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Solubility Enhancement of Rosuvastatin Calcium by Fusion Method

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ABSTRACT
Objective: The objective of the present investigation was to enhance the solubility of Rosuvastatin calcium using fusion method by solid dispersion. Materials and Method: In this work a new attempt was made to prepare solid dispersion by various polymers like PEG 4000 and PEG 6000 with various concentrations. The resultant batches were evaluated for flow properties and characterization of formulation like % practical yield, solubility study, drug content analysis and *in vitro* dissolution study. Results and Discussion: The optimized batch SD6 containing Rosuvastatin calcium: PEG 6000 (1:5) was showed drug content 99.24%, solubility 2.54 mg/ml and % cumulative drug release 98.16 % in 30 mins among all other batches. The result of stability study of the batch SD6 showed that there were no significant changes in all post formulation parameters after period of one month when stored at 40° ± 2 °C and 75 ± 5% RH. Conclusion: From the study it was concluded that solid dispersion of Rosuvastatin calcium is an acceptable method to enhance solubility which was successfully prepared for the treatment of Hyperlipidemia.

1. INTRODUCTION:

Hyperlipidemia is a metabolic disorder characterized by elevated total or low-density lipoprotein (LDL) cholesterol levels or reduced high-density lipoprotein (HDL) cholesterol levels and is a major risk factor for coronary heart disease and stroke. The condition is often asymptomatic initially but, if persistent, may present with xanthomas, xanthelasma, arcus senilis, and signs of atherosclerosis, leading to complications such as hypertension, myocardial infarction, cerebrovascular accidents, peripheral artery disease, fatty liver, and kidney or eye damage, particularly in individuals with diabetes or smoking habits. The pathophysiology involves genetic defects in lipid metabolism along with environmental and lifestyle factors such as poor diet and physical inactivity. Management includes lifestyle modification through diet, exercise, weight reduction, smoking cessation, and alcohol avoidance, while pharmacological treatment primarily involves lipid-lowering agents such as HMG-CoA reductase inhibitors (statins), bile acid sequestrants, fibrates, and niacin, used alone or in combination when necessary.[1-3]

Developing an effective pharmaceutical formulation requires detailed investigation to achieve optimal therapeutic performance. Rosuvastatin calcium is commonly administered orally for the management of Hyperlipidemia; however, conventional oral formulations may exhibit limitations in drug release and absorption, necessitating the development of improved formulation strategies to enhance treatment consistency.[4]

Rosuvastatin calcium is classified as a BCS Class II drug, characterized by low aqueous solubility and high permeability, resulting in an absolute oral bioavailability of approximately 20% and a time to peak plasma concentration of 3–5 hours following oral administration. Owing to these limitations, advanced formulation approaches such as solid dispersion techniques-particularly those prepared

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by the fusion method-have gained attention for their ability to enhance solubility, improve dissolution rate, and increase effective bioavailability, thereby leading to improved and more consistent therapeutic outcomes.[5-6]

MATERIALS AND METHODS:[7-10]

Materials:

Rosuvastatin calcium was supplied by Livmore Life Sciences, Vadodara, Gujarat, India. PEG 4000 and PEG 6000 were provided by Chemdyes Corporation, Rajkot, Gujarat, India.

Composition of mixture for solid dispersion:

Solid dispersions of Rosuvastatin calcium were prepared by using PEG 4000 and PEG 6000 as carriers. Six formulations were developed by mixing the drug with the polymers in different ratios. Formulations SD1, SD2, and SD3 contained Rosuvastatin calcium: PEG 4000 in ratios of 1:1, 1:3, and 1:5, respectively. Formulations SD4, SD5, and SD6 contained Rosuvastatin calcium: PEG 6000 in the same ratios of 1:1, 1:3, and 1:5.

Method of preparation solid dispersion:

The solid dispersion was prepared using the fusion method. The carrier is placed in a porcelain dish and heated till melting over steam bath. The accurately weighed amount of drug is dispersed into molten carrier gradually using glass rod. After complete dispersion of drug within carrier, the dish is removed from steam bath and left aside to cool at room temperature till solidification of its contents. Then the solid dispersion formed is pulverized and sieved. All solid dispersions' composition were listed in Table 1.

