Usnig B-cyclodextrin and Plasdone K-30 Polymers for Enhancing Drug Solubility by Spray Drying

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Research Article

Keywords: Carvedilol, Drug Solubility, β-Cyclodextrin, PlasdoneK-30, Solid dispersion

Posted Date: June 10th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-4465828/v1

Additional Declarations: No competing interests reported.

Abstract

The purpose of this study was to investigate improving solubility using hydrophilic/water-soluble polymers as β-Cyclodextrin and Plasdone K-30 in a solid dispersion formulation of Carvedilol a poorly soluble drug. The developed solid dispersion consisted of two components, a drug and a polymer, and the drug was dispersed as amorphous particles in a polymer matrix using the spray drying method. Polymeric solid dispersions were evaluated using solubility tests, in vitro dissolution tests, powder X-ray diffraction, differential scanning calorimetry, scanning electron microscopy, and particle size distribution analysis. The study was observed that solid dispersions of each drug showed increase in dissolution rate in comparison and improving drug solubility. However, the beneficial actions require to be verified by adopting various *in vivo* techniques along with clinical trials for their efficient use as potential remedial moiety.

INTRODUCTION

Hypertension remains a significant global health concern, with its management often necessitating the use of antihypertensive drugs. Carvedilol, a widely used beta-blocker, has demonstrated efficacy in hypertension treatment. However, its limited aqueous solubility poses challenges for optimal therapeutic delivery and bioavailability. In recent years, efforts to overcome this limitation have led to the investigation of various solubility enhancement strategies. One promising approach involves the utilization of β-cyclodextrin and Plasdone K-30 polymer as solubility enhancers.[1] β-cyclodextrin, a cyclic oligosaccharide, is known for its ability to form inclusion complexes with hydrophobic molecules, thereby improving their solubility and dissolution rates. Similarly, Plasdone K-30 polymer, a water-soluble polymer, has been shown to enhance drug solubility through mechanisms such as solid dispersion and complexation.[2–4]

In the realm of hypertension therapy, the quest for innovative solutions to enhance the efficacy of antihypertensive drugs has never been more pressing. One promising avenue of research involves the utilization of polymers to improve drug delivery and therapeutic outcomes. Among these polymers, Plasdone K-30 stands out as a versatile and effective candidate for solubility enhancement and formulation optimization.[5–6] Carvedilol is a non-selective beta-blocker and alpha-1 blocker used primarily for the management of hypertension, heart failure, and left ventricular dysfunction following myocardial infarction. It exerts its therapeutic effects by blocking the action of both beta-1 and beta-2 adrenergic receptors, resulting in decreased heart rate, reduced myocardial contractility, and vasodilation. Additionally, its alpha-1 blocking activity contributes to peripheral vasodilation and further lowers blood pressure. This multifaceted pharmacological profile makes carvedilol particularly beneficial for patients with comorbid conditions such as hypertension and heart failure.[7–10] It has been shown to improve symptoms, exercise tolerance, and overall survival in patients with heart failure, making it a cornerstone therapy in the management of this condition. Moreover, carvedilol's vasodilatory properties help alleviate symptoms of hypertension by reducing systemic vascular resistance and blood pressure.

Several studies have explored the use of β-cyclodextrin[11–13] and Plasdone K-30 polymer to enhance the solubility of poorly water-soluble drugs[4], including those used in cardiac therapy. These studies have demonstrated promising results in terms of increased drug solubility, dissolution rates, and bioavailability, leading to improved therapeutic outcomes. The purpose of this research is to investigate the potential of β-cyclodextrin and Plasdone K-30 polymer in elevating the solubility of carvedilol, a poorly water-soluble antihypertensive drug.[14–16] By employing advanced solubility enhancement techniques, such as solid dispersion and inclusion complexation, This study builds upon previous research findings and aims to contribute to the development of more effective therapeutic strategies for hypertension treatment.[17–18]

There are certain drugs, which have low solubility and need to provide action into body in manner with aim to delay drug release by several hours to treat heart diseases which follows a circadian rhythm. Poor solubility will result in elimination of drug from body without showing therapeutic action. Low solubility becomes limiting step in absorption hence less amount of drug reaches to systemic circulation which is insufficient to produce desired plasma concentration and thereby therapeutic output. Hence there is strong need to explore simple, time-saving method for development of poorly soluble drug to reach desired therapeutic output after oral administration. Thus, present research highlighted developing such polymers using and drug with poor solubility which results in delay in drug release by several hours to treat heart diseases which follows a circadian rhythm with maximizing delivery of drug and attain desired therapeutic effect to nullify the risk of heart attack.

MATERIAL

Carvedilol was obtained as a gift sample from Niksan Pharmaceutical Ltd., Ankleshwar, India. B-Cyclodextrin was purchased by unique chemicals and Plasdone K-30 was gifted by Lupin Ltd., Pune. All chemicals and solvents used were of pharmaceutical and analytical grade. Double-distilled water was used throughout study for all experimental procedures.

METHOD

Pretreatment on Carvedilol for solubility enhancement and characterization

Carvedilol is a BCS II drug with low solubility and high permeability, and thus it becomes a rate-limiting step in drug absorption; hence, it is necessary to explore any simple spry drying technique for enhancement of solubility and dissolution rate prior to formulating it as a pulsatile drug delivery device. We were prepared at three drug: polymer molar ratios, 1:1, 1:2 and 1:3 proportions found better results for enhancement of solubility and dissolution rate, hence selected for further formulation using spray drying technique.

Studies on Carvedilol and polymers physical mixture

Various characterization parameters were carried out on pre-treated Carvedilol including saturation solubility, FTIR, DSC, and XRD, as per the standard procedures described.[19-20]

In-vitro dissolution study of treated Carvedilol

An accurately weighed amount of pure Carvedilol and physical mixture equivalent to 20 mg of nifedipine with β-Cyclodextrin and Plasdone K-30 in 1:2 proportions were weighed and added to dissolution medium. Dissolution study was performed in simulated intestinal fuid (SIF) pH 6.5 using USP II apparatus (EDT 08LX Electrolab) at 37±0.5 °C and 100 rpm paddle speed. Samples were withdrawn from dissolution media at specified time interval up to 60 min, and absorbance of sample was recorded spectrophotometrically (Shimadzu UV spectrophotometer 1800) at 241 nm. Dissolution profiles are shown.

