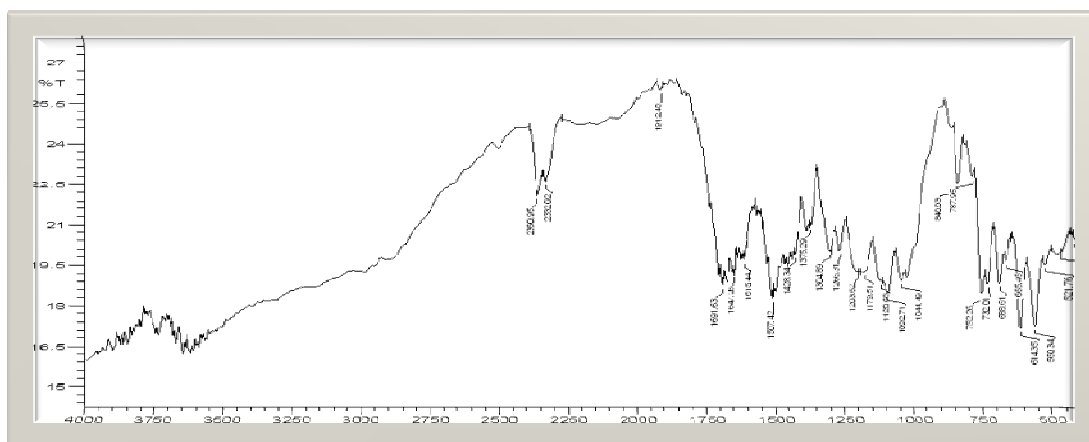


Fig : IR spectra of formulation DCP<sub>3</sub>

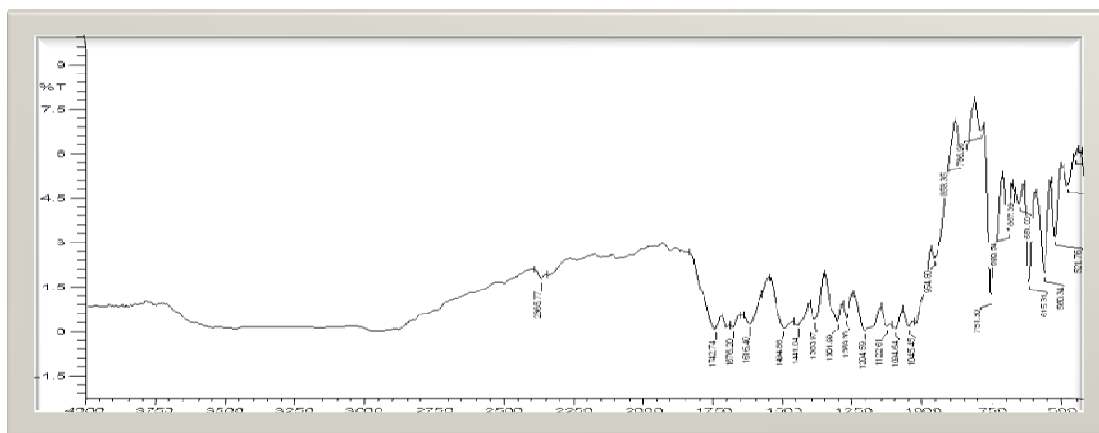


Fig : IR spectra of formulation SBC<sub>3</sub>

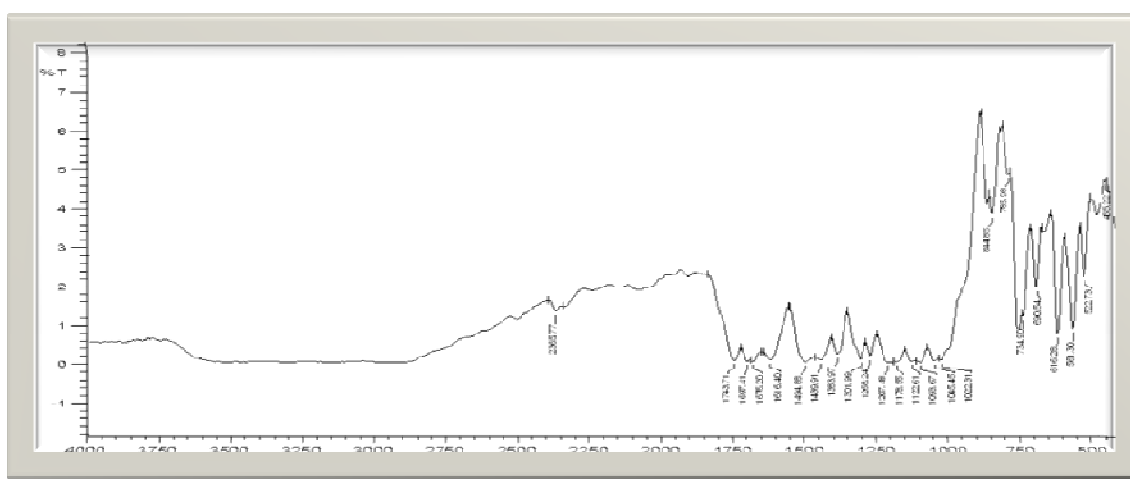


Fig : IR spectra of formulation SBS<sub>3</sub>

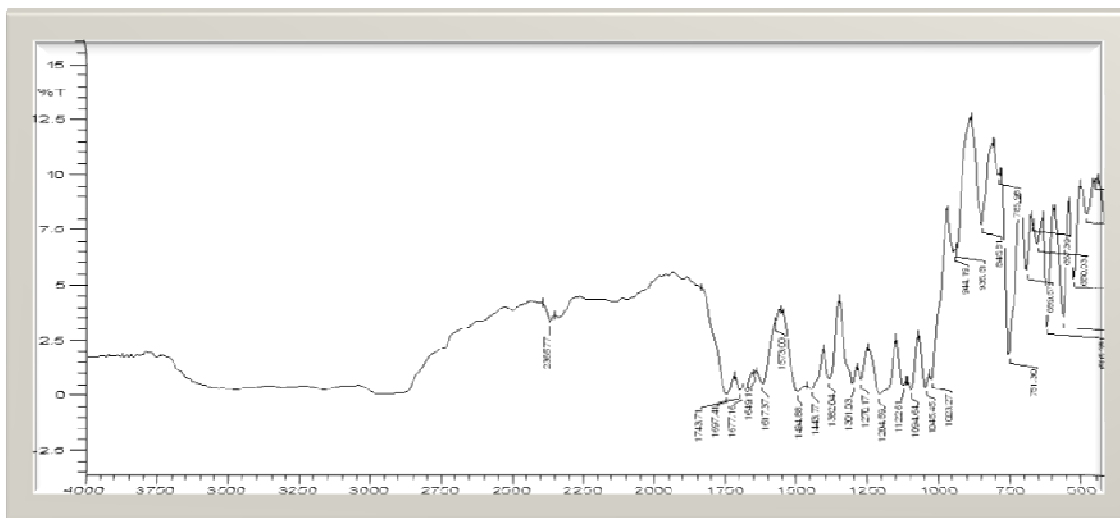


Table :Post-compression parameters for Direct Compression method.

Formulation Code	Hardness* (Kg/cm <sup>2</sup> )	Friability (%)	Thickness* (mm)	Average Weight* (mg)
DCC <sub>1</sub>	3.6 ± 0.11	0.81	2.29 ± 0.12	149 ± 1.78
DCC <sub>2</sub>	3.7 ± 0.11	0.64	2.30 ± 0.15	148 ± 1.32
DCC <sub>3</sub>	3.9 ± 0.10	0.31	2.42 ± 0.10	150 ± 0.56
DCS <sub>1</sub>	3.7 ± 0.12	0.62	2.31 ± 0.10	149 ± 1.97
DCS <sub>2</sub>	3.8 ± 0.18	0.47	2.32 ± 0.17	150 ± 0.65
DCS <sub>3</sub>	3.6 ± 0.10	0.65	2.36 ± 0.15	150 ± 1.93
DCP <sub>1</sub>	3.7 ± 0.15	0.82	2.28 ± 0.12	149 ± 1.21
DCP <sub>2</sub>	3.6 ± 0.21	0.80	2.26 ± 0.09	149 ± 1.50
DCP <sub>3</sub>	3.9 ± 0.10	0.64	2.27 ± 0.19	151 ± 0.18

\* Average of three determinations

Table: Post-compression parameters for Sublimation method.

