Research Article

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SOLUBILITY AND DISSOLUTION ENHANCEMENT OF ROSUVASTATIN CALCIUM BY USING HPMC & GUAR GUM POLYMERS AND FORMULATED INTO CAPSULE DOSAGE FORM

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Abstract

The main objective of the current study was to prepare the solid dispersions of Rosuvastatin calcium and created in the dose form of capsules with the combination of different polymers. Solid dispersions are prepared by fusion method by using combination of polymers in different concentrations such as HPMC and Guar gum. Solid dispersion technique will be selected as an efficient means for improving the solubility, dissolution rate and improves the bioavailability of water insoluble drugs. Solid dispersion of Rosuvastatin by the above mentioned method increases the dissolution rate of Rosuvastatin. These solid dispersions will be evaluated by parameters such as drug content, solubility, X-RD, percentage yield, DSC and in-vitro dissolution profile. The preparations are durable throughout a wide variety of storage settings, according to the stability research conducted in a stability chamber at both accelerated as well as intermediate circumstances, in accordance with ICH guideline Q1A.

***Keywords*:** Solid dispersions; Rosuvastatin; Guar Gum; Hydroxy propyl methyl cellulose Hyperlipidemia; Fusion method.

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Introduction

A collection of solid products made up of two or more distinct components, usually composed of a hydrophilic medium and a hydrophobic medicament, are referred to as solid dispersions. The medication may be distributed as crystalline, amorphous, or molecular particles (clusters) by melting or solvent method [1,2].

The term 'solubility' is defined as maximum amount of solute that can be dissolved in a given amount of solvent. It can also be defined quantitatively as well as qualitatively [3].

Solid dispersions would be prepared using HPMC and Guar Gum as carrier in different drug carrier ratio. Solvent evaporation method would be used for preparing formulations of such solid dispersions.[1]One statin drug used for treating abnormal lipids while avoiding cardiovascular illness in high-risk individuals is rosuvastatin, which is also marketed under the trade name Crestor. It is advised to be used in conjunction with exercise, dietary modifications, and weight loss. It is consumed orally. Rosuvastatin is primarily used to relieve abnormal levels of cholesterol and prevent cardiovascular illness in people at high risk.Rosuvastatin is a competitive inhibitor of HMG-CoA reductase. HMG-CoA reductase catalyzes the conversion of HMG-CoA to mevalonate, an early rate-limiting primarily in the liver [4].

The purpose of the present investigational study was to prepared solid dispersions of Rosuvastatin calcium with different polymers that increases the solubility and dissolution rate of the water insoluble drug and finally formulated into capsule dosage form.

Materials

Table 1: List of Chemical Used in the Research Work

S.No	Name	Manufacturer
1.	Rosuvastatin Calcium	Dr. Reddy pharmaceutical pvt. Ltd. Baddi
2.	Hydroxy propyl methyl cellulose(HPMC)	Signet Chemicals Pvt.Ltd., Mumbai
3.	Gum Guar	Loba ChemPvt. Ltd., Mumbai
4.	Ethanol	S.D. Fine Chem. Ltd., Mumbai
5.	Methanol	S.D. Fine Chem. Ltd.,

		Mumbai
6.	Disodium hydrogen phosphate	Nice Chem. Pvt. Ltd., Ambala
7.	Potassium dihydrogen phosphate	Nice Chem. Pvt. Ltd., Ambala
8.	Hydrochloric acid	E.Merck (India) Ltd., Mumbai
9.	Lactose	Loba ChemPvt. Ltd., Mumbai
10.	Magnesium Stereate	Central Drug House (P) Ltd., Mumbai
11.	Talc	Central Drug House (P) Ltd., Mumbai

Methods

Physical Appearance

Physical appearance of drug was examined by organoleptic properties like color, state, odour and taste. A white crystalline powder, odorless, tasteless powder and non-hygroscopic.

Melting Point Determination

The melting point of the drug (Rosuvastatin) was determined by capillary fusion method.

Infrared Spectral Assignment

The IR analysis of sample was carried out for qualitative compound identification. The infrared spectra of Rosuvastatin was performed on Fourier transformed infrared spectrophotometer.

Determination of Absorption Maxima (λ max)

A UV absorption maxima of the drug was determined by scanning (10µg/ml) solution of drug in methanol between 200-400nm.

Preparation of Calibration Curve [4,5]

Phosphate buffer (pH 6.8) is used as preparation for the calibration curve.

A little amount of methanol was employed as a cosolvent for dissolving 10 mg of rosuvastatin, which was subsequently mixed to create 100 milliliters of phosphate buffer (pH6.8). A stock solution containing 250µg/ml was created by diluting 50 ml of this solution into 100ml using phosphate buffer (pH 6.8). Aliquots of 2, 4, 6, 8, 10, and 12 were taken from this prepared solution and added to a volumetric flask of 10 ml using phosphate buffer to get the volume up to 10 ml. Utilizing phosphate buffer as a blank, the wavelength of absorption of the resulting solutions was determined at 239.5 nm.

The calibration graph is created in distilled water

Same procedure is as of aboveand 10 milliliters of distilled water were added to the capacity. With pure water as a blank, the wavelength of absorption of the resulting solutions was determined at 239 nm.

Preparation of Calibration Curve in 0.1N Hydrochloric acid (HCL)

Same procedure is as of above and volume was made up to 10ml with 0.1N Hydrochloric acid. The absorbance of these solutions was measured at 238nm using 0.1N HCL as blank.

