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SOLUBILITY ENHANCEMENT OF ATORVASTATIN USING SOLID DISPERSION TECHNIQUE WITH POLOXAMERS.

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ABSTRACT

Objective: This study aims to enhance solubility and dissolution rate of a BCS class II drug atorvastatin by formulating it into solid dispersion using poloxamer 188 and poloxamer 407.

Method: Solid dispersions were prepared using Melt dispersion and solvent evaporation techniques based on 2^2 factorial design. Drug excipient compatibility was studied using FTIR. The prepared formulations were characterized for flow properties, saturation solubility, crystalline behaviour (X-ray diffraction), and in vitro dissolution performance.

Results: Compatibility studies performed show no significant interactions between drug and excipients and X-ray diffraction analysis indicated a reduction in the crystallinity of atorvastatin in the solid dispersion form. Saturation solubility and dissolution studies showed a significant increase in drug solubility and dissolution rate compared with the pure drug. Among all formulations, solid dispersions prepared with Poloxamer 188 with 1:0.8 drug ratio by the solvent evaporation method showed the highest improvement in aqueous solubility of 3.362± 0.024.

Conclusion: the formulated solid dispersion with poloxamers have showed increased solubility then upon further increase in concentration of poloxamers the solubility has slightly decreased this might be because of the hydrophobic nature of carrier at high concentration this can be further utilized for development of efficient oral drug delivery system.

Key words: Atorvastatin, melt dispersion, solvent evaporation, poloxamer 188

INTRODUCTION

According to the Biopharmaceutics Classification System (BCS), Class II drugs are characterized by high membrane permeability but poor aqueous solubility1,2. The limited solubility of these drugs in water often results in reduced bioavailability3. For effective absorption, a drug must be present in its dissolved molecular state, therefore poor solubility becomes a critical limiting factor for these compounds. Several approaches have been developed to enhance the bioavailability of BCS Class II drugs4,5,6, including prodrug modification7,8, salt formation9,10, particle size reduction11, co-solvent techniques, and solid dispersion methods12. Solid dispersion (SD) is considered one of the most effective approaches for improving the dissolution profile of poorly water-soluble drugs. In this technique, the drug is dispersed in a carrier matrix at the molecular or particulate level, resulting in modification of the drug's solid state13. This physical transformation, often involving conversion from

crystalline to amorphous form, enhances the solubility and dissolution rate of the drug14. Poloxamers are non-ionic triblock copolymers widely used as pharmaceutical excipients owing to their excellent solubilizing properties, biocompatibility, and surfactant behavior. Poloxamer 188 and Poloxamer 407, in particular, have been reported to enhance drug solubility by improving wettability and forming micellar systems that facilitate drug dissolution. Additionally, these carriers can inhibit drug recrystallization, thereby maintaining the drug in an amorphous or partially amorphous state.

MATERIALS AND METHODS

Table 1: Materials and suppliers

S.No.	Name of the Chemical Used	Supplier
1	Atorvastatin calcium	Capricorn pharma, Hyd, India
2	Poloxamer 188 and poloxamer 407	Capricorn pharma, Hyd, India
3	Methanol	SD Fine Chemical, Mumbai, India
4	Potassium Dihydrogen Phosphate	SD Fine Chemical, Mumbai, India
5	Sodium hydroxide (NaOH)	SD Fine Chemical, Mumbai, India

All the materials used in the study were of analytical grade

Construction of Standard Calibration Curve

Stock Solution Preparation

A stock solution of Atorvastatin was prepared by accurately weighing 50 mg of the drug and dissolving it in 50 mL of 50% Methanol in a volumetric flask to obtain a concentration of 1000 µg/mL. The stock solution was further diluted with phosphate buffer (pH 6.8) to obtain working standard solutions of concentrations of 2, 4, 6, 8, and 10 µg/mL. The absorbance of these solutions was measured at 242 nm using a double-beam UV–Visible spectrophotometer (Elico SL-210, India UV–Vis Spectrophotometer), and a calibration curve of absorbance versus concentration was constructed.

Preparation of Phosphate Buffer (pH 6.8)

Phosphate buffer (pH 6.8) was prepared by transferring 50 mL of 0.2 M Potassium Dihydrogen Phosphate into a 200 mL volumetric flask, followed by the addition of an appropriate volume of 0.2 M Sodium Hydroxide. The solution was then diluted to volume with distilled water and mixed thoroughly.

FTIR studies

Fourier Transform Infrared (FTIR) spectroscopy was performed to investigate possible drug–excipient interactions between Atorvastatin and the formulation components. The spectra were recorded using a Shimadzu FTIR-8700 spectrophotometer over a wavelength range of 4000–400 cm^{-1}.