Formulation Code	Hardness* (Kg/cm <sup>2</sup> )	Friability (%)	Thickness* (mm)	Average Weight* (mg)
SBC <sub>1</sub>	3.1 ± 0.11	0.32	2.32 ± 0.12	149 ± 1.78
SBC <sub>2</sub>	3.2 ± 0.11	0.32	2.35 ± 0.15	149 ± 1.32

<b>SBC<sub>3</sub></b>	3.3 ± 0.10	0.64	2.26 ± 0.10	149 ± 0.56
<b>SBS<sub>1</sub></b>	3.2 ± 0.12	0.47	2.30 ± 0.10	150 ± 1.97
<b>SBS<sub>2</sub></b>	3.5 ± 0.18	0.80	2.35 ± 0.17	148 ± 0.65
<b>SBS<sub>3</sub></b>	3.4 ± 0.10	0.63	2.38 ± 0.15	147 ± 1.93
<b>SBP<sub>1</sub></b>	3.2 ± 0.15	0.98	2.28 ± 0.12	148 ± 1.21
<b>SBP<sub>2</sub></b>	3.5 ± 0.21	0.48	2.30 ± 0.09	150 ± 1.50
<b>SBP<sub>3</sub></b>	3.5 ± 0.10	0.78	2.40 ± 0.19	149 ± 0.18

\* Average of three determinations

**Table: Post-compression parameters for direct compression method.**

<b>Formulation Code</b>	<b>In vitro dispersion time* (sec)</b>	<b>Wetting time* (sec)</b>	<b>Water absorption ratio*</b>	<b>Drug Content* (%)</b>
<b>DCC<sub>1</sub></b>	32 ± 2.78	67 ± 2.51	70 ± 1.54	98.05 ± 0.72
<b>DCC<sub>2</sub></b>	31 ± 1.0	65 ± 2.0	72 ± 1.86	96.11 ± 1.07
<b>DCC<sub>3</sub></b>	28 ± 1.0	61 ± 2.40	78 ± 1.35	99.44 ± 0.50
<b>DCS<sub>1</sub></b>	48 ± 2.0	76 ± 1.89	56 ± 1.58	96.94 ± 0.73
<b>DCS<sub>2</sub></b>	50 ± 1.5	73 ± 2.20	63 ± 1.21	97.50 ± 0.87
<b>DCS<sub>3</sub></b>	53 ± 1.7	69 ± 1.0	68 ± 1.57	96.66 ± 0.90
<b>DCP<sub>1</sub></b>	38 ± 2.8	69 ± 2.25	63 ± 1.20	99.16 ± 1.07
<b>DCP<sub>2</sub></b>	35 ± 1.45	67 ± 2.15	68 ± 1.05	98.88 ± 0.39
<b>DCP<sub>3</sub></b>	34 ± 1.28	65 ± 1.0	71 ± 1.73	97.22 ± 0.77

\* Average of three determinations

**Table: Post-compression parameters for Sublimation method.**

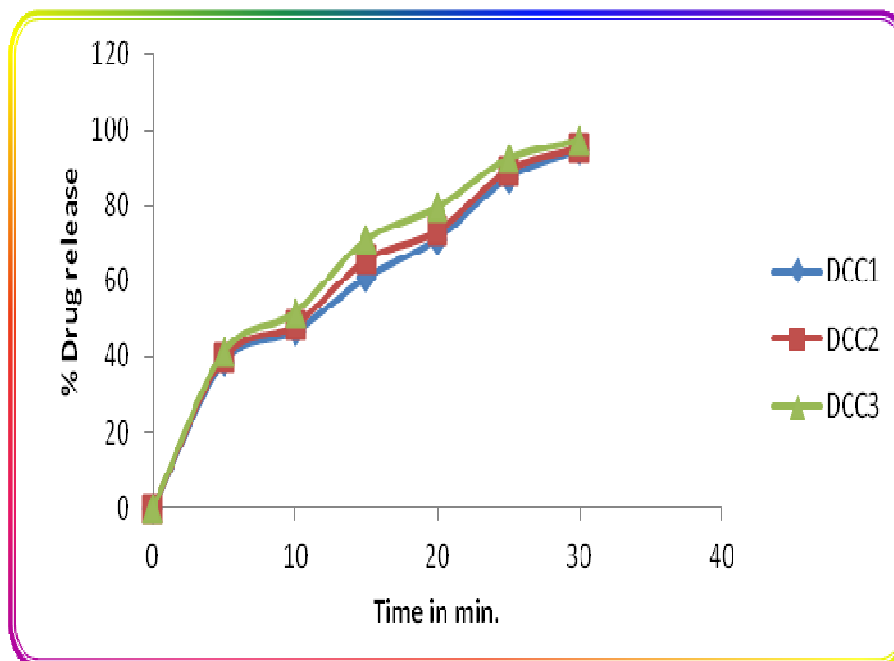
<b>Formulation Code</b>	<b>In vitro dispersion time* (sec) ± SD</b>	<b>Wetting time* (sec) ± SD</b>	<b>Water absorption ratio* ± S.D</b>	<b>Drug Content* (%) ± SD</b>
<b>SBC<sub>1</sub></b>	29 ± 2.78	60 ± 2.51	75 ± 1.54	95.83 ± 0.72
<b>SBC<sub>2</sub></b>	27 ± 1.0	58 ± 2.0	76 ± 1.86	98.61 ± 1.07
<b>SBC<sub>3</sub></b>	25 ± 1.0	55 ± 2.40	82 ± 1.35	95.55 ± 0.50