Drug-excipient compatibility studies

These studies were performed for the confirmation of drug-incipient compatibility and included FTIR and DSC as per the standard reported procedure.

FTIR spectroscopy study

FTIR has been employed as a useful tool to identify drug-excipient interactions. Samples were analyzed by the potassium bromide pellet method in IR spectrophotometer (Alpha T. Bruker) in region from 4000 to 400 cm−1. FTIR studies were carried out for pure Carvedilol, pure β-Cyclodextrin and Plasdone K-30 and 1:1 proportion of all these with drug. Scans were evaluated for presence of principle peaks of drug, shifting and masking of drug peaks, and appearance of new peaks due to polymer interaction.[21-22]

DSC study

DSC was performed in order to assess the thermotropic properties and thermal behaviour of the drug (Carvedilol) and the preparedsolid dispersion. Samples were sealed in an aluminium pan and heated at the rate of 10^0C/min from 30^0C-300^0 Cunder nitrogen atmosphere with flow rate of 10ml/min. Thermograms of pure Carvedilol and optimized batch of solid dispersion were recorded using METTLER DSC 30S, Mettler Toledo India Pvt. Ltd. instrument equipped with an intracooler.

SEM analysis

SEM analysis pure drug Carvedilol mixture as well as β-Cyclodextrin and Plasdone K-30 mixture was studied with help of SEM (VEG A3 TESCAN), at 15 keV accelerating voltage[23]. Samples were coated in a vacuum using thin gold layer before investigation. SEM images of Carvedilol and different physical mixtures with spectra shown.

Formulation of Solid Dispersion using Spray Drying Technique:

A. Composition of solid dispersion of Carvedilol-

Solid dispersions of Carvedilol with β-cyclodextrin and Plasdone K-30 were prepared at three drug: polymer molar ratios, 1:1, 1:2 and 1:3 using spray drying technique. The formulation table is shown in Table No.1.

Table No. 1: Formulation Table for preparing solid dispersion

Batch Code	Carvedilol(gm)	β-cyclodextrin(gm)	Plasdone K-30(gm)
SD1	1	1	-
SD2	1	2	-
SD3	1	3	-
SD4	1	-	1
SD5	1	-	2
SD6	1	-	3

B. Formulation of solid dispersion using Spray Drying-

Carvedilol solid dispersions were prepared by solvent evaporation method using carriers (β- cyclodextrin and PlasdoneK-30) inproportionsviz.1:1, 1:2 and 1:3(drug: carrier). The drug and carrier were dissolved in methanol (100 ml). The solvent was evaporated by spray drying process, which was carried out using laboratory scale spray dryer.

The parameters of spray drying were set as shown in Table No.2. The powder was stored in desiccators until further evaluation.

Table No. 2: Spray Drying Parameters

Sr. No.	Parameters	Values
1	InletTemperature	35^0C
2	Outlet Temperature	35^0C
3	Cool Temperature	50^0C
4	Inlethigh	50^0C
5	Outlethigh	40^0C
6	AspiratoryFlow Rate	40 Nm^2/hr
7	FeedPumpFlowRate	2 ml/min
8	D-Blockon	1 second
9	D-Blockoff	60 second
10	DataLogInterval	60 second

Formulation of Immediate Release Press-Coated Tablets:

A. Formulation of immediate release core tablets using direct compression-

The inner core tablets were prepared by using direct compression method. Carvedilol, microcrystalline cellulose, croscarmellose sodium, lactose and sunset yellow were weighed accurately, dry blended for 20 min, followed by addition of magnesium stearate. 100mg of resultant and powder blend was manually compressed using KBr hydraulic press at a pressure of

1 ton, with a 10mm punches and dies to obtain the core tablet. Table No.3 shows the formulation table for core tablet.

Table No.3: Formulation Table for core tablet

Ingredients	Batch Code			
	L1 (mg)	L2 (mg)	L3 (mg)	L4 (mg)
Carvedilol Solid Dispersion (Batch SD6)	Equivalent to 12.5mgCarvedilol			
Croscarmellose sodium	20	20	10	-
Microcrystalline Cellulose	-	10	20	20
Lactose	q.s.	q.s.	q.s.	q.s.
Magnesium Stearate	0.25	0.25	0.25	0.25
Talc	1	1	1	1
Sunset Yellow	1	1	1	1

B. Formulation of mixed blend for barrier layer-

As given in the Table No.4 the various barrier layer compositions containing ethyl cellulose and L-HPC were prepared. These were weighed; dry blended for about 10 min. and used as press-coating material to prepare press-coated pulsatile tablets (PCT1-PCT5) by direct compression method using 13mm die and punch.

Table No. 4: Compositions of barrier layer coating

Batch Code	Ethylcellulose (mg)	L-HPC (mg)
PCT1	100	0
PCT2	12.5	87.5
PCT3	87.5	12.5
PCT4	50	50
PCT5	0	100

C. Preparation of press-coated tablets-

The core tablets were press-coated with 400mg of barrier coat as given in Table No.4. 200mg of barrier layer material was weighed and transferred into a 13mm die then the core tablet was placed manually at the center. The remaining 200mg of the barrier layer material was added into the die and compressed at a pressure of 5 tons for 3min using KBr hydraulic press.