Preparation of Calibration Curve in Methanol

Same procedure is as of above and volume was made up to 10ml with methanol. The absorbance of these solutions was measured at 238nm using methanol as blank.

Preparation of Physical Mixtures of Rosuvastatin

Physical mixtures of Rosuvastatin calcium were prepared by pulverization using Hydroxy propyl methyl cellulose and Guar gum and Hydroxy propyl methyl cellulose as a carrier in a different weight ratios. Firstly drug (Rosuvastatin calcium) and carrier (Hydroxy propyl methyl cellulose) was weighed and mixed by using mortar and pestle. Secondly drug (Rosuvastatin calcium) and carrier (Hydroxy propyl methyl cellulose and Guar Gum) was weighed and mixed by using mortar and pestle.Then both mixtures were passed through the sieve no. 60. The resulted product was stored in desiccators to carry out further analysis.

Table 2: Physical Mixtures composition of Rosuvastatin calcium -Hydroxy propyl methyl cellulose

Formulation code	Drug : Carrier weight ratio
ROSU 1	1:1
ROSU 2	1:3
ROSU 3	1:5

Table 3 : Physical Mixtures composition of Rosuvastatin calcium -Hydroxy propyl methyl cellulose and Guar Gum

Formulation code	Drug : Carrier weight ratio
ROSU 4	1:1
ROSU 5	1:3
ROSU 6	1:5

Preparation of Solid Dispersions of Rosuvastatin

Solid dispersion of rosuvastatin was prepared by Fusion Method& Solvent Evaporation Methods [2,6].

Characterization of Physical Mixtures And Solid Dispersion [7-10, 11-15]

Determining the Drug Content

Correctly measured solid dispersion solutions containing 10 mg of rosuvastatin were mixed in 10 milliliters of methanol. The resulting mixture went through filtering, appropriately diluted, and its drug content was determined using a UV Spectrophotometer at 238 nm.

Saturation solubility studies

The method of determining saturation solubility involved adding excess dispersed solids into water as well as biorelevant medium at 37°C ± 0.5°C, accordingly. The samples' wavelength was determined at 238 nm using an ultraviolet (UV) spectrophotometer, and the quantities in µg/ml were calculated.

Powder X-Ray Diffraction (XRD) Analysis

XRPD was used to examine the crystalline structure of samples by Cu-Kα radiation and a Bruker diffractometer (WI 1140, Japan). The diffractograms were recorded with a plot the pace of 2°/2 cm per 2θ angle and also ran at 2.5 °C min-1.

In vitro Drug Release

The USP dissolving apparatus II held 900 ml of dissolution media (6.8 phosphate buffer) that was mixed at a rate of 50 rpm at 37±0.5˚C with a precisely weighed dispersed solid equivalent to 10 mg of Rosuvastatin. At 10, 20, 30, 40, 50, and 60 minutes, 5 ml aliquots were removed and replaced with 5 ml of brand-new dissolving media (37˚C). The ultraviolet-visible spectrophotometer was used to assess the collected specimens at 239.5 nm in comparison to a blank, and the in vitro investigations for the pure medication were conducted in an identical way.

Fourier Transform Infrared (FTIR) Spectroscopy

FT-IR was used to characterize rosuvastatin and the solid dispersion in more detail. FTIR recording was performed on samples produced on KBr discs using an FTIR-8400S, CE (Shimadzu, Japan) apparatus (SEM). Data were gathered between 4000 and 400 cm-1 in the broad range.

Differential Scanning Calorimetry (DSC) Analysis

The following procedure was used to carry out a DSC for Rosuvastatin and solid dispersed in a nitrogen surroundings: the specimens were placed in an aluminum pan that was sealed tightly, and they were heated in the presence of a differential scanning calorimeter (Perkin Elmer, DSC-7, adjusted using indium) at a chart rate of 10mm min-1 over a temperature range of 160–280ºC at a scanning rate of 10º min-1.

Scanning Electron Microscopy

On an aluminum stump, a dual-sided sticky tape was affixed with a small amount of samples. Within an argon environment, the prongs were plated by platinum to a thickness of approximately 10 Å. The space inside inside the scanning electron microscope was filled with the stubs holding the plated specimens.

Formulation and Prepration of Capsule

The optimized solid dispersion were prepared by using the excipients as lactose, talc and magnesium stearate grinded in pestle and motor and mixed for 5 minutes and passed through sieve no. 60. The mixture filled into “0” size hard gelatin capsule shell by direct filling and 100mg capsule dosage form prepared.

Evaluation of Capsule Dosage Form [16]

General appearance

The capsule shell's appearance in general, distinguishing features, and "elegantness" were defined.

Weight variation

Measuring each unaffected capsule separately allowed us to run the weight variation test and calculate the mean weight. The differences between each unique net content and the average were calculated after these were averaged. The conditions for the exam were fulfilled: 1. In the event that more than two individual variances exceed 10% of the average; 2. In the event that the average variance exceeds 25%.

Disintegration test

Disintegration test equipment was used to calculate the experimental time required for breakdown. A disk might be added unless the capsule floats on the medium's surface. In this case, a disc was put in to every single of the six apparatus tubes, which are three inches long, opening at the top for ventilation, and held up against a ten-mesh screen at the base of the basket rack assembly. Every capsule was then inserted inside each of the six tubes. The basket rack arrangement was placed at 37°C/20°C in one liter of purified water. It was timed to see how long it took the capsule to fully break apart and go through the screen. Run the device for thirty minutes, unless instructed differently.