The potassium bromide (KBr) disc method was employed for sample preparation. Pure drug and physical mixtures (containing the maximum proportion of excipients used in the formulations) were analysed. The powdered samples were thoroughly mixed with dry powdered Potassium Bromide and compressed into transparent discs under high pressure (5

tons for 5 min) using a hydraulic press with special dies. The prepared discs were placed in the sample holder of the spectrophotometer, and the spectra were recorded.

Preparation of solid dispersions

Solid dispersions (SDs) of Atorvastatin were prepared using Poloxamer 188 and Poloxamer 407 as carriers by melt dispersion and solvent evaporation methods. In the solvent evaporation method, drug-to-carrier ratios of 1:0.25, 1:0.5, 1:0.75, 1:0.8, 1:0.9, and 1:1 were employed, whereas in the melt dispersion method ratios of 1:0.25, 1:0.5, 1:0.6, 1:0.7, 1:0.75, and 1:0.8 were used. The formulations were developed based on a 2^2 factorial design to evaluate the influence of two independent variables: type of poloxamer (two levels) and method of preparation (two levels)

Table 2: Composition of solid dispersion prepared by solvent evaporation

S. No.	Method	Carrier			Ratio's			
			1:0.25	1:0.5	1:0.75	1:0.8	1:0.9	1:1
1	Solvent evaporation	Poloxamer 188	FP1	FP2	FP3	FP4	FP5	FP6
		Poloxamer 407	FP13	FP14	FP15	FP16	FP17	FP18

Table 3: Composition of solid dispersion prepared by melt dispersion

S. No.	Method	Carrier			Ratio's			
			1:0.25	1:0.5	1:0.6	1:0.7	1:0.75	1:0.8
1	Melt dispersion	Poloxamer 188	FP7	FP8	FP9	FP10	FP11	FP12
		Poloxamer 407	FP19	FP20	FP21	FP22	FP23	FP24

Melt dispersion method

The required quantity of carrier was accurately weighed and transferred to a china dish placed on a hot plate and heated to its melting point. The calculated amount of atorvastatin was then added to the molten carrier and thoroughly mixed by levigation to obtain a uniform dispersion. The resulting solid mass was allowed to cool at room temperature.

Solvent evaporation method

The accurately weighed carrier was dissolved in 10 mL of Methanol in a 250 mL round bottom flask. The required amount of atorvastatin was added to the methanol and dissolved to obtain a clear solution. An air condenser (L-tube) was attached to the round bottom flask using a rubber cork, and the assembly was connected to a vacuum pump to facilitate solvent evaporation. The resulting solid mass was collected, passed through a #60 sieve, and stored in a tightly closed container until further use.

Evaluation of Solid Dispersions

Flow properties

1. Bulk density

Blend was weighed and transferred to a measuring cylinder. The bulk volume was noted, and the bulk density is measured using following formula

$$\text{Bulk density} = \frac{\text{Mass of the powder}}{\text{Bulk volume}}$$

2. Tapped density

After weighing the blend, it was moved to a measuring cylinder and taped 100 times. The volume was then recorded as tapped volume. Tapped density is calculated by using the following formula

$$\text{Tapped density} = \frac{\text{Mass of the powder}}{\text{Tapped volume}}$$

3. **Carr's index**

Carr's index was calculated by using the following formula

$$\text{carr's index} = \frac{\text{tapped density} - \text{bulk density}}{\text{Tapped density}} \times 100$$

4. **Hausner's ratio**

Hausner's ratio was calculated by using the following formula

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Solubility Studies

The solubility of pure Atorvastatin and its solid dispersions was determined in phosphate buffer (pH 6.8) at 37 ± 0.5 °C. Accurately weighed 100 mg of pure drug and solid dispersions equivalent to 100 mg of drug were added separately to 100 mL of phosphate buffer in 250 mL conical flasks. The flasks were placed in an orbital shaking incubator and maintained at 37 °C for 24 h to achieve equilibrium. The samples were then filtered, and the filtrate was appropriately diluted with phosphate buffer. The drug content was analyzed using a UV–Visible spectrophotometer (Elico SL-210, India UV–Vis Spectrophotometer) at 242 nm

X-Ray Diffraction (XRD) Analysis

The crystalline characteristics of the pure drug and solid dispersions were evaluated using X-ray diffraction analysis. Diffraction patterns were recorded using a Bruker D8 X-Ray Powder Diffractometer (Bruker AXS, Germany) equipped with D8 TOOLS software, a theta compensating slit, and a silicon detector. The scans were performed over a 2θ range of 2– 50°, with a step size of 0.03° and a count time of 0.5 s at 25 °C, using copper radiation.