<b>SBS<sub>1</sub></b>	45 ± 2.0	70 ± 1.89	60 ± 1.58	97.77 ± 0.73
<b>SBS<sub>2</sub></b>	48 ± 1.5	68 ± 2.20	65 ± 1.21	98.60 ± 0.87
<b>SBS<sub>3</sub></b>	50 ± 1.7	65 ± 1.0	71 ± 1.57	96.65 ± 0.90
<b>SBP<sub>1</sub></b>	35 ± 2.8	63 ± 2.25	66 ± 1.20	96.94 ± 1.07
<b>SBP<sub>2</sub></b>	32 ± 1.45	60 ± 2.15	68 ± 1.05	98.33 ± 0.39
<b>SBP<sub>3</sub></b>	30 ± 1.28	58 ± 1.0	73 ± 1.73	97.51 ± 0.77

\* Average of three determinations

**Table: Release profile of amlodipine besilate tablets containing croscarmellose sodium.**

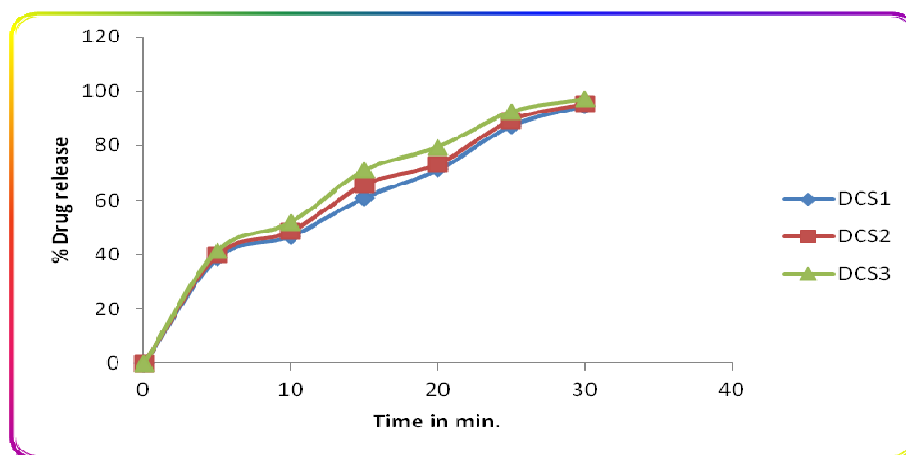
Time in min	% Drug Release		
	DCC <sub>1</sub>	DCC <sub>2</sub>	DCC <sub>3</sub>
5	37.22	38.17	39.36
10	46.24	48.35	49.37
15	61.91	67.90	73.08
20	70.94	75.23	80.16
25	86.13	89.42	93.51
30	93.90	94.36	97.56



**Fig: Release profile of amlodipine besilate tablets containing croscarmellose sodium**

**Table: Release profile of amlodipine besilate tablets containing sodium starch glycolate.**

Time in min	% Drug Release		
	DCS <sub>1</sub>	DCS <sub>2</sub>	DCS <sub>3</sub>
5	30.14	32.63	35.11
10	39.02	43.25	43.34
15	51.13	53.42	68.44
20	69.15	74.03	76.82
25	82.07	84.33	87.12
30	90.10	91.94	94.11