Content uniformity

Specific individual monographs carried out the task of maintaining content homogeneity. If nine out of ten have a strength within the limits of 85 to 115% as well as the last one is not beyond 75 to 125%, then the standards for the capsules are satisfied.

In-vitro dissolution test

Utilizing the rotary paddles technique, dissolution investigations were carried out on the filled capsule form of medication in a phosphate buffer solution with a pH of 6.8. 10 mg of rosuvastatin was incorporated to 900 cc of pH 6.8 phosphate buffer (100 rpm at 37±0.5oC) in capsule form. At various times, 10 ml of aliquots were removed, instantly filtered, and reintroduced with 10 ml of freshly made dissolving medium. The amount of medication released from the capsules (%DE60) and the amount contained of rosuvastatin was detected by spectroscopy at 239.5 nm for comparison with the pure drug [11,2,97].

Stability studies

In accordance with ICH recommendations, accelerated stability experiments were conducted on produced a solid mixture capsule formulations in amber-colored screw-capped containers. The samples were monitored for a month at 40±2oC and 75±5% RH. Stability chamber was used to store the capsules. After being withdrawn at each scheduled time for the first seven, fourteen, twenty-one, and thirty days, the samples were analyzed for in vitro dissolution tests, physical characterisation, and content homogeneity. The dissolution profiles were compared using the similarity factor (f2). The profiles of disintegration. When f2 falls between 50 and 100, the dissolution profiles are seen to be comparable. The dissolution patterns in the C1 preparation have been assessed utilizing a similarity factor (f2), and this is derived from what follows, prior to and following formula stability assessment.

$$f2 = 50 \log \{[1+\frac{1}{n}\sum_{t=1}^{n}(Rt - Tt)2]\text{-}0.5\ 100\}$$

Where, n is the dissolution time and Rj and Tj are the reference and test dissolution values at time t. (Morre Flamer equation).

Result (Tables& Graphs)

2. DSC

The DSC of the drug sample Rosuvastatin shows a sharp endothermic peak at 152.67oC .

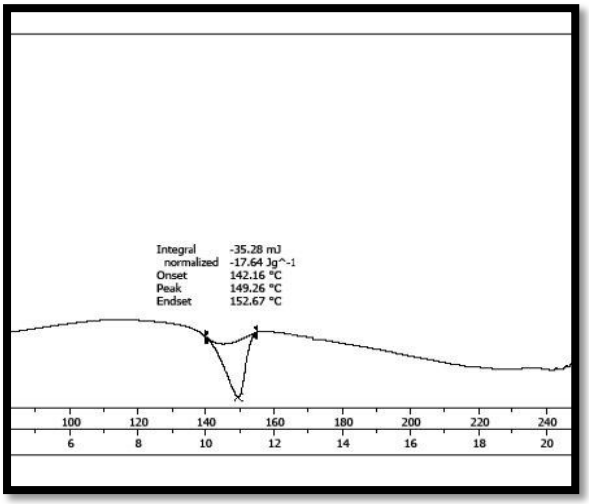


Figure 1 : DSC thermo gram of Rosuvastatin

3. FTIR

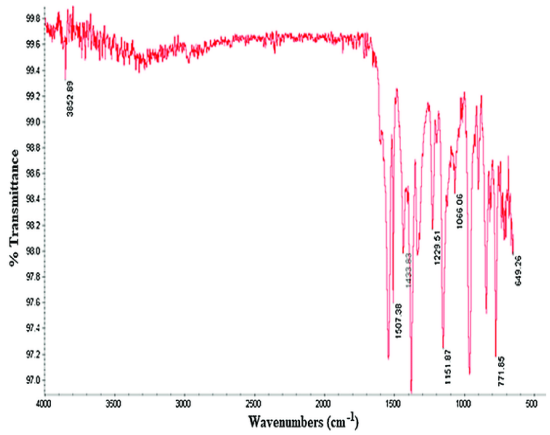


Figure 2: FTIR of Pure Rosuvastatin Calcium

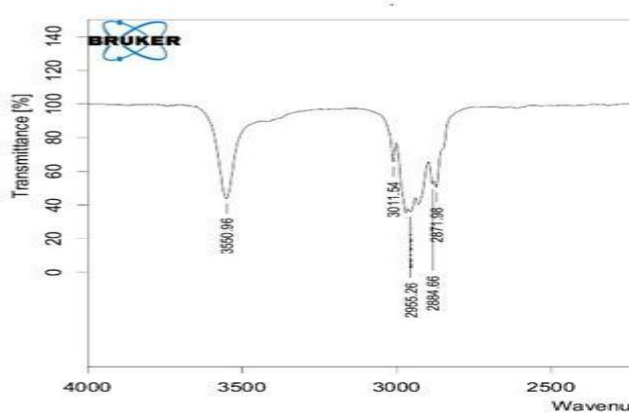


Figure 3: FTIR of Reference Rosuvastatin Calcium from BRUKER

Table 4 : Characterization of peak in FT-IR spectrum of pure Rosuvastatin

Functional groups	Observed Peaks (cm¯1)
O-H	3552.26
C-H	2932.24, 2958.12, 2876.31
C=O	1708.8
C-H	1466.32, 1388.28
C-O	1266.12