RESULTS

Characterization of Carvedilol physical mixture Characterization of Carvedilol was carried out compared to pure drug for saturation solubility studies, FTIR, DSC, SEM analysis, and in-vitro dissolution studies. A remarkable enhancement in solubility of Carvedilol in presence of sepitrap 4000 compared to pure Carvedilol was observed in saturation solubility studies. There was increase in solubility in case of physical mixture of Carvedilol with polymers which clearly indicated that use of novel solubilizer like β- cyclodextrin and PlasdoneK-30 is most useful for solubility

enhancement of poorly soluble drugs. Physical mixture of Carvedilol and β-cyclodextrin and PlasdoneK-30 does not show any additional peaks and also retained principle IR peaks of pure Carvedilol, which indicates no interaction between Carvedilol and solubilizer. Overall results of FTIR showed that polymers can be used as solubilizer for pre-treatment of Carvedilol, as it is compatible with Carvedilol.

These results were supported by DSC thermogram, as peak broadening, reduction in intensity, and early onset as compared to pure Carvedilol indicate that polymers is useful in reduction of drug's crystalline, which definitely affects its solubility. SEM images of Carvedilol and β-cyclodextrin and PlasdoneK-30 physical mixture show slight changes in its surface structure due to hydrogenated castor oil in solid form, which may not affect solubility enhancement. In-vitro dissolution study showed approximately fourfold increase in percent drug dissolution in physical mixture with polymers as compared to pure drug at end of 60 min Fig. 1. Carvedilol dissolution was significantly improved, mainly due to increase in both wet ability and localized solubilization. Overall characterization of Carvedilol and polymers as compared to pure Carvedilol showed positive effect of use of novel solubilizer for enhancement of solubility and dissolution rate, which will be further beneficial in development of pulsatile tablets to overcome absorption, a rate-limiting step.

FTIR (drug–polymer compatibility study)

FTIR spectra of physical mixtures of Carvedilol and β-cyclodextrin and PlasdoneK-30 polymers did not show any new peaks, indicating no new chemical bonds were created due to any interaction. FTIR spectra of Carvedilol, along with all excipients used for compression coating and in core tablet, did not show any appreciable change in characteristics of pure drug, indicating various polymers used for formulation were compatible and did not interact with Carvedilol shown in Fig. 2.

DSC study

Thermal analysis was employed in addition to FTIR studies to demonstrate any unexpected interaction between Carvedilol with β-cyclodextrin and Plasdone K-30 polymer used for pulsatile formulation, including Croscarmellose sodium, Microcrystalline Cellulose, Lactose, Magnesium Stearate, Talc, Sunset Yellow etc. A sharp endothermic peak with onset temperature of 115 °C and a peak at 117 °C corresponds to melting point of Carvedilol was observed in thermogram of pure Carvedilol. Physical mixture of Carvedilol showed broadening of peak with reducing peak intensity, and onset temperature. Peak broadening, reduction in intensity and early onset as compared to pure Carvedilol indicate that β-cyclodextrin and Plasdone K-30 mixture shows dominance of its amorphous form, which describes positive effect. DSC thermogram of Carvedilol with all excipients together showed onset at 115.48°C and peak at 117. 65°C indicating slight shift of peak with marked broadening, which corresponds to influence of other excipients used in formulation. DSC studies supported results of FTIR and which indicates there was compatibility between Carvedilol and all other additives used for press-coated pulsatile formulation. DSC thermogram of pure Carvedilol, physical mixture of Carvedilol with novel with all excipients are shown in Fig. 3

PXRD study

The X-ray diffractogram of the drug powder with excipients was characterized by the presence of sharp peaks indicative of the crystalline nature of drug. The XRD curve of shown in Fig. 4.

Evaluation of pre-compression parameters for core tablet blend

Physical mixtures as per formulas of various batches of core tablets were evaluated for flow properties before compression. Values of bulk density, tapped density, Carr's index, and Hausner's ratio were calculated and depicted in

Table 5. From physical properties of powder blends of various batches of core tablets, it was confirmed that all of them are suitable to formulate tablets using direct compression technique. Bulk density and tap density of powder blend for core tablet batch L1 were found to be 0.464 g/ml and 0.586 g/ml, respectively (Batch L1) was used for further development of pulsatile tablet). Hausner's ratio of 1.23 further confirms good compressibility and passable flow property of the material, which is confirmed by Carr's index of 22.04%.

Table No. 5: Pre-compression evaluation of core tablet blend

Batch Code	Bulk Density* (g/cm^3)	Tapped Density* (g/cm^3)	Angle of Repose* (°)	Bulkiness (cm^3/gm)	Carr's Compressibility Index (%)*	Hausner's ratio*
L1	0.464±0.02	0.586±0.02	25.24±0.14	2.3407	22.4±0.03	1.23±0.01
L2	0.475±0.01	0.567±0.03	29.61±0.15	2.4281	20.5±0.01	1.24±0.01
L3	0.467±0.03	0.597±0.01	26.47±0.13	2.4304	21.6±0.02	1.26±0.03
L4	0.439±0.02	0.549±0.04	29.80±0.15	2.4972	21.7±0.02	1.24±0.05

Evaluation of post compression parameters of core tablets

Core tablets from each batch were evaluated for average weight, thickness, disintegration time, drug content, hardness, and % friability. Tablets showed good weight uniformity, as indicated by low value of relative standard deviation (RSD≤ 1%). Tablet thickness was found in range of 0.302±0.04 mm to 0.328±0.03 mm. Core tablets, which contain 10% disintegrant in their composition show disintegration time of 32±0.078 s, which was closer to core tablet composition containing 12.5% disintegrant; hence, core tablet batch L1 was further used to develop press-coated pulsatile tablet. Drug content uniformity of tablet was found to comply with official specification, as assay value was found to be in range of 97.52±0.08 to 99.65±0.23% of theoretical value. Tablet hardness varied from 2.8±0.2 to 3.5±0.6 kg/cm2 , which was sufficient for core tablet as it was compressed again in subsequent step of pulsatile formulation. Tablets passed friability test, as all batches were within Pharmacopoeia limit (F ≤ 1%). Results of various post-compressional parameters are reported in Table 6.