Table 1: Composition of various solid dispersion of Rosuvastatin calcium

Sr. No.	Formulation code	Composition	Ratio
1.	SD1	Drug : PEG 4000	1 : 1
2.	SD2	Drug : PEG 4000	1 : 3
3.	SD3	Drug : PEG 4000	1 : 5
4.	SD4	Drug : PEG 6000	1 : 1
5.	SD5	Drug : PEG 6000	1 : 3
6.	SD6	Drug : PEG 6000	1 : 5

*SD: Solid dispersion

Determination of melting point of Rosuvastatin calcium:[11]

The melting point of Rosuvastatin calcium was determined using the capillary method. A small quantity of the drug was filled into a thin-walled capillary tube sealed at one end and placed in a melting point apparatus. The temperature was gradually increased, and the temperature range at which the drug sample began to melt and completely melted was recorded as the melting point of Rosuvastatin calcium.

Compatibility study of drug and excipients by FTIR:[12]

To identify the medication and excipients and assess their compatibility, FTIR spectroscopy was employed. To determine whether the drug and excipients were compatible, FTIR spectroscopy was performed on both pure drugs and physical mixtures of drugs and excipients.

Identification by UV Spectroscopy:

Calibration curve of Rosuvastatin calcium in distilled water:

Ten milligrams of Rosuvastatin calcium were dissolved in one hundred milliliters of distilled water to create a standard stock solution with a concentration of 100 µg/ml. By pipetting out 0.2, 0.4, 0.6, 0.8, and 1.0 ml of the stock solution of 100 µg/ml and diluting it up to 10 ml in a volumetric flask, working solutions with concentrations of 2, 4, 6, 8, and 10 µg/ml were created. Working solutions' absorbance was measured three times at λ_{max} 244 nm using distilled water as a blank.

Characterization of formulation:[13-15]

Bulk density, Tapped density, Hausner's ratio, Compressibility index, Angle of repose, Void volume, % Porosity were all measured. Good flow qualities were indicated by the powder mixture's minimum Carr's index, Hausner's ratio, and Angle of repose.

Bulk density:

Accurately weighed the powder mixture and transferred to measuring cylinder carefully measure the volume of powder without compacting.

$$\text{Bulk density (gm/ml)} = \frac{\text{Mass of powder (gm)}}{\text{Bulk volume of powder (ml)}}$$

Tapped density

Tapped density was measured by placing graduated cylinder containing formulation blend on mechanical tapping apparatus. Tapped volume was measured until constant tapped volume is not achieved.

$$\text{Tapped density (gm/ml)} = \frac{\text{Mass of powder (gm)}}{\text{Tapped volume of powder (ml)}}$$

Hausner's ratio

Hausner's ratio is a ratio of tapped density to bulk density.

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

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Table 2: Relationship between Hausner's ratio and Powder flow

Hausner's ratio	Powder flow
1.00 - 1.11	Excellent
1.12 - 1.18	Good
1.19 - 1.25	Fair
1.26 - 1.34	Passable
1.35 - 1.45	Poor
1.46 - 1.56	Very poor
>1.60	Extremely poor

$$\% \text{ Practical yield} = \frac{\text{Actual weight of solid dispersion obtained}}{\text{Total weight of drug and polymer added}} X\ 100$$

Compressibility index (Carr's index)

Carr's index is 100 times the ratio of the difference of tapped density and bulk density to tapped density.

$$\text{Compressibility Index (\%)} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} X\ 100$$

Table 3: Relationship between % Compressibility and Powder flow

% Compressibility	Powder flow
<10	Excellent
11 – 15	Good
16 – 20	Fair
21 – 25	Passable
26 – 31	Poor
32 – 37	Very poor
>38	Extremely poor

Angle of repose:

It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane; Angle of repose was determined by funnel method. Powder blend was poured from funnel that can be raised vertically until it reaches maximum cone height (h) was obtained. Radius (r) of the pile was measured. Angle of repose was measured by following formula.