4. Absorption maxima (λ max) of drug:

Table 5: Observed Peaks of Rosuvastatin Calcium

Functional groups	Peaks(cm^{-1})
C≡N	2393.68
N-H	3396.66
C=O	1153.44,1228.44
C-H	1381.23,1438.94

Table 6: Absorption maxima (λmax) of the Rosuvastatin Calcium in different solvent

Solvent	(λmax)nm
Phosphate buffer	242nm
Water	241nm
Methanol	239nm

5. Solubility

Table 7: Solubility of Rosuvastatin Calcium in different solvents

Solvent	Solubility
Phosphate buffer	4.028±0.556
Water	1.648±0.328
Methanol	2.668±0.124

Data Expressed as mean ± S.D (n=3)

6. Drug Excipientcompatibility studies:

Table 8 : Drug Excipient Compatibility Study Data

	Week 1	Week 2	Week 3	Week 4
Drug + Polymer	-	-	-	3629.51,1800.08,1343.03, 1200.53, 1058.12
Drug, Polymer and Gum	-	-	-	3619.57, 2992.96, 1783.87, 1367.10, 869.27

7. Standard curves/ plot:

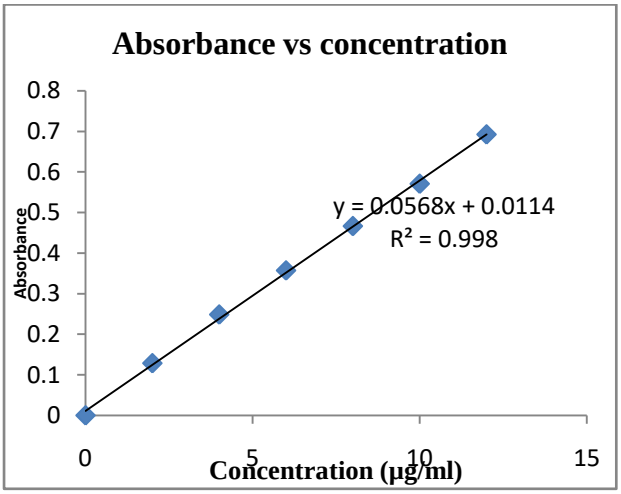


Figure 4: Standard plot of Rosuvastatin in Phosphate Buffer (pH6.8) at 239.5nm

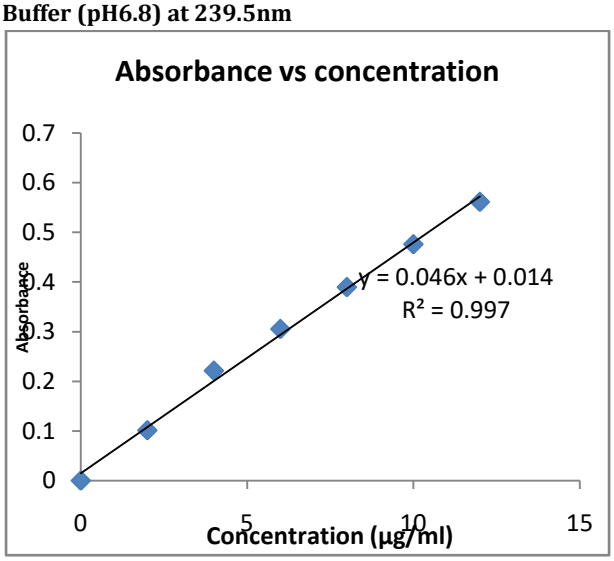


Figure 5: Standard plot of Rosuvastatin in Methanol at 238nm

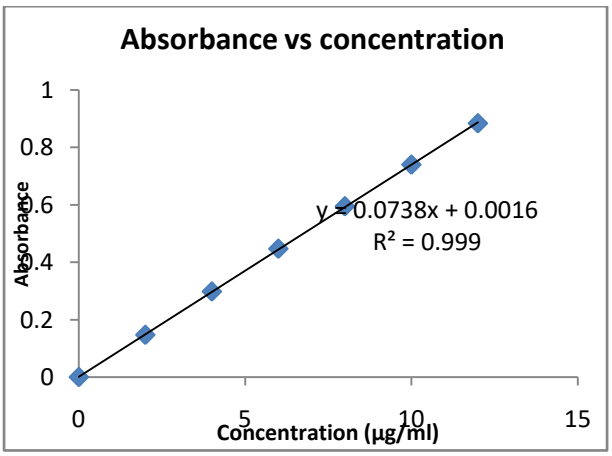


Figure 6: Standard Plot of Rosuvastatin in 0.1N HCL at 238nm

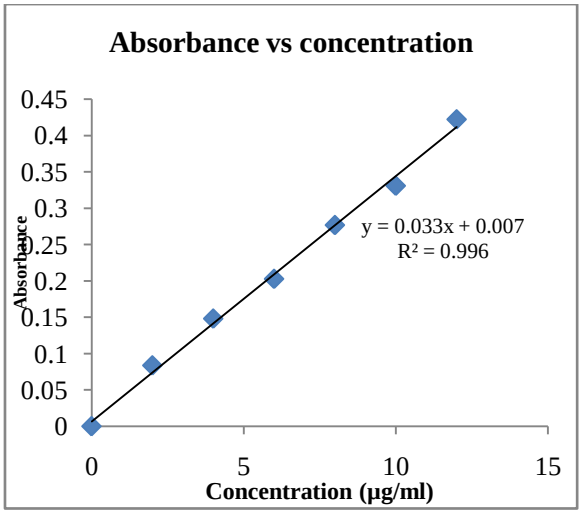


Figure 7: Standard plot of Rosuvastatin in Water at 239nm

Table 9: Characteristics of GumGuar and HPMC

Parameter	HPMC	GUM GUAR
Loss on drying	≥10.0%	≥15%
Apparent viscosity	75 to 140%	-
Swelling index	-	5.66±0.06
pH	5.0-8.0	4.5-5.0
Apparent density	0.25~0.70g/cm3	-
Surface tension	42 to 56 mN/m	44.8 mN/m