Table No. 6: Post-compression evaluation of core tablets

Batch Code	Average Weight (mg)	Thickness (mm)*	Hardness (kg/cm^2)*	Friability (%)*	Disintegration Time(sec)*	% Drug content [n=3]
L1	99.0	0.302±0.04	3.2±0.02	0.197±0.003	32±0.078	98.87±0.44
L2	98.3	0.312±0.03	3.5±0.06	0.104±0.007	37±0.240	99.65±0.23
L3	99.5	0.328±0.03	2.8±0.02	0.132±0.001	34±0.015	97.52±0.08
L4	98.1	0.311±0.02	3.5±0.04	0.146±0.005	39±0.317	98.02±0.31

In-vitro dissolution study of core tablet

The drug release study of the core tablets was performed as mentioned in the experimental study. The maximum drug release was observed at 30min. Hence, these core tablets can be used as immediate release tablets in formulation of Press-coated tablets for treatment of hypertension. The cumulative drug release profile of the immediate release tablets is shown in Table 7. As the concentration of CCS was increased, the disintegration time decreased and dissolution rate of drug increased. From the observations, L1 was selected as best formulation since it showed maximum drug release in 30 minutes with greater disintegration rate. This batch was further used to formulate press-coated tablets.

TableNo.7: Cumulative Drug Release data of immediate release core tablets

Sr. No	Time (min)	% Cumulative drug release*			
		L1	L2	L3	L4
1	0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
1	5	25.21±0.12	23.63±0.13	29.73±0.13	25.35±0.13
2	10	43.44±0.15	42.19±0.15	43.57±0.12	48.49±0.12
3	15	79.56±0.14	77.61±0.12	67.50±0.12	75.27±0.15
4	20	86.81±0.12	85.96±0.13	78.48±0.13	81.61±0.13
5	25	95.67±0.12	88.49±0.12	89.18±0.14	87.69±0.13
6	30	98.58±0.13	92.34±0.12	95.73±0.15	90.88±0.12

In-vitro drug release study of solid dispersion

a. Saturation solubility of prepared solid dispersions in various solvents-

The solubility of spray dried solid dispersions of Carvedilol in distilled water, 0.1N HCl (pH 1.2) and in phosphate buffer (pH 6.8) was determined so as to select an appropriate batch of solid dispersion for further formulation of tablets. The increase in solubility was found to be linear with respect to the increase in the concentration of carrier. The batch SD6 with drug to Plasdone K-30 ration of 1:3 showed greater increase in the solubility as compared to β-cyclodextrin. This is due to the greater hydrophilicity of Plasdone K-30 than β-cyclodextrin. PVP polymers cause a reduction in the interfacial tension between the drug and the dissolving solution. Moreover, it was suggested that Plasdone K-30 might form soluble complexes with the drug. Also the wettability and porosity of the particles was also increased. The results of solubility study of solid dispersion of Carvedilol are tabulated in Table No.8.

TableNo.8: Saturation Solubility of various batches of solid dispersion

Batch Code	Polymer	Drug: Polymer ratio	Solvents		
			Distilled water*	0.1NHCl (pH 1.2)*	Phosphate buffer(pH 6.8)*
SD1	β- cyclodextrin	1:1	0.3854±0.2	0.8754±0.3	0.6749±0.4
SD2		1:2	0.6749±0.2	0.9916±0.2	0.8443±0.1
SD3		1:3	0.8357±0.4	1.2837±0.4	1.3786±0.1
SD4	Plasdone K-30	1:1	0.3774±0.3	1.8412±0.3	0.7692±0.2
SD5		1:2	0.8576±0.4	2.6348±0.4	1.0428±0.3
SD6		1:3	1.1729±0.4	4.1587±0.2	1.4287±0.2

b. The dissolution profiles of solid dispersion batches

The dissolution profiles of solid dispersion batches are shown in table No. 9. It was evident that the pure drug exhibited a slow dissolution even after 60 minutes where the percentage of drug dissolved after 60 minutes only reached about 18.58±0.02%. This is due to the hydrophobicity, poor wetability and/or agglomeration of Carvedilol particles resulting into hindering its dissolution. All solid dispersions showed enhanced dissolution rate compared to pure Carvedilol that might be due to the effect of hydrophilic carriers on drug wetability and solubility. These results could be attributed to the general phenomenon of particle size reduction of Carvedilol particle during the spray drying operation. Also solubilization, molecular/colloidal dispersion of drug in the mixture and reduction in the drug crystallinity (i.e. polymorphic transformation of drug crystals) that were obtained via the formulation of solid dispersions using spray dryer could have contributed to the increase in solubility. The batch SD6 with Carvedilol to Plasdone K-30 ratio of 1:3 showed the maximum drug release as compared to the other batches. The drug release profile of the solid dispersion batches is shown in table No. 9.

Table No.9: Cumulative % drug release data of Solid dispersion batches

Sr. No	Time (min)	% Cumulative drug release*						
		Pure drug	SD1	SD2	SD3	SD4	SD5	SD6
1	0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
2	10	3.31±0.03	12.45±0.05	19.34±0.06	26.47±0.05	32.67±0.03	39.57±0.03	43.56±0.03
3	20	5.73±0.01	33.48±0.06	39.37±0.03	37.46±0.02	48.29±0.01	47.67±0.03	58.26±0.02
4	30	8.06±0.03	48.87±0.05	46.35±0.02	52.67±0.03	54.42±0.03	59.34±0.01	69.41±0.06
5	40	11.41±0.02	66.48±0.04	59.14±0.03	68.77±0.03	63.97±0.03	69.44±0.02	84.19±0.03
6	50	13.67±0.02	75.95±0.06	76.73±0.03	80.91±0.01	71.26±0.01	76.99±0.01	89.61±0.04
7.	60	18.58±0.02	79.37±0.04	81.16±0.01	88.38±0.03	78.96±0.03	89.76±0.03	93.39±0.06

Differential Scanning Calorimetry (DSC) study of optimized solid dispersion batch (SD6)-

The DSC thermogram of solid dispersion showed a disappearance of the endothermic peak which was observed in the DSC curve for pure Carvedilol and also there was change in the peak intensity shown in Fig No. 5. The absence of

endothermic peak might be due to the formation of solid dispersion of the drug in the presence of hydrophilic polymer where the crystalline drug could be transformed into an amorphous state. This amorphousness might be related to the intermolecular hydrogen bonding and complexation between drug and Plasdone K-30, respectively. The thermogram of spray dried particles of Carvedilol showed change in the melting point which is shown as a broad peak at 95^0C. Such change in the melting point indicates changes in the crystalline state of Carvedilol after spray drying process. Also, the melting temperature of solid dispersion decreases with decreasing their particle size. The melting temperature increases as the particle size increases. Thus, as the particle size decreases surface area-to-volume ratio of the particle increases. The larger surface area allows a greater interaction with the solvent and ultimately enhances the solubility of the drug.