$$\text{Tan } \theta = \frac{h}{r} \qquad \theta = \tan^{-1}\frac{h}{r}$$

Where, θ = Angle of repose,
h = Height of pile,
r = Radius of pile

Table 4: Relationship between Angle of repose and Powder flow

Angle of repose	Powder flow
<25	Excellent
25 – 30	Good
30 – 40	Passable
>40	Very poor

Void volume:

The volume of the space between particles was determined by applying the following formula:

$$\text{void volume} = \text{bulk volume} - \text{tapped volume}$$

% Porosity:

The % Porosity of the granules of each prepared batch was determined using the following formula:

$$\% \text{ Porosity} = \frac{1 - \text{Tapped volume}}{\text{Bulk volume}} X\ 100$$

% Practical yield:

The prepared solid dispersion was collected and weighed. The measured weight was divided by the total amount of all non-volatile components which were used for the preparation of the solid dispersion.

Solubility studies:

Solid dispersion of drug equivalent to 10 mg of Rosuvastatin calcium were added to 100 ml of distilled water in a beaker. The contents of the beaker were stirred for 6 hours using a mechanical stirrer (1000 rpm) at 37 ± 0.5 ºC. After stirring, the beaker was allowed to stand for 12 hours for equilibration at 37 ± 0.5 ºC. The resultant solution was filtered through a 0.45 μm membrane filter, and the filtrate was analyzed by UV spectrophotometer at 244 nm.

Table 5: Parameters of Solubility

Descriptive Term	Parts of solvents required for 1 part of solute
Practically insoluble	10000 and more
Very slightly soluble	From 1000 to 10000
Slightly soluble	From 100 to 1000
Sparingly soluble	From 30 to 100
Soluble	From 10 to 30
Freely soluble	From 1 to 10
Very soluble	Less than 1

Drug content analysis:[16]

The amount of drug present in 10 mg equivalent amount of solid dispersion was determined by dissolving the powder mixture in 25 ml of distilled water and suitably diluted with distilled water and UV absorbance was measured at 244 nm. Drug concentration was determined from standard graph.

***In-vitro* drug release study:**[17]

In-vitro drug release of formulated batches in distilled water was carried out in dissolution apparatus type II (paddle).Dissolution study was performed in 900 ml distilled water. The stirring speed was 50 rpm, and the temperature was maintained at 37ºC±0.5 ºC. the sample were withdrawn periodically and were replenished with fresh dissolution medium. The sample were filtered, diluted and analyzed by UV spectrophotometer at 244 nm using distilled water as blank.

Stability study:[18]

In the current investigation, the optimized batch's stability was investigated for one month at 40° ± 2°C / 75 ± 5% relative humidity. The formulation was shielded from light by being wrapped in

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aluminum foil. Solid dispersion was assessed for solubility, drug content and *in vitro* drug release study after a 30-day period.

RESULTS AND DISCUSSION:

Melting point of Rosuvastatin calcium

One common method for identifying drugs is melting point determination, which uses melting point apparatus. The melting point of Rosuvastatin calcium was determined to be between 153 and 159°C. The melting temperature of Rosuvastatin calcium is comparable to the reported melting point of 155–160°C. As stated in Table 6.

Table 6: Melting point of Rosuvastatin calcium

Sr. No.	Reported Melting Point	Observed Melting point
1.	155-160°C	154 - 156 ºC
2.		153 - 157 ºC
3.		154- 159 ºC

Identification of drug by FTIR:

FTIR spectroscopy was used to identify the drug and evaluate its compatibility with excipients. The FTIR spectrum verified that it was Rosuvastatin calcium and conformed with the original medication. FTIR spectrum of Rosuvastatin calcium is shown in Figure 1, and the interpretation of the corresponding peaks is presented in Table 7. When Rosuvastatin calcium was mixed with the polymers, no significant changes or disappearance of characteristic IR peaks were observed, indicating the absence of chemical interaction. The FTIR spectrum of Rosuvastatin calcium with excipients is shown in Figure 2, and the interpretation of these peaks is summarized in Table 8, confirming the compatibility of Rosuvastatin calcium with the selected excipients.