**Fig: Release profile of amlodipine besilate tablets containing sodium starch glycolate.**

**Table: Release profile of amlodipine besilate tablets containing crosspovidone.**

Time in min	% Drug Release		
	DCP <sub>1</sub>	DCP <sub>2</sub>	DCP <sub>3</sub>
5	35.06	36.41	38.21
10	44.11	46.05	47.89
15	50.00	56.68	70.17
20	67.91	70.01	78.11
25	85.45	87.04	91.62
30	92.73	93.35	96.64

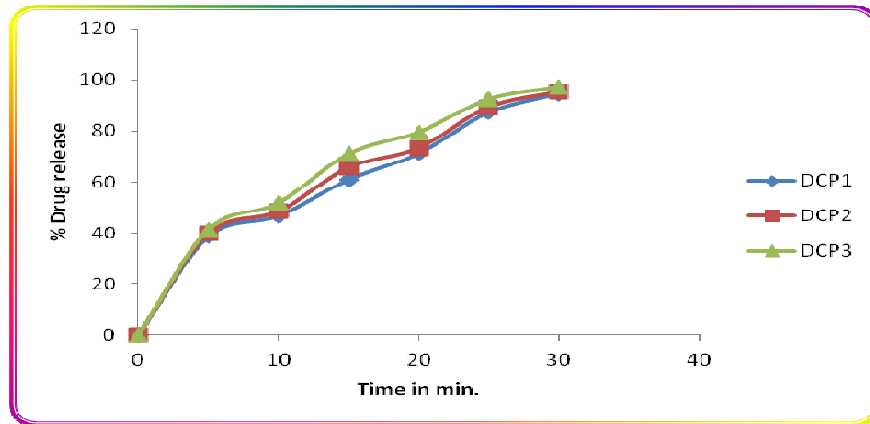


Fig: Release profile of amlodipine besilate tablets containing crospovidone.

B) Release profile of Amlodipine besilate Orodispersible tablets prepared by sublimation method:

Table 23: Release profile of amlodipine besilate tablets containing croscarmellose sodium.

Time in min	% Drug Release		
	SBC <sub>1</sub>	SBC <sub>2</sub>	SBC <sub>3</sub>
5	40.72	41.90	42.22
10	48.01	49.52	52.11
15	63.12	69.24	74.21
20	72.10	74.35	81.36
25	89.69	90.81	94.18
30	95.75	96.12	98.23

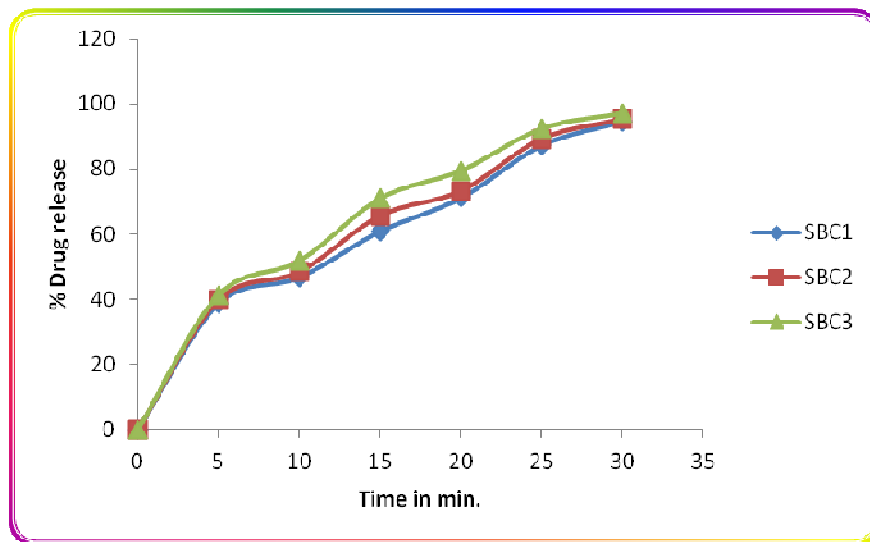
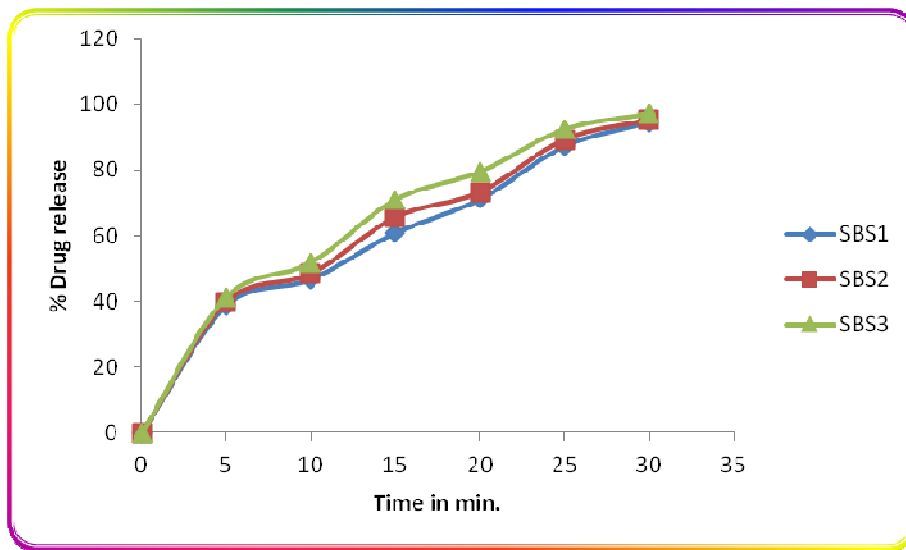