Scanning Electron Microscopy (SEM) of solid dispersion batch SD6-

SEM images of the prepared Carvedilol solid dispersion is shown in Fig.6. The particles of the solid dispersion were found to be spherical in shape. The particle size of the spray dried particles is also decreased. This is essential to enhance the solubility. SEM showed smooth surface of Carvedilol solid dispersion particles with greater number of pores which indicated that there is increase in the porosity and hence the dissolution rate of these particles was also increased. This shows that transformation of the crystalline drug into amorphous state has occurred with enhanced solubilization and dissolution rate of the spray dried particles.

CONCLUSION

In this present study, an increased solubility and dissolution rate of Carvedilol were achieved by preparing pulsatile tablet by spray drying technique using different ratio of drug and polymer. DSC, FT-IR and XRD studies showed that there is no change in the crystal structure of Carvedilol during the spray drying process. Use of β-Cyclodextrin and Plasdone K-30 polymers in core tablet was successfully evaluated to overcome solubility problem of Carvedilol and which is useful for complete drug release after lag time in intestinal fluid. From the results, it could be concluded that the solubility and dissolution rate of the poorly soluble drug Carvedilol improves using polymer.

Declarations

ETHICAL STATEMENT:

The research conducted on the topic "Usnig B-Cyclodextrin and Plasdone K-30 Polymers for Enhancing Drug Solubility by Spray Drying" strictly adhered to ethical principles and guidelines. No animals were used in any phase of this study, ensuring the humane treatment of living organisms. The research team prioritized the well-being and ethical considerations of all individuals involved in the research process, including researchers, participants, and the environment. The decision to exclude animal testing was made in alignment with our commitment to ethical research practices and respect for all forms of life. This study upholds the highest standards of integrity, transparency, and ethical conduct in scientific research.

Author Contribution

YLP contributed to formal analysis, experimental and writing—original draft; SRS contributed to supervision, review and editing; MHP contributed to designing of experiments, analyzed and interpreted the data; SDT contributed to analysis and interpreted the data; MDK contributed to metheodology and writing—review and editing.

Acknowledgement

Authors are thankful to the Niksan Pharmaceutical Ltd., Ankleshwar, India. for providing gift sample of r Carvedilol, B-Cyclodextrin was purchased by unique chemicals and Plasdone K-30 was gifted by Lupin Ltd., Pune and Shree Pushpasen Sawant College of Pharmacy, Jaywant Nagar, Humarmala, Tal. Kudal Dist. Sindhudurg and Nootan College of Pharmacy Kavathemahankal Dist Sangli are acknowledged for assistance with analytical work.