8. Percent yield and drug content

Table 10: Percentage yield and drug content of Solid dispersion of Rosuvastatinand HPMC

Formulation code	Percentage yield	Drug content
ROSU 1	93.18±0.76	91.36±0.02
ROSU 2	92.84±0.18	90.24±0.04
ROSU 3	90.32±0.54	92.24±0.06

Data are expressed as mean ± S.D. (n=3)

Table 11: Percentage yield and drug content of Solid dispersion of Rosuvastatin, HPMC and Gum Guar

Formulation code	Percentage yield	Drug content
ROSU 4	90.48±0.59	92.46±0.04
ROSU 5	87.16±0.25	96.23±0.05
ROSU 6	88.64±0.57	93.56±0.01

Data are expressed as mean ± S.D. (n=3)

9. Solubility study

Table 12: Solubility of pure drug and solid dispersion (Drug: HPMC)

Formulation code	Solubility(mg/ml)
Pure drug	3.956±0.58
ROSU 1	4.486±0.64
ROSU 2	6.458±0.02
ROSU 3	8.718±0.74

Data are expressed as mean ± S.D. (n=3)

Table 13 : Solubility of pure drug and solid dispersion (Drug: Guar Gum+HPMC)

Formulation code	Solubility(mg/ml)
Pure drug	3.968±0.58
ROSU 4	5.768±0.56
ROSU 5	6.763±0.58
ROSU 6	9.264±0.71

Data are expressed as mean ± S.D. (n=3)

10. Dissolution studies

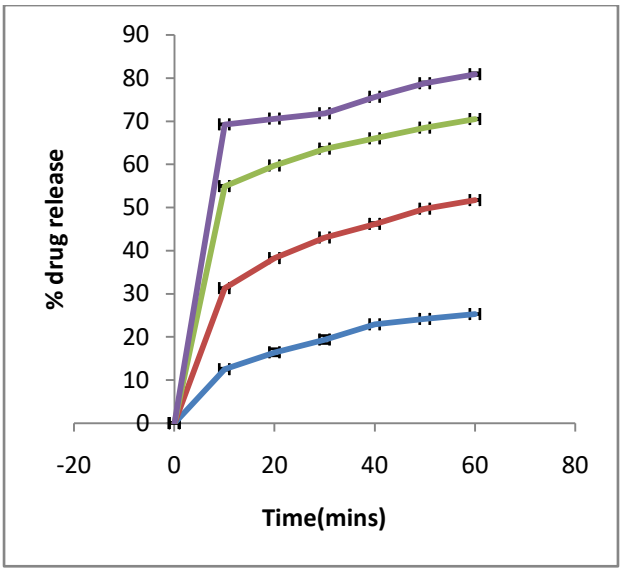


Figure 8: In vitro dissolution profile of %pure drug released vs time solid dispersions with HPMC

---------- Pure Drug
---------- ROSU 1
---------- ROSU2
---------- ROSU 3

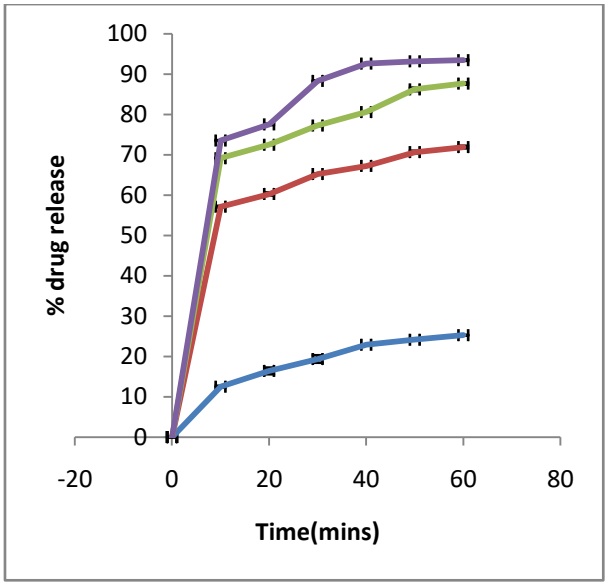


Figure 9: In vitro dissolution profile of %pure drug released vs time solid dispersions with HPMC and Guar Gum