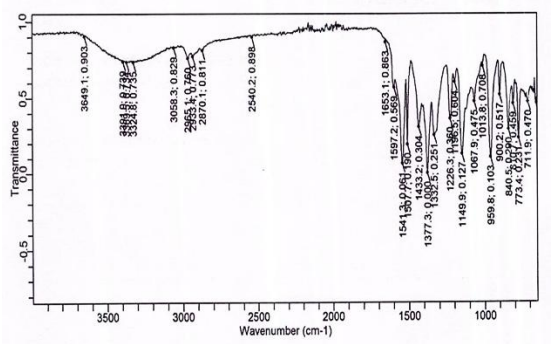

Figure 1: FTIR spectrum of Rosuvastatin calcium

Table 7: Interpretation of FTIR spectrum of Rosuvastatin calcium

Sr. No.	Functional group	Standard value(cm^{-1})	Observed value(cm^{-1})
1.	O-H stretch	1610-1300	1541.25
2.	C-H stretch	2960-2850	2965.1
3.	C=C stretch	1680-1620	1653.07
4.	C-F stretch	1400-1000	1377.25
5.	C-N stretch	1350-1000	1149.88
6.	C-C stretch	650-610	711.92

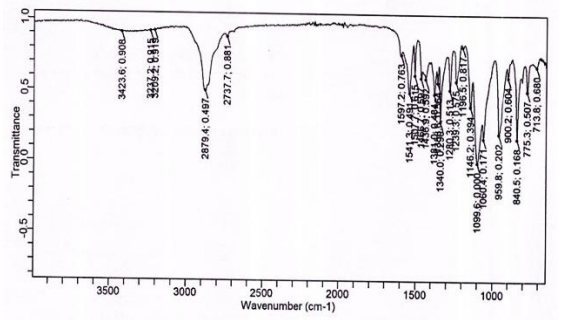

Figure 2: FTIR spectrum of Rosuvastatin calcium with PEG 6000

Table 8: Interpretation of FTIR spectrum of Rosuvastatin calcium with excipients

Sr. No.	Functional group	Standard value(cm^{-1})	Observed value(cm^{-1})
1.	O-H stretch	1610-1300	1541.3
2.	C-H stretch	2960-2850	2879.4
3.	C=C stretch	1680-1620	1597.2
4.	C-F stretch	1400-1000	1381.0
5.	C-N stretch	1350-1000	1099.6
6.	C-S stretch	650-610	713.8

Identification of drug by UV spectroscopy method:

Drug overlay spectra were acquired by scanning solutions with varying concentrations (2, 4, 6, 8, and 10 µg/ml) at 244 nm. Given that the reported λ_{max} is 244 nm, it can be inferred that the medication was Rosuvastatin calcium. Figure 3 displays the Rosuvastatin calcium overlay spectra.

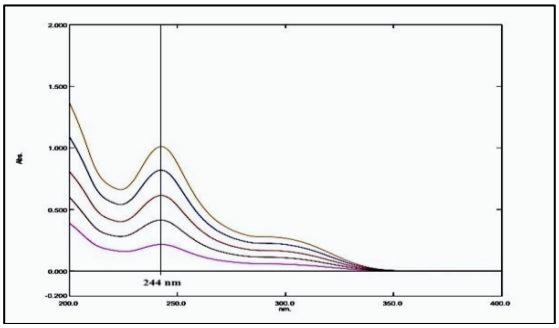

Figure 3: Overlay Spectra of Rosuvastatin calcium in distilled water

Table 9: UV Absorbance data for calibration curve of Rosuvastatin calcium in distilled water

Sr. No.	Concentration (µg/ml)	Absorbance			Mean Absorbance ± SD (n=3)
		I	II	III	
1	2	0.219	0.223	0.218	0.22 ± 0.00216
2	4	0.41	0.422	0.418	0.4166 ± 0.00499
3	6	0.612	0.615	0.617	0.6146 ± 0.00020
4	8	0.801	0.809	0.81	0.8066 ± 0.00403