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Figures

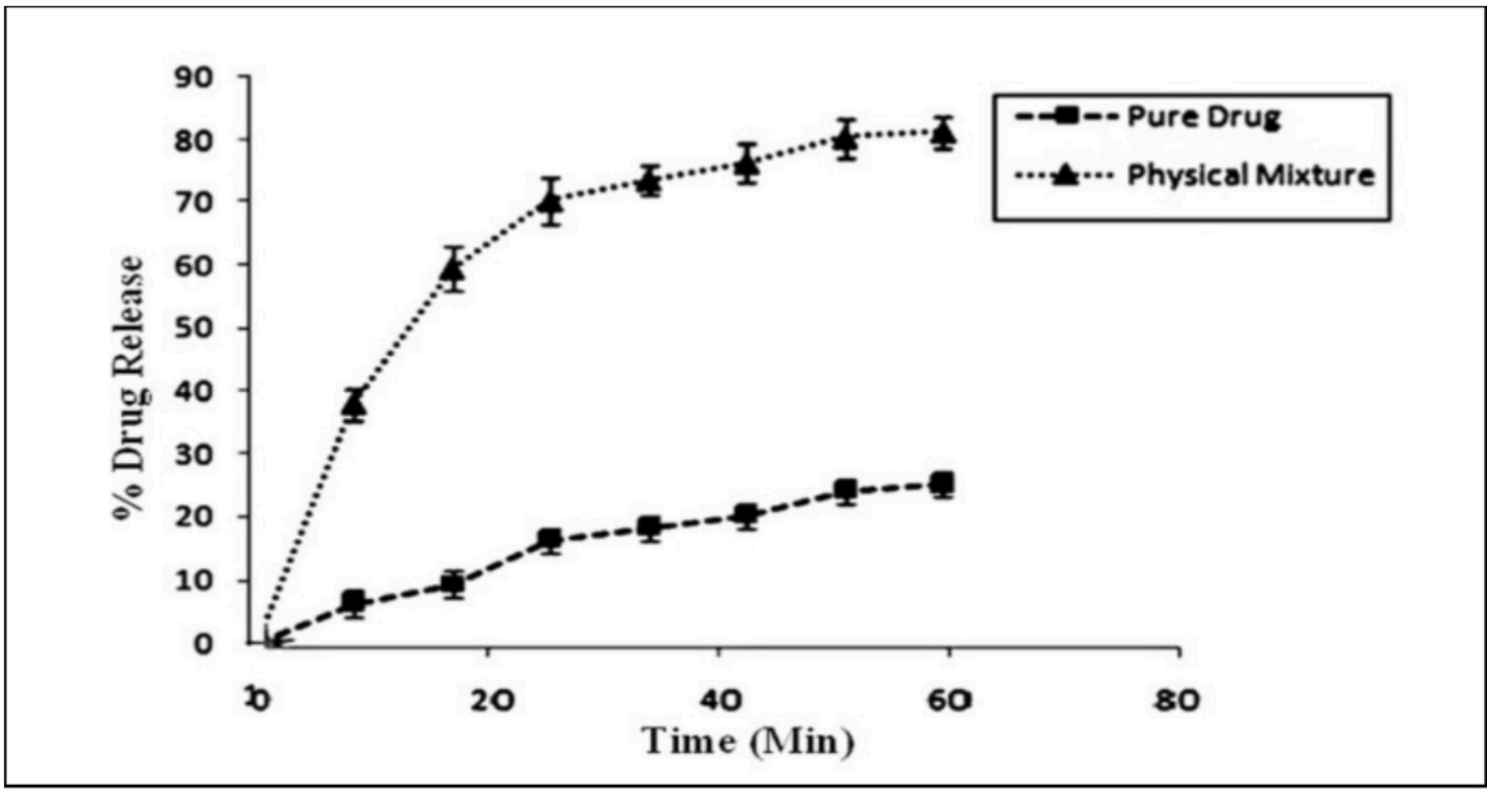

Figure 1

Dissolution profile of pure Carvedilol and β-cyclodextrin and PlasdoneK-30 physical mixture