Fig: Release profile of amlodipine besilate tablets containing croscarmellose sodium.

**Table: Release profile of amlodipine besilate tablets containing sodium starch glycolate.**

Time in min	% Drug Release		
	SBS <sub>1</sub>	SBS <sub>2</sub>	SBS <sub>3</sub>
5	32.08	36.71	38.38
10	43.21	45.37	49.19
15	53.00	61.18	72.02
20	70.61	72.23	76.70
25	85.09	87.84	90.32
30	91.31	93.20	94.83



**Fig: Release profile of amlodipine besilate tablets containing sodium starch glycolate**

**Table: Release profile of amlodipine besilate tablets containing crospovidone.**

Time in min	% Drug Release		
	SBP <sub>1</sub>	SBP <sub>2</sub>	SBP <sub>3</sub>
5	38.78	39.86	41.29
10	46.85	48.44	51.77
15	60.96	65.65	70.91
20	71.24	73.29	79.43
25	87.38	89.27	92.29
30	94.76	95.25	97.00

**Table: Result for stability at 40°C/75% RH for 3 months.**

Sl. No.	Formulation code	Hardness Kg/cm <sup>2</sup>	% Friability	Dispersion time (second)	% Drug release
1.	DCC <sub>3</sub>	4.3	0.31	35	98.61
2.	DCS <sub>3</sub>	3.9	0.65	55	96.38
3.	DCP <sub>3</sub>	4.4	0.48	40	97.50
4.	SBC <sub>3</sub>	3.3	0.64	23	95.55
5.	SBS <sub>3</sub>	3.5	0.63	37	96.11
6.	SBP <sub>3</sub>	3.5	0.79	27	96.94

### Conclusion

Based on the above studies following conclusions can be drawn:

- Tablet prepared by direct compression and sublimation methods were found to be good and were free from chipping and capping.
- Post compression parameters (hardness, friability, thickness and drug content) was within the acceptable limit.
- IR spectroscopic studies indicated that the drug is compatible with all the excipients.
- Based on the disintegration time, formulation DCC<sub>3</sub> (8% croscarmellose sodium) and SBC<sub>3</sub> (8% croscarmellose sodium) were found to be promising and showed a dispersion time of 28 and 25 sec, wetting time of 76 and 70 sec respectively, which facilitate the faster dispersion in the mouth.
- The formulation DCS<sub>3</sub> and SBS<sub>3</sub> have displayed good water absorption ratio of 56.25 and 60.00%, which indicate better and faster swelling ability of the disintegrants in presence of little amount of water.
- The *in vitro* drug release from mouth dissolving tablets of Amlodipine besilate prepared by direct compression DCC<sub>3</sub> and sublimation SBC<sub>3</sub> methods were found to be 97.56% and 98.23% respectively

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within 30 minute. Among the two methods the sublimation method was found to be superior to direct compression method.

- The stability study shows that no significant changes in drug content after three month study.

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The Author (s) declare (s) that they have no conflicts of interest to disclose.

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