---------- Pure Drug
---------- ROSU 4
---------- ROSU5
---------- ROSU 6

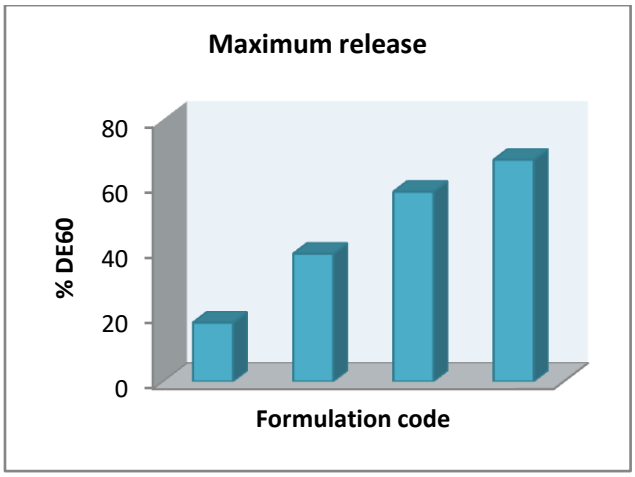


Figure 10: Comparison of %DE60 of pure drug and different formulations with HPMC (Pure Drug Vs. ROSU 1,ROSU 2,ROSU 3)

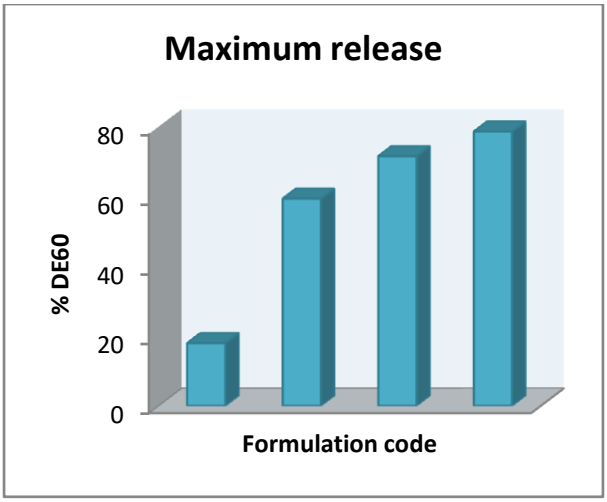
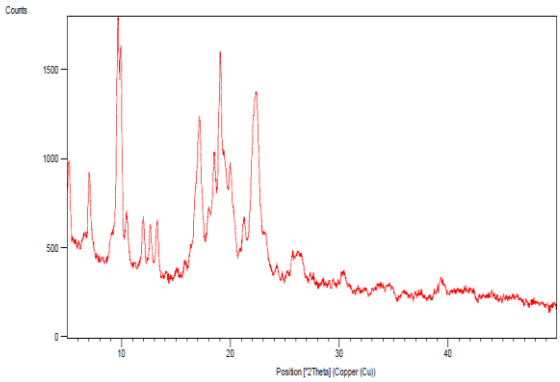


Figure 11:Comparison of %DE60 of pure drug and



different formulations with HPMC and Guar gum (Pure Drug Vs. ROSU 4,ROSU 5,ROSU 6)

Table 14: Dissolution efficiency and percentage yield of optimized formulations

Optimized formulations	%DE 60	%Yield
ROSU 6	78.64±1.22	88.68±0.58

11. Differential scanning calorimetry

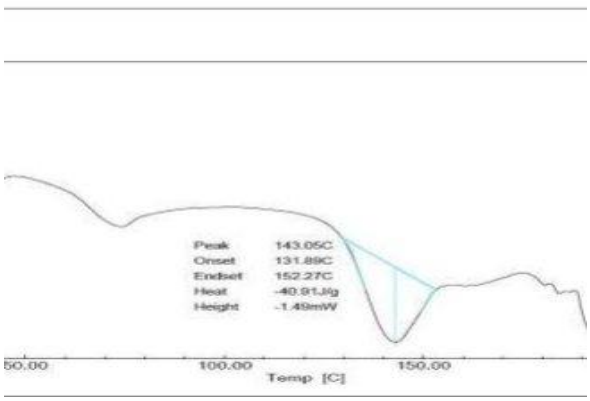
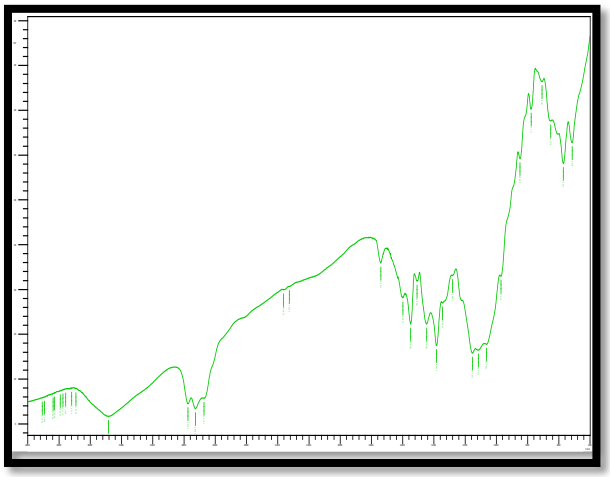