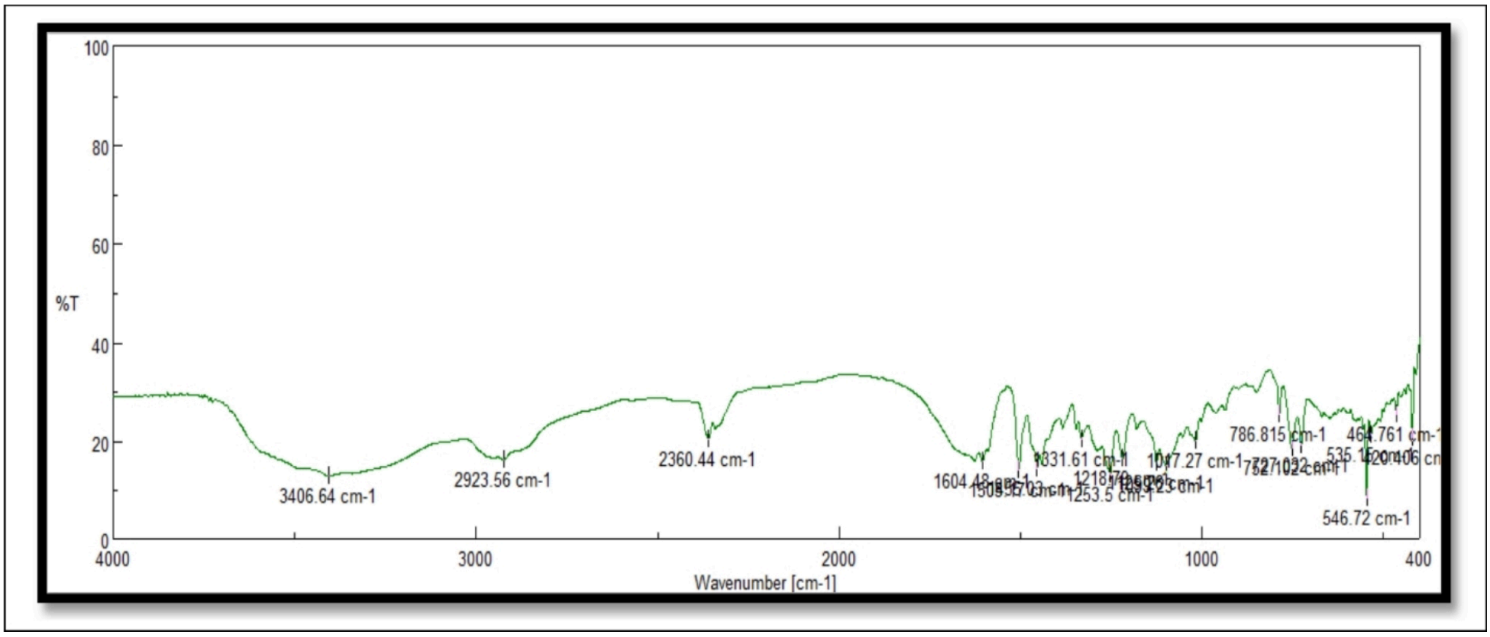

Figure 2

FTIR spectra of Carvedilol with β-cyclodextrin and Plasdone K-30 polymer

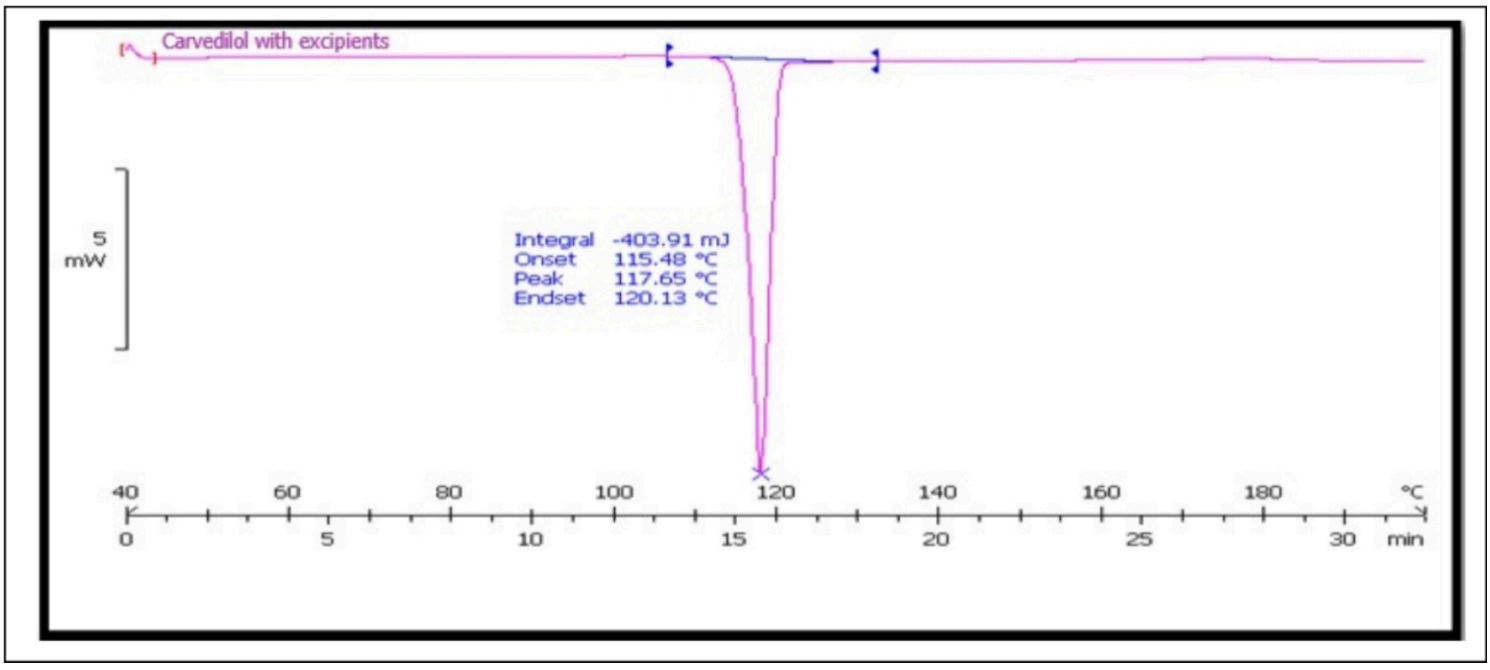

Figure 3

DSC curve of Carvedilol with excipients

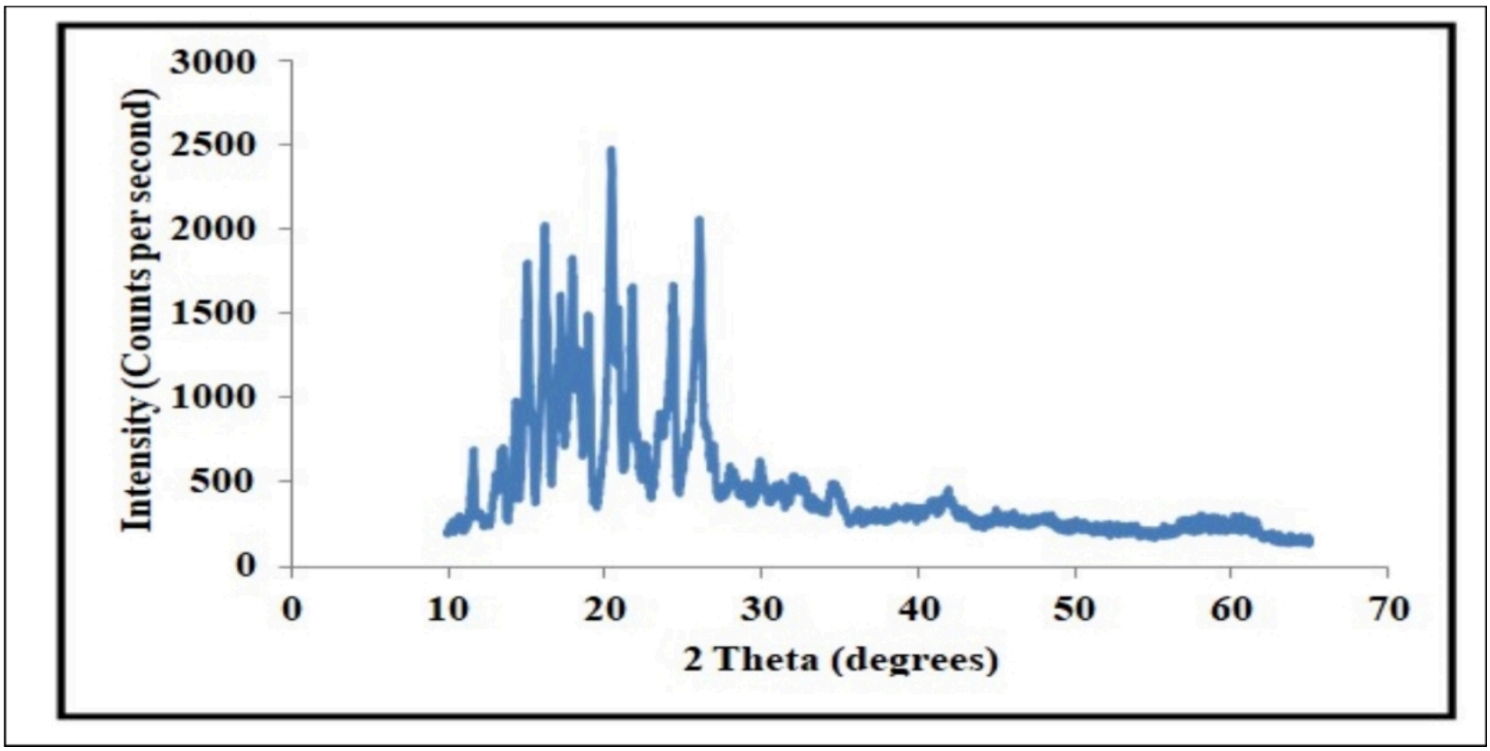