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5	10	1.01	1.013	1.009	1.0106 ± 0.00170

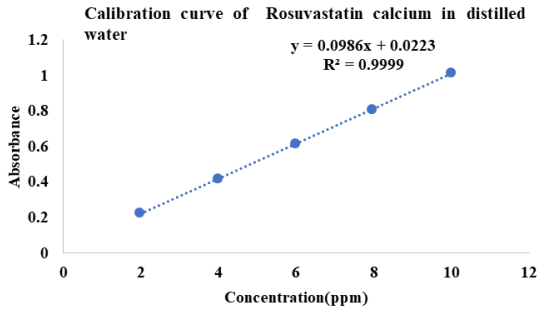

Figure 4: Calibration curve of Rosuvastatin calcium in distilled water

Flow properties of Rosuvastatin calcium solid dispersion

The solid dispersion's Bulk density, Taped density, Hausner's ratio, Carr's index, and Angle of repose were all measured. It was discovered that every parameter had acceptable flow characteristics. The tapped density ranged from 1.33 to 1.53 gm/ml, while the bulk density was found to be between 1.01 and 1.17 gm/ml. Compressibility index (Carr's index) was computed using the two data points mentioned above. The range of the compressibility index was 21.05% to 28.37%. Data on compressibility and flow ability showed that all powder mixes had adequate flow characteristics. Angle of repose also demonstrated the superior flow characteristics of all powder blends. The angle of repose was in the range of 27.48º to 34.65°, void volume was found to be in the range of 19.68% to 28.08% and % porosity was found to be in the range of 21.05% to 28.36% so it indicates good flow property. As listed in Table 10.

Table 10: Flow properties of Rosuvastatin calcium solid dispersions

S.D. Batch	Bulk Density (gm/ml) ± SD	Tapped Density (gm/ml) ± SD	Carr's Index (%) ± SD	Hausner's Ratio (%) ± SD	Angle of Repose (°Θ) ± SD	% Void Volume ± SD	% Porosity ± SD
SD1	1.05 ± 0.009	1.33 ± 0.008	21.05 ± 0.10	1.26 ± 0.009	34.65 ± 0.010	20.04 ± 0.09	21.05 ± 0.09
SD2	1.17 ± 0.010	1.53 ± 0.009	23.52 ± 0.09	1.3 ± 0.008	27.75 ± 0.009	20.12 ± 0.08	23.54 ± 0.09
SD3	1.05 ± 0.008	1.42 ± 0.010	26.12 ± 0.11	1.35 ± 0.010	29.05 ± 0.011	24.92 ± 0.07	26.14 ± 0.07
SD4	1.01 ± 0.011	1.41 ± 0.008	28.37 ± 0.12	1.39 ± 0.011	32.82 ± 0.010	28.08 ± 0.08	28.36 ± 0.08
SD5	1.02 ± 0.009	1.38 ± 0.010	26.08 ± 0.09	1.35 ± 0.009	31.52 ± 0.008	25.54 ± 0.07	26.06 ± 0.07
SD6	1.11 ± 0.010	1.42 ± 0.009	21.83 ± 0.11	1.27 ± 0.008	27.48 ± 0.010	19.68 ± 0.09	21.84 ± 0.08

*SD: Solid dispersion, All values are expressed as mean ± SD; (n=6)

The percentage practical yield of the prepared solid dispersion batches ranged from 89.57% to 92.66%, indicating good recovery during the preparation process. The amount of drug soluble varied between 1.48 mg/mL and 2.54 mg/mL, demonstrating a significant improvement in solubility across the formulations. The drug content of the solid dispersions was found to be within the range of 94.32% to 99.24%, confirming uniform drug distribution and acceptable content uniformity. As listed in Table 11 & showed in Figure 5.