In Vitro Dissolution Studies

In vitro dissolution studies were conducted for the selected solid dispersions using a USP Dissolution Test Apparatus II (paddle type). The dissolution conditions were maintained as follows: temperature 37 ± 0.1 °C, rotation speed 75 rpm, and 900 mL of phosphate buffer (pH 6.8) as the dissolution medium. Samples of 5 mL were withdrawn at predetermined time intervals (5, 10, 15, 20, 30, 40, 50, and 60 min) and replaced with an equal volume of fresh dissolution medium to maintain constant volume. The collected samples were filtered and analysed spectrophotometrically at 242 nm to determine the amount of drug release.

RESULTS AND DISCUSSION

Standard Calibration Curve of Atorvastatin

Table 4: calibration data of Atorvastatin

S. No.	Concentrations (µg/ml)	Absorbance
1	0	0
2	2	0.077
3	4	0.1475
4	6	0.219
5	8	0.2868
6	10	0.3555

The calibration curve of atorvastatin showed good linearity with a correlation coefficient ($R^2 = 0.999$).

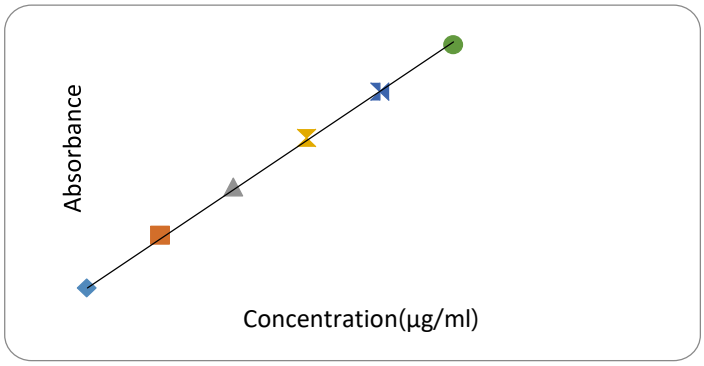

Figure 1: calibration curve of Atorvastatin

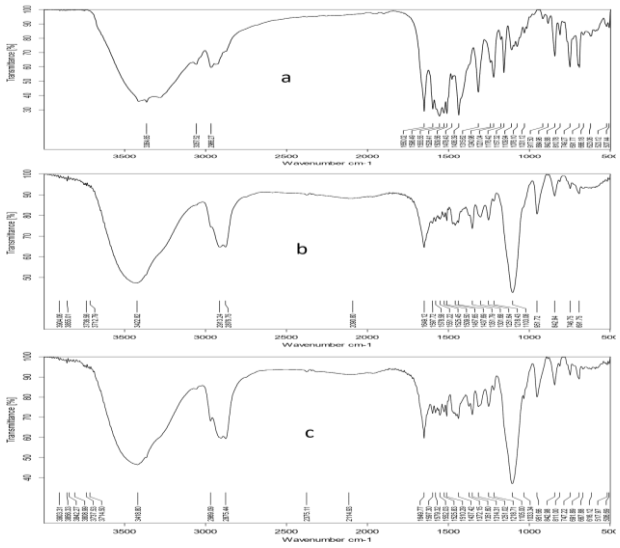

Figure 2: FTIR spectra of (a) pure atorvastatin, (b) physical mixture of atorvastatin and Poloxamer 188, and (c) physical mixture of atorvastatin and Poloxamer 407.

Table 5: Flow properties for Atorvastatin solid dispersion with Poloxamer 188 by solvent evaporation method

S.No.	Solid Dispersion	Results of various flow properties (avg. ± S.D. for n = 3)					
		Carr's Index (%)		Hausner's Ratio		Angle of Repose (θ)	
		Without Talc	With Talc	Without Talc	With Talc	Without Talc	With Talc
1	FP1	21.43± 0.21	15.37± 0.12	1.27± 0.008	1.18± 0.005	30.49± 0.27	24.98± 0.20
2	FP2	22.86± 0.19	14.05± 0.11	1.29± 0.007	1.16± 0.004	31.00± 0.25	25.50± 0.21
3	FP3	24.28± 0.22	12.69± 0.10	1.32± 0.006	1.14± 0.005	31.88± 0.24	23.94± 0.22
4	FP4	25.00± 0.21	11.99± 0.09	1.33± 0.009	1.13± 0.007	30.54± 0.28	23.60± 0.20
5	FP5	25.72± 0.23	11.28± 0.08	1.29± 0.007	1.12± 0.006	32.29± 0.26	22.68± 0.19
6	FP6	23.57± 0.20	15.62± 0.12	1.30± 0.008	1.18± 0.005	33.30± 0.29	21.99± 0.20

Table 6: Flow properties for Atorvastatin solid dispersion with Poloxamer 188 by melt dispersion method