Figure 12: DSC Thermogram of optimized batch

12. Infrared spectroscopy

Figure 13:FTIR of Optimized batch



13. X-ray diffraction studies

Figure 14: XRD of optimized batch of Optimized batch

14. Scanning electron microscopy (SEM)

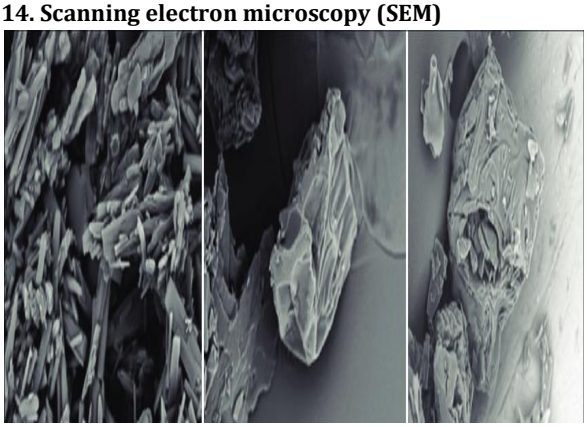


Figure 15: Scanning electron photomicrographs of Rosuvastatinoptimized solid dispersion at 250 X, 350 X& 500 X

15. Evaluation parameters

Table 15: Evaluation parameters of Capsule dosage form ROSUCAP with HPMC and Guar Gum

Formulation code ROSUCAP	Weight variation (mg)	Disintegration time (min)	Content uniformity
1	0.116±0.002	29	96.98 ± 0.08
2	0.108±0.006	26	98.22±0.08
3	0.108±0.004	27	99.68±0.08
4	0.106±0.006	32	99.96 ± 0.06
5	0.112±0.002	26	95.52±0.26
6	0.106±0.006	29	98.98±0.08
7	0.108±0.002	28	97.26±0.54

8	0.108±0.004	32	96.34±0.04
9	0.109±0.004	25	97.58 ± 0.04
10	0.104±0.002	28	96.92 ± 0.06

Data are expressed as mean ±S.D (n = 3)

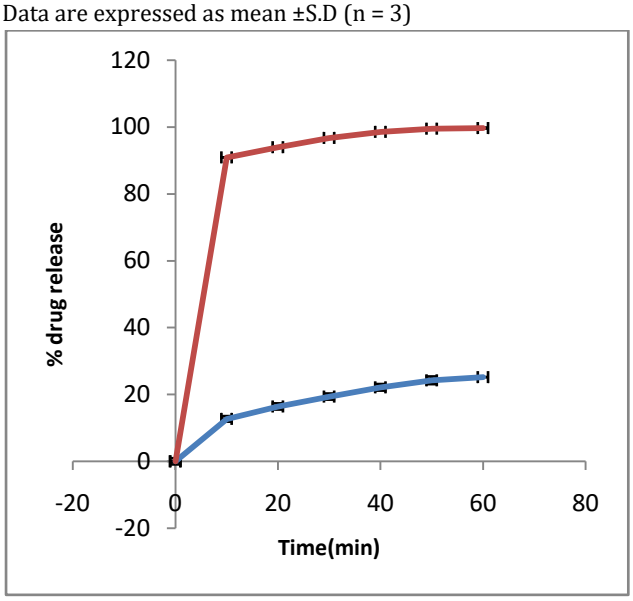


Figure16: In vitro dissolution profile of %drug released vs time of pure drug and Capsule dosage form

---------- Pure Drug

---------- ROSUCAP

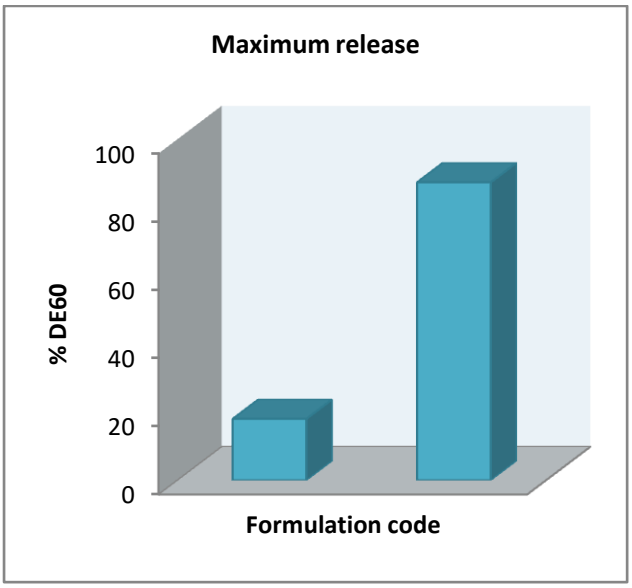


Figure17: Comparison of % DE60 with pure drug and capsules dosage formulations (Pure Drug vs. ROSUCAP)

Stability studies:

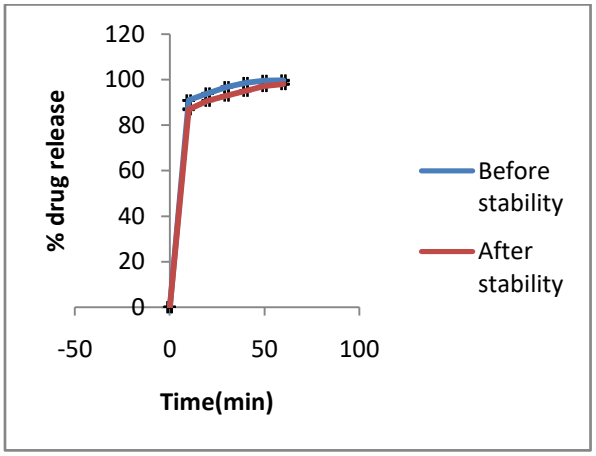


Figure 18: In vitro dissolution profile of %drug released vs time of pure drug and Capsule dosage forms ROSUCAP

Discussion

Physical Appearance And Melting Point

The drug was white in color and crystalline in nature. The Melting point was of the drug sample was found to be 135° to 138°C by Capillary method.