Table 11: Practical yield, drug content & solubility of various solid dispersions of Rosuvastatin calcium

Solid Dispersion Batch	% Practical Yield	Amount of Drug Soluble (mg/ml)	Drug Content (%)
Rosuvastatin calcium	-	0.33	-
SD1	91.51	1.48	97.27
SD2	90.66	1.86	98.13
SD3	89.57	1.51	98.96
SD4	92.66	2.11	94.32
SD5	91.48	1.94	97.55
SD6	92.38	2.54	99.24

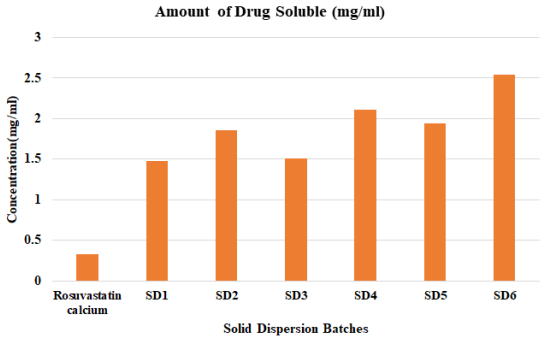

Figure 5: Solubility of Solid Dispersion Batch SD1 to SD6

In Vitro Drug Release study

900 ml of water was used as a dissolve medium in an *in vitro* drug release investigation utilizing a dissolution test apparatus type II (paddle) at 37° ± 0.5 °C and 50 rpm. The amount of medication released from the solid dispersion increases with the polymer concentration. More than 50 % of drug released in less than 5 mins. Formulations SD1 to

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SD3 containing PEG 4000 shows drug release of 33.2 %, 40.1 % and 50.1 % at 5 min to 71.3 %, 74.02 %, and 96.0 % at the end of 35 and 30 mins, respectively. Formulations SD4 to SD6 containing PEG 6000 shows drug release of 48.1 %, 54.10 % and 60.02 % at 5 min to 93.23 %, 94.10 % and 98.16 % at the end of 35 and 30 mins, respectively. Drug release profile indicates that as drug: carrier PEG 6000 ratio increases from 1:1 to 1:5 ratio *In vitro* Drug Release profile is increases as compared to PEG 4000. By *in vitro* drug release study SD6 batch is optimized batch which shows 98.16% drug release in 30 mins. As listed in Table 12 and showed in Figures 6 and 7.

Table 12: *In vitro* drug release of Rosuvastatin calcium solid dispersions

Time (min)	Rosuvastatin calcium (%)	SD1 (%)	SD2 (%)	SD3 (%)	SD4 (%)	SD5 (%)	SD6 (%)
0	0	0	0	0	0	0	0
5	26.23 ± 1.25	33.2 ± 2.87	40.1 ± 1.69	50.1 ± 2.06	48.1 ± 2.86	54.10 ± 2.06	60.02 ± 1.63
10	39.16 ± 3.06	48.3 ± 3.26	51.0 ± 3.26	56.2± 3.26	50.0 ± 2.05	59.23 ± 1.70	68.32 ± 2.05
15	42.28 ± 3.26	51.0 ± 1.25	53.2 ± 2.05	68.1± 1.63	58.2 ± 3.26	65.02 ± 1.25	74.06 ± 3.51
20	49.09 ± 1.63	54.1 ± 2.27	60.0 ± 2.86	79.2 ± 2.87	71.0 ± 1.69	78.15 ± 3.27	85.28 ± 1.69
25	54.14 ± 2.86	59.2 ± 1.64	63.1 ± 1.24	89.1± 1.24	79.0 ± 2.04	86.28 ± 1.63	93.09 ± 2.86
30	56.32 ± 2.05	62.1 ± 3.05	69.3 ± 2.87	96.0± 1.69	83.1 ± 3.06	94.10 ± 2.87	98.16 ± 2.05
35	61.21 ± 1.25	71.3 ± 2.06	74.02 ± 2.1	-	93.23 ± 1.24	-	-

All values are expressed as mean ± SD; (n=6)