S.No.	Solid Dispersion	Results of various flow properties (avg. ± S.D. for n = 3)					
		Carr's Index (%)		Hausner's Ratio		Angle of Repose (θ)	
		Without Talc	With Talc	Without Talc	With Talc	Without Talc	With Talc
1	FP7	26.43± 0.22	14.28± 0.11	1.35± 0.010	1.16± 0.008	30.96± 0.27	25.40± 0.21
2	FP8	24.13± 0.21	13.59± 0.10	1.31± 0.009	1.15± 0.007	32.86± 0.25	24.46± 0.20
3	FP9	25.52± 0.24	12.90± 0.11	1.34± 0.008	1.14± 0.006	33.50± 0.28	26.01± 0.22
4	FP10	26.89± 0.21	11.48± 0.09	1.36± 0.009	1.12± 0.007	32.70± 0.24	23.02± 0.19
5	FP11	27.58± 0.22	15.86± 0.12	1.38± 0.011	1.18± 0.008	30.02± 0.25	22.29± 0.20
6	FP12	28.27± 0.23	15.19± 0.11	1.39± 0.012	1.17± 0.006	31.54± 0.26	24.65± 0.22

Table 7: Flow properties for Atorvastatin solid dispersion with Poloxamer 407 by solvent evaporation method:

S.No.	Solid Dispersion	Results of various flow properties (avg. ± S.D. for n = 3)					
		Carr's Index (%)		Hausner's Ratio		Angle of Repose (θ)	
		Without Talc	With Talc	Without Talc	With Talc	Without Talc	With Talc
1	FP13	26.20± 0.22	14.51± 0.11	1.35± 0.009	1.16± 0.006	30.62± 0.27	25.87± 0.21
2	FP14	28.96± 0.21	13.11± 0.10	1.40± 0.008	1.15± 0.005	33.18± 0.28	24.32± 0.22
3	FP15	22.53± 0.20	11.66± 0.10	1.29± 0.008	1.13± 0.004	31.79± 0.24	23.41± 0.20
4	FP16	23.94± 0.21	15.32± 0.12	1.31± 0.007	1.18± 0.005	30.28± 0.27	22.19± 0.19
5	FP17	25.34± 0.22	13.93± 0.11	1.33± 0.010	1.16± 0.003	32.04± 0.28	25.78± 0.21
6	FP18	26.05± 0.23	12.49± 0.10	1.35± 0.009	1.14± 0.005	32.61± 0.23	24.03± 0.22

Table 8: Flow properties for Atorvastatin solid dispersion with Poloxamer 407 by melt dispersion method

S.No.	Solid Dispersion	Results of various flow properties (avg. ± S.D. for n = 3)					
		Carr's Index (%)		Hausner's Ratio		Angle of Repose (θ)	
		Without Talc	With Talc	Without Talc	With Talc	Without Talc	With Talc
1	FP19	26.76± 0.22	15.57± 0.12	1.36± 0.009	1.18± 0.009	33.20± 0.30	23.50± 0.21
2	FP20	24.64± 0.21	14.16± 0.11	1.32± 0.008	1.16± 0.008	31.13± 0.29	22.53± 0.20
3	FP21	27.46± 0.23	14.39± 0.10	1.37± 0.010	1.16± 0.007	30.37± 0.28	24.56± 0.21

4	FP22	23.60± 0.22	12.81± 0.11	1.30± 0.008	1.15± 0.005	32.45± 0.28	25.68±0.22
5	FP23	25.00± 0.21	12.29± 0.10	1.33± 0.009	1.14± 0.006	30.83± 0.26	22.87± 0.19
6	FP24	26.38± 0.22	13.00± 0.11	1.35± 0.010	1.14± 0.008	31.46± 0.27	24.18± 0.21

Solubility studies

Table 9: Solubility profile for Atorvastatin solid dispersion with Poloxamer 188 by solvent evaporation technique

S. No.	Concentration of poloxamer 188 (%w/w)	Solubility(mg/ml) in	
		Water	pH 6.8 phosphate buffer
1	0.00 (Atorvastatin)	1.009± 0.005	1.4547± 0.009
2	20 .00 (FP1)	2.079± 0.011	2.298± 0.018
3	33.33 (FP2)	3.176± 0.020	3.402± 0.025
4	42.85 (FP3)	3.219± 0.022	3.605± 0.026
5	44.44 (FP4)	3.362± 0.024	3.964± 0.027
6	47.36 (FP5)	3.091± 0.021	3.327± 0.027
7	50.00 (FP6)	2.962± 0.019	3.127± 0.024

Table 10: Solubility profile for Atorvastatin solid dispersion with Poloxamer 188 by melt dispersion technique