DSC

The DSC of the drug sample Rosuvastatin shows a sharp endothermic peak at 152.67oC that supports the purity and authenticity of the sample.

FTIR

The pure form of drug's FT-IR spectra have been observed to be comparable to Clarkes' analysis. IR spectra of pure drug were obtained, and no significant differences were found between the pure sample drug's and the reference spectrum's characterized absorption peaks.

Solubility: Solubility of the Rosuvastatin Calcium found to be higher in phosphate buffer as compared to other solvents.

Drug Excipient compatibility studies

Drug Excipient studies showed that there was no discoloration, liquefaction between drug and polymer. The FTIR spectra of Rosuvastatin Calcium and HPMC /GG physical mixture are shown below which indicate that Rosuvastatin compatible with the HPMC and GG.

Calibration curve

The standard curve of Rosuvastatin Calcium was found to be linear in the concentration range of 2-12 µg/ml in Phosphate buffer (pH 6.8), methanol, 0.1N HCl and water and obey Beer' s Lambert Law.

The percent yield and drug content

Because it was harder to sieve at greater concentrations of surfactants and polymers, the percentage yields dropped at higher concentrations.

Solubility study

Solubility of drug increased with increased in the ratio of polymer.

Dissolution studies

The presence of HPMC:GG increases the dissolution of Rosuvastatin Calcium from the solid dispersion, which increases the dissolution rate. It indicates that the solid dispersion (1:5) of Rosuvastatin Calcium: HPMC: GG gives fastest dissolution of drug as compared to other formulation.

DSC: The DSC curve for Rosuvastatin showed a sharp melting peak at 142.8oC corresponding to its melting indicates its crystalline nature.

IR SPECTROSCOPY

FTIR spectra of the physical mixture of drug and polymer showed no physical interaction between drug and the polymer used and revealed that both the drug and polymer are compatible with each other. The spectrum of solid dispersions exhibited significant decrease in intensity of O-H stretching vibrations which may be due to intermolecular2 hydrogen bonding.

X-ray diffraction studies

The reduced height of the peak area in the optimized dispersed solid peaks suggests that the crystal-like state of rosuvastatin calcium has decreased, since part of the medication has changed into an amorphous state in the solid dispersions..

SEM

Rosuvastatin was found to be an extremely crystallized substance with needle-shaped crystals. The medication was also found to be uniformly dispersed throughout the matrix of polymers of the polymer, and surfactant was found in the solid dispersions.

Stability Studies

During the test period at varied settings (40±2ºC and 75±5% RH), none of the three produced capsule dosage formulations preserved for stability tests exhibited a significant fluctuation in any of the metrics. In order to compare the dissolving profiles of capsule formulations prior to and following stability testing, the similarity factor was computed. For ROSUCAP, the f2 value was discovered to be 72.01. As a consequence, the produced capsule compositions' durability was validated by the stability study findings.

Conclusion

For the creation of solid dispersions, the melt and solvent evaporation methods were employed. The medicine rosuvastatin (BCS II) was chosen because of its poor solubility and high permeability. Solid dispersions were made to increase the drug's water solubility and rate of dissolution. Using the melt approach, the polymer, or HPMC, was added at various concentrations to create the solid dispersions in the ratios of 1:1, 1:3, and 5.

Guar gum was chosen as the carrier to increase the rate of dissolution, and solid dispersions of Rosuvastatin with polymer (HPMC) and Guar gum in the ratios of1:1,1:3, and 1:5 were created by employing the solvent evaporation technique for 30 minutes, respectively. In vitro drug release tests, drug content, % yield, and solubility of solid dispersions in phosphate buffer pH 6.8 were all evaluated for six formulations. Rosuvastatin dissolves more quickly when it is solidly dispersed using the previously described technique.

When the ratio of medication to carrier rose, the dissolution also increased. The percentage ratio of the area under the dissolution curve up to time t to the area of the rectangle defined by 100% dissolution at the same time was used to calculate the magnitude of %DE at 60 min (%DE60) for each formulation. Combination carriers have been employed recently, and there has been a reported larger increase in drug dissolution. Because it was harder to sieve at greater concentrations of surfactants and polymers, the percentage yields dropped at higher concentrations.

Low percent yield and drug content standard deviation data suggested that the medication was evenly distributed throughout all solid dispersions and that all formulations demonstrated consistency and repeatability in the outcomes attained.

The maximum percent yield and percent DE60 were obtained by optimizing the medication to polymer ratio and surfactant concentration. Using x-ray diffraction investigations and Fourier transform infrared spectroscopy, the optimum solid dispersions were created and characterized. There was no indication of a drug-carrier interaction seen in the FTIR experiments. The PXRD research verified the drug's amorphization.

The final capsule dosage form is prepared by filling the optimized solid dispersions into hard gelatin capsule shells containing talc, lactose, and magnesium sterate. The evaluation parameters of the final capsule dosage form include weight variation, content uniformity, disintegration test, and in vitro dissolution studies. After that, it was contrasted with the medication in its pure form, and after 60 minutes, it was discovered that the produced capsule dosage form had a higher dissolving efficiency.Before and after stability trials, the capsule dose form did not significantly alter.

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Conflicts of interests

There are no conflicts of interest.

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