Figure 4

PXRD curve of Carvedilol with excipients

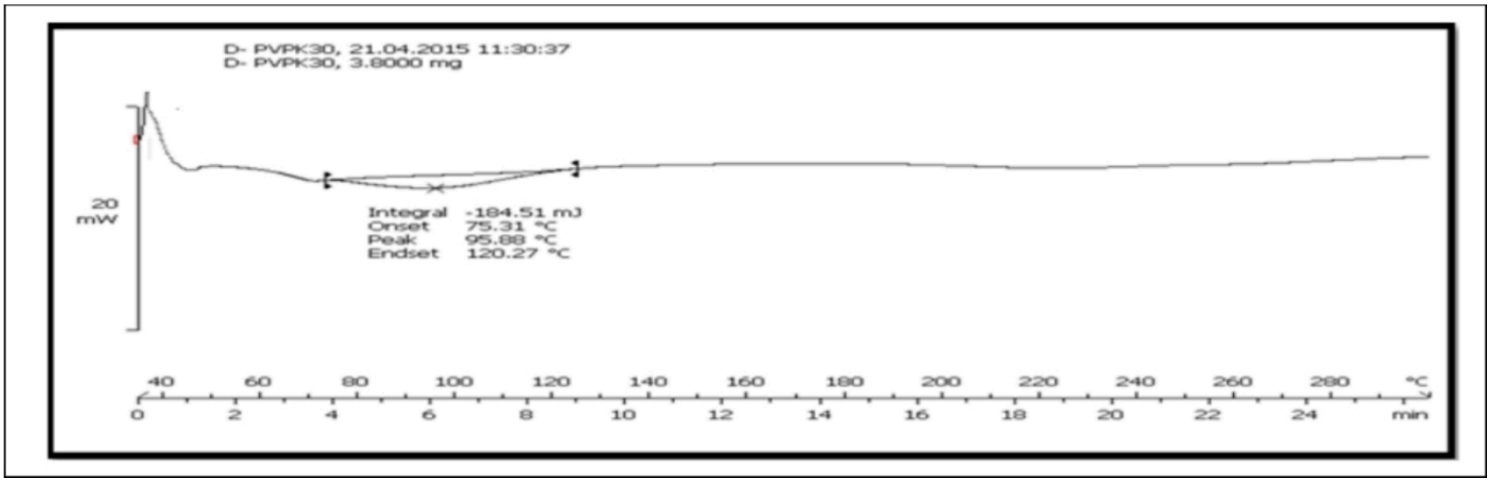

Figure 5

DSC curve of batch SD6

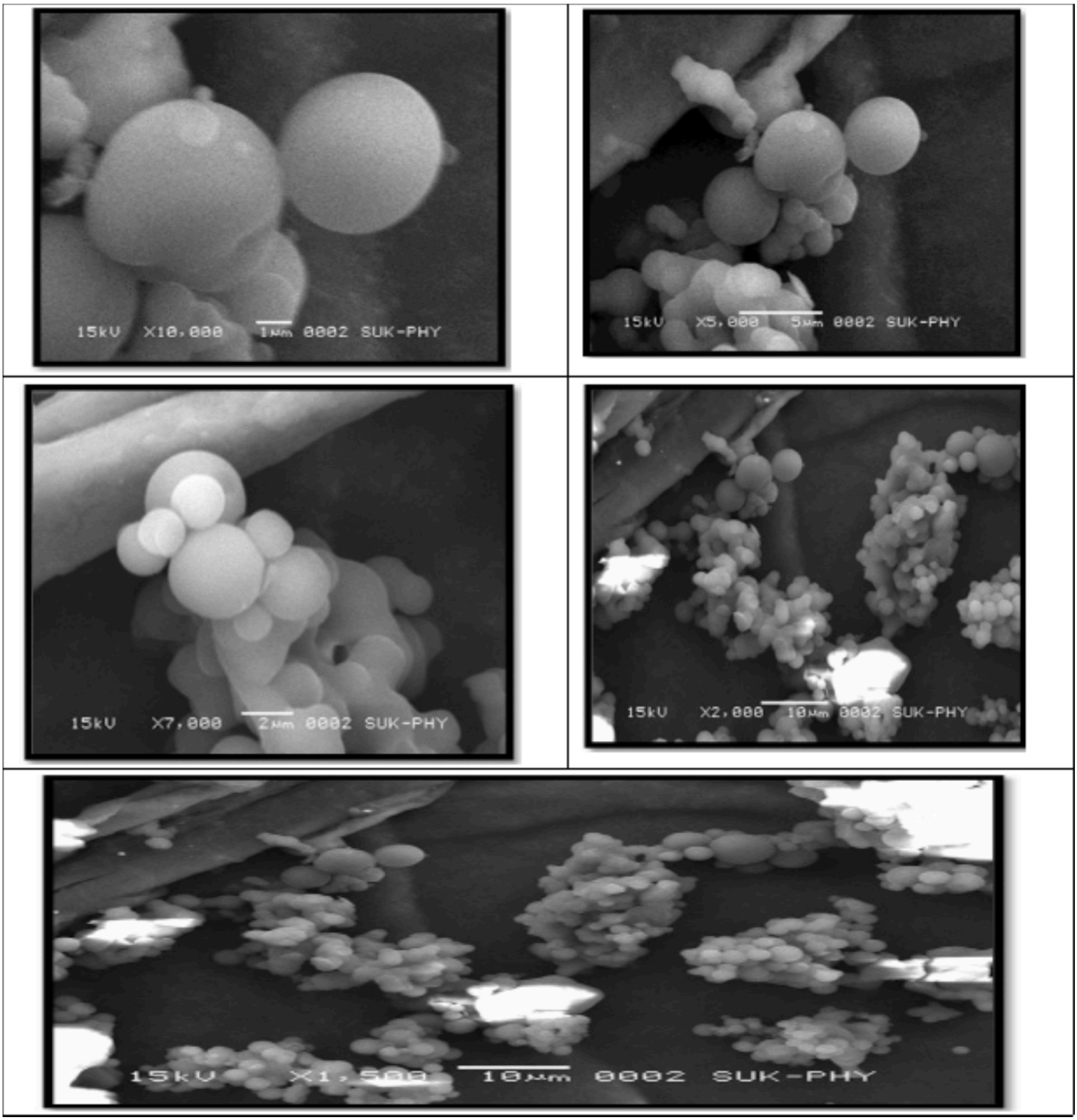

Figure 6

SEM images of Solid dispersion batch SD6.