S. No.	Concentration of poloxamer 188 (%w/w)	Solubility(mg/ml) in	
		Water	pH 6.8 phosphate buffer
1	0.00 (ATC)	1.009± 0.008	1.455± 0.011
2	20 .00 (FP7)	2.107± 0.017	2.375± 0.018
3	33.33 (FP8)	2.827± 0.021	3.091± 0.026
4	37.5 (FP9)	2.989± 0.024	3.276± 0.024
5	41.18 (FP10)	3.109± 0.026	3.361± 0.027
6	42.85 (FP11)	2.682± 0.020	3.192± 0.026
7	44.44 (FP12)	2.572± 0.021	3.017± 0.025

Table 11: Solubility profile for Atorvastatin solid dispersion with Poloxamer 407 by solvent evaporation technique

S. No.	Concentration of poloxamer 407 (%w/w)	Solubility(mg/ml) in	
		Water	PH 6.8 phosphate buffer
1	0 .00 (ATC)	1.009± 0.008	1.455± 0.011
2	20 .00 (FP13)	2.171± 0.015	2.496± 0.020
3	33.33 (FP14)	3.126± 0.025	3.402± 0.024
4	42.85 (FP15)	3.277± 0.026	3.575± 0.026
5	44.44 (FP16)	3.277± 0.024	3.605± 0.027
6	47.36 (FP17)	3.416± 0.029	3.909± 0.029
7	50.00 (FP18)	3.323± 0.027	3.715± 0.033

Table 12: Solubility profile for Atorvastatin solid dispersion with Poloxamer 407 by melt dispersion technique

S. No.	Concentration of poloxamer 407 (%w/w)	Solubility (mg/ml) in	
		Water	pH 6.8 phosphate buffer
1	0.00 (ATC)	1.009± 0.008	1.4547± 0.011

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2	20.00 (FP19)	2.201± 0.018	2.682± 0.022
3	33.33 (FP20)	2.892± 0.022	3.107± 0.028
4	37.50 (FP21)	3.019± 0.027	3.384± 0.029
5	41.18 (FP22)	2.929± 0.024	3.258± 0.029
6	42.85 (FP23)	2.891± 0.026	3.201± 0.027
7	44.44 (FP24)	2.762± 0.022	3.147± 0.026

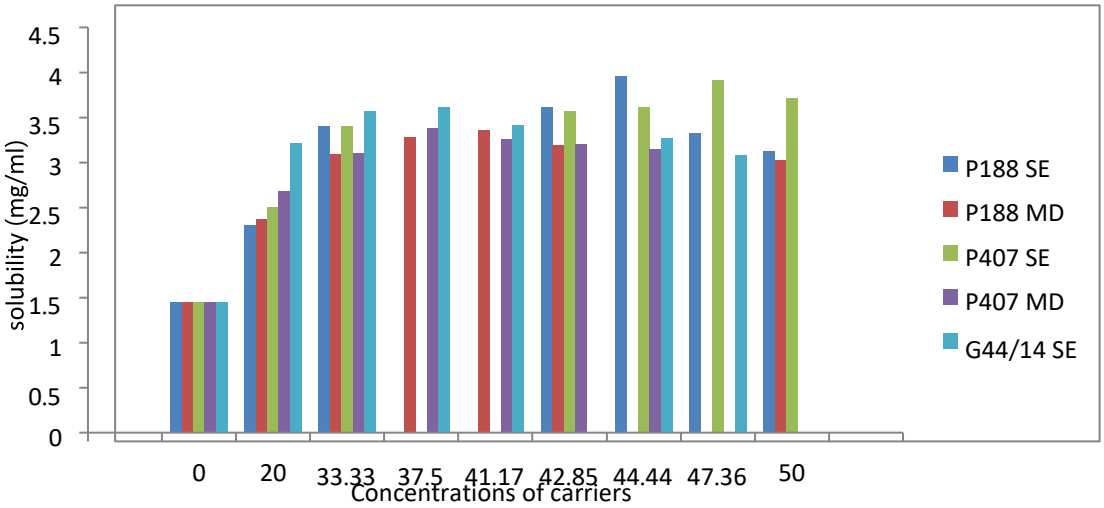

Figure 3: Solubility profile for Atorvastatin solid dispersions with carriers by solvent evaporation and melt dispersion techniques in pH 6.8 phosphate buffer.

X-Ray Diffraction Studies:

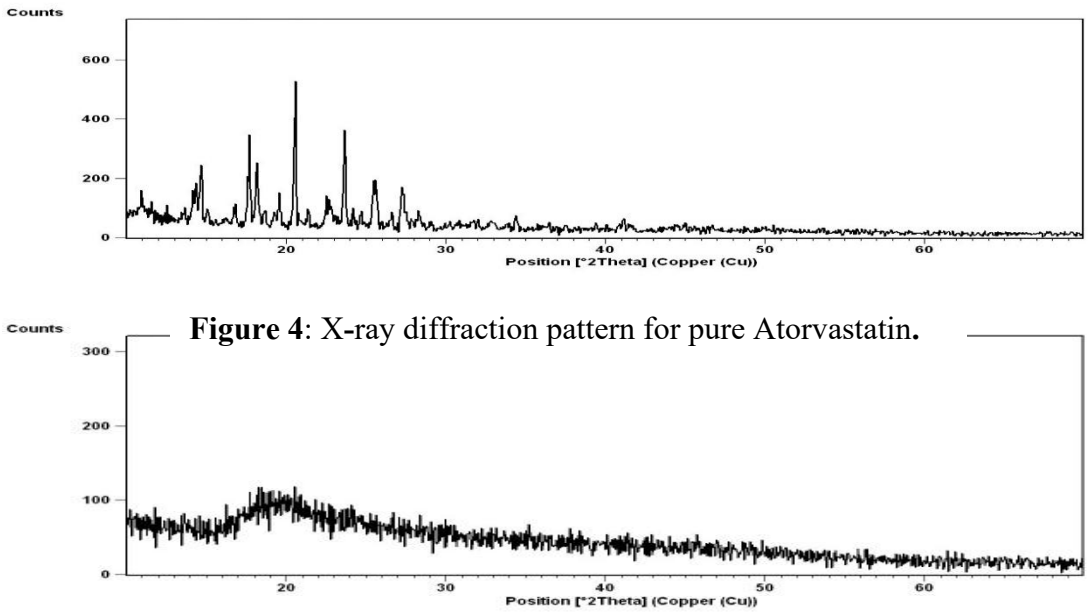

Figure 4: X-ray diffraction pattern for pure Atorvastatin**.**

Figure 5: X-ray diffraction pattern of Atorvastatin solid dispersion with Poloxamer 188 by solvent evaporation technique

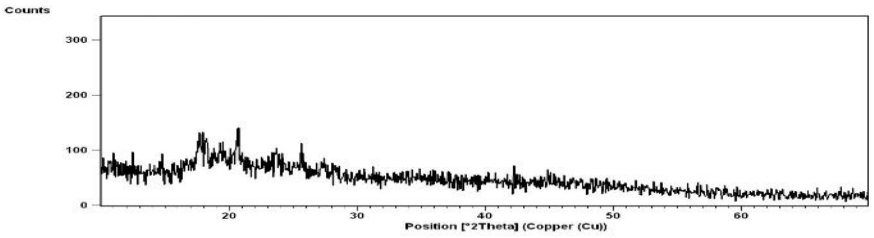

Figure 6: X-ray diffraction pattern of Atorvastatin solid dispersion with Poloxamer 188by melt dispersion technique**.**

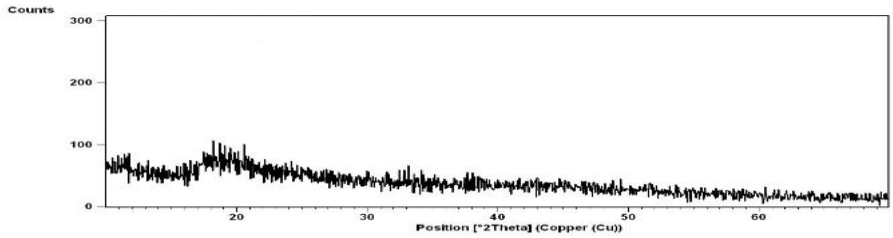

Figure 7:X-ray diffraction pattern of Atorvastatin solid dispersion with poloxamer 407 by solvent evaporation technique**.**

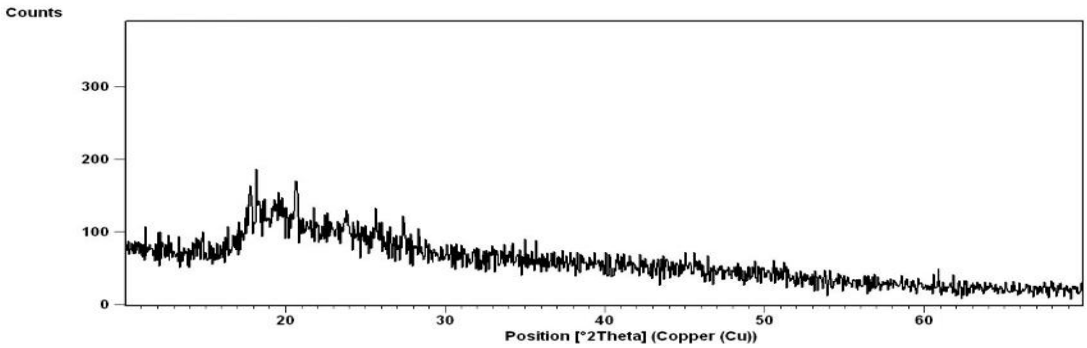

Figure 8: X-ray diffraction pattern of Atorvastatin solid dispersion with poloxamer 407 by melt dispersion technique