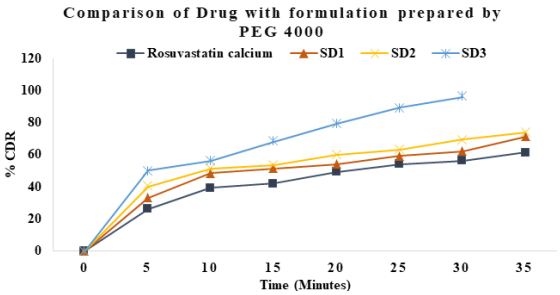

Figure 6: *In-vitro* drug release profiles of Pure drug, Batches SD1 to SD3

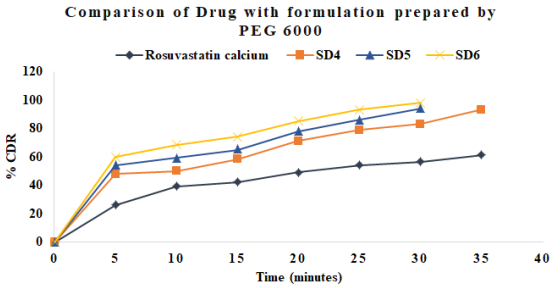

Figure 7: *In-vitro* drug release profiles of Pure drug, Batches SD4 to SD6

Stability studies:

As indicated in Table 13 and 14, the optimized batch underwent a month of stability testing and was determined to be stable in terms of solubility, drug content and *in vitro* drug release research.

Comparison study between the result of optimized batch and after time period of stability is graphically illustrated in Figure 8.

Table 13: Result of the stability study

Evaluation parameter	Results of optimized batch	Result after 1 month at 40 ± 2°C and 75 ± 5 % RH
Solubility (mg/ml)	2.54	2.51
Drug Content (%)	99.24	98.46

Table 14: *In Vitro* Drug Release study of Stability batch SD6

Time(min)	% CDR of Optimized Batch SD6 (Initial)	% CDR of SD6 after time period of 1 month
0	0	0
5	60.02±1.631	57.36±2.314
10	68.32±2.054	64.98±1.982
15	74.06±3.511	72.01±2.055
20	85.28±1.694	82.12±1.524
25	93.09±2.863	90.21±2.551
30	98.16±2.051	96.24±1.992

All values are expressed as mean ± SD; (n=6)

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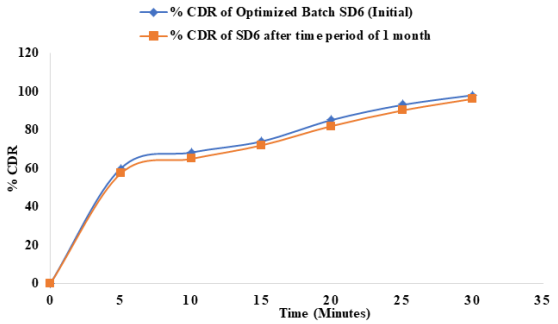

Figure 8: Comparison of *In vitro* drug release study of optimized batch initially and after stability period

CONCLUSION:

The present study demonstrates the successful preparation of Rosuvastatin calcium solid dispersion using the fusion method. Formulations SD1-SD3 were prepared using PEG 4000 as the carrier in drug-to-polymer ratios of 1:1, 1:3, and 1:5, while formulations SD4-SD6 were prepared using PEG 6000 in the same respective ratios. Compatibility studies carried out using FTIR spectroscopy confirmed the absence of any significant interaction between Rosuvastatin calcium and the selected excipients. All prepared formulations were subsequently evaluated for their flow properties, including Bulk density, Tapped density, Angle of repose, Compressibility index (Carr's index), and the results indicated satisfactory flow properties. On the basis of various parameters, batch SD6 containing Rosuvastatin calcium and PEG 6000 in a 1:5 ratio was identified as the optimized batch, as it increased drug solubility from 0.33 mg/ml (pure drug) to 2.54 mg/ml and achieved a % cumulative drug release of 98.16 % in 30 minutes among all other 6 batches of solid dispersions. Stability studies of the optimized batch SD6 showed no significant changes in parameters after one month of storage at 40° ± 2 °C and 75 ± 5% relative humidity. Overall, the study successfully developed a stable and effective formulation of solid dispersion of Rosuvastatin calcium.

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CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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