In-vitro dissolution Studies

Table 13: Results of Dissolution studies of Atorvastatin solid dispersion with Poloxamer 188 by solvent evaporation method:

S. No.	Time (min.)		Percentage (%) of drug released (avg. ± S.D. for n = 3)					
		Pure drug	FP1	FP2	FP3	FP4	FPP5	FP6
1	5	31.47 ± 0.19	43.24 ± 0.26	48.40 ± 0.28	62.33 ± 0.51	64.69 ± 0.48	53.16 ±0.32	61.54 ±0.53
2	10	35.47± 0.25	61.78± 0.48	64.31± 0.36	75.87± 0.62	79.39± 0.56	70.71± 0.49	62.82± 0.55
3	15	37.99± 0.28	70.36± 0.51	70.00± 0.40	88.19± 0.70	91.18± 0.70	78.70± 0.55	68.59± 0.59
4	20	41.45± 0.30	80.51± 0.53	78.25± 0.45	92.10± 0.78	98.50± 0.85	82.24± 0.64	75.28± 0.61

5	30	49.92± 0.38	87.31± 0.62	86.08± 0.50	98.21± 0.80	100.00± 0.89	87.27± 0.66	80.97± 0.72
6	40	58.08± 0.42	90.94± 0.71	97.98± 0.61	100.00±0.85	-	93.91± 0.76	83.23± 0.76
7	50	61.95± 0.45	91.73± 0.76	98.94± 0.65	-	-	93.98± 0.79	85.61± 0.79
8	60	67.71± 0.54	93.15± 0.80	100.00±0.86	-	-	91.13± 0.82	85.68± 0.82

Table 14: Results of dissolution studies of Atorvastatin solid dispersions with Poloxamer 188 by melt dispersion method:

S. No.	Time (min.)		Percentage (%) of drug released (avg. ± S.D. for n = 3)				
		FP7	FP8	FP9	FP10	FP11	FP12
1	5	27.33± 0.22	46.13± 0.32	54.99± 0.38	42.26± 0.31	31.11± 0.22	31.35± 0.20
2	10	45.27± 0.28	59.07± 0.38	60.46± 0.46	57.45± 0.42	55.10± 0.36	49.86± 0.32
3	15	60.66± 0.35	70.92± 0.46	72.80± 0.50	66.43± 0.50	71.11± 0.46	52.51± 0.39
4	20	64.89± 0.42	74.95± 0.50	76.49± 0.55	75.07± 0.60	71.64± 0.48	57.91± 0.41
5	30	74.12± 0.55	89.17± 0.53	86.88± 0.59	85.58± 0.60	81.39± 0.57	71.88± 0.53
6	40	81.03± 0.58	95.81± 0.64	92.40± 0.64	90.44± 0.75	88.71± 0.70	74.66± 0.59
7	50	85.57± 0.64	96.60± 0.67	97.56± 0.70	96.25± 0.79	98.71± 0.82	87.66± 0.70
8	60	95.11± 0.75	100.00± 0.80	100.00±0.85	100.00±0.82	100.00±0.86	100.00±0.89

Table 15: Results of dissolution studies of Atorvastatin solid dispersions with Poloxamer 407 by solvent evaporation method.

S. No.	Time (min.)		Percentage (%) of drug released (avg ± S.D. for n = 3)					
		PURE DRUG	FP13	FP14	FP15	FP16	FP17	FP18
1	5	31.47 ± 0.26	37.75 ± 0.30	46.40 ± 0.35	50.29 ± 0.39	57.13 ± 0.41	67.37 ± 0.45	54.22 ± 0.41
2	10	35.47± 0.27	51.55± 0.41	69.55± 0.49	74.39± 0.52	72.92± 0.50	86.58± 0.74	67.67± 0.49
3	15	37.99± 0.29	64.78± 0.49	77.44± 0.53	77.36± 0.56	80.14± 0.65	91.24± 0.81	81.26± 0.65
4	20	41.45± 0.31	73.21± 0.56	85.38± 0.63	88.33± 0.72	87.60± 0.69	93.59± 0.84	87.29± 0.68
5	30	49.92± 0.35	87.39± 0.65	92.90± 0.75	95.46± 0.77	96.54± 0.75	100.00±0.91	96.99± 0.75
6	40	58.08± 0.43	92.65± 0.76	97.70± 0.79	96.36± 0.82	100.00±0.88	-	97.66± 0.79
7	50	61.95± 0.47	99.21± 0.51	99.61± 0.83	100.00±0.90	-	-	99.64± 0.85
8	60	67.71± 0.50	100.00±0.91	100.00±0.92	-	-	-	100.00±0.93

Table 16: Results of dissolution studies of Atorvastatin solid dispersions with Poloxamer 407 by melt dispersion method.

S. No.	Time (min.)		Percentage (%) of drug released (avg. ± S.D. for n = 3)				
		FP19	FP20	FP21	FP22	FP23	FP24
1	5	49.84± 0.38	49.22± 0.37	45.74± 0.36	41.96± 0.31	47.68± 0.35	39.85± 0.29
2	10	60.56± 0.42	70.70± 0.55	58.30± 0.43	54.62± 0.42	68.04± 0.49	51.30± 0.40
3	15	71.82± 0.50	71.41± 0.58	69.81± 0.49	62.57± 0.48	72.71± 0.53	61.61± 0.49
4	20	77.24± 0.56	76.24± 0.60	75.60± 0.57	70.80± 0.53	77.05± 0.62	72.43± 0.52
5	30	86.98± 0.63	85.04± 0.64	87.98± 0.66	85.34± 0.60	87.63± 0.73	83.37± 0.70
6	40	93.94± 0.80	90.59± 0.76	94.93± 0.76	95.82± 0.75	90.77± 0.80	93.10± 0.81
7	50	96.98± 0.91	97.44± 0.83	99.44± 0.89	96.64± 0.86	93.04± 0.86	95.38± 0.83
8	60	100.00± 0.93	100.00± 0.90	100.00± 0.92	98.40± 0.89	96.60± 0.93	100.00± 0.89

Table 17: Dissolution kinetic parameters of FP1to FP24

S. No.	Solid spersion	Regression coefficient		Dissolution Rate constant (K) (min^{-1})	D50% (min.)	D90% (min.)	Dissolution Efficiency
		Zero order	First order				
	Pure drug	0.419	0.793	0.0207	33	-	36.176
	FP1	0.007	0.806	0.0529	13	42	63.912
	FP2	0.104	0.957	0.0875	8	26	64.365
	FP3	0.377	0.985	0.1335	5	17	77.130
	FP4	0.325	0.955	0.1865	4	12	80.50
	FP5	0.39	0.739	0.0598	11	38	68.868
	FP6	0.57	0.358	0.0414	16	54	64.477
	FP7	0.528	0.950	0.0437	15	50	50.788
	FP8	0.175	0.975	0.0713	10	31	62.956
.	FP9	0.273	0.977	0.0644	10	32	64.968
.	FP10	0.268	0.956	0.0713	11	36	60.722
.	FP11	0.417	0.895	0.0690	10	32	57.699
.	FP12	0.920	0.931	0.0391	17	-	48.744
.	FP13	0.425	0.990	0.06900	10	33	58.552
.	FP14	0.04	0.987	0.0921	8	24	69.061
.	FP15	0.022	0.934	0.0944	8	24	71.668
.	FP16	0.199	0.977	0.1105	6	21	73.024
.	FP17	0.211	0.917	0.1543	5	15	80.932
.	FP18	0.19	0.929	0.1404	5	16	71.848
.	FP19	0.083	0.976	0.0713	10	32	64.178
.	FP20	0.03	0.920	0.0690	10	33	65.124
.	FP21	0.218	0.983	0.0736	9.5	31	62.544
.	FP22	0.358	0.975	0.0690	10	32	58.453
.	FP23	0.09	0.917	0.0575	12	39	65.275
.	FP24	0.419	0.989	0.0621	11	36	57.466

The dissolution data were fitted to first order and zero-order kinetic models to determine the drug release mechanism. The first-order plots showed good linearity with higher correlation coefficient (R^2) values for the formulations, indicating that the drug release from the solid dispersion formulations followed **first-order kinetics**.

CONCLUSION

In the present investigation, Atorvastatin exhibited significantly enhanced aqueous solubility through the formulation of solid dispersions using Poloxamer 188, Poloxamer 407 as hydrophilic carriers. Analytical evaluation confirmed accurate spectrophotometric quantification at 242 nm, while compatibility studies demonstrated no drug–excipient interactions. Solid-state characterization revealed a marked reduction in crystallinity upon dispersion, contributing to improved dissolution behaviour.

Among the carriers and methods employed, Poloxamer 188 in combination with the solvent evaporation technique produced the highest solubility enhancement, achieving a maximum solubility of 3.964 mg/ml at 44.44% w/w carrier concentration—over a threefold increase compared to intrinsic solubility. Although all carriers improved solubility to varying extents, Poloxamer 188 consistently outperformed Poloxamer 407 across both solvent evaporation and

melt dispersion methods. Overall, the findings confirm that carrier type, carrier concentration, and preparation method play critical roles in optimizing the solubility of BCS Class II drugs, with solvent evaporation–based solid dispersions of Atorvastatin offering the most promising enhancement.

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AUTHORS CONTRIBUTIONS

All the authors contributed equally

ETHICAL APPROVAL

This study does not involve any human participants or experimental animals

CONFLICT OF INTERESTS

Declared none

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