IJBPAS, May, 2026, 15(5): 2442-2453

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

FORMULATION AND EVALUATION OF ROSUVASTATIN CALCIUM NANOPARTICLES

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Received 20th April 2025; Revised 25th May 2025; Accepted 6th Aug. 2025; Available online 1st May 2026

https://doi.org/10.31032/IJBPAS/2026/15.5.10203

ABSTRACT

The poor solubility of Rosuvastatin calcium affects its dissolution rate and, in turn, its bioavailability. The aim was to develop Rosuvastatin loaded nanoparticles and to evaluate it. The main aim of designing nanoparticles as a drug delivery system is due to reduction in particle size and thereby increases surface area, solubility and dissolution rate. The Rosuvastatin calcium nanoparticles were prepared by ionotropic gelation method. Chitosan, Gelatin and HPMC K4M were used as polymers in different concentration. FTIR studies revealed no interaction between drug and polymers. The prepared Rosuvastatin calcium nanoparticles were evaluated for Percentage yield, Entrapment efficiency and the in vitro release studies were performed. F3 formulation containing chitosan 150 mg shows the release of 98.09% in 8hrs was considered as optimum formulation. The optimized formulation (F3) was subjected to determine of particle size, polydispersity index, zeta potential and Scanning electron microscopy (SEM) studies. All the studies showed good results. The PDI for the optimized formulation of Rosuvastatin calcium nanoparticles is 0.402 which indicates a highly monodisperse sample with a very narrow size distribution. The optimized formulation of Rosuvastatin calcium nanoparticles (F3) has the zeta potential of -25.3 mV, the result suggest be that the optimized formulation was found to physically stable. The SEM images of Rosuvastatin calcium nanoparticles showed reduced crystallinity of drug.

Keywords: Rosuvastatin calcium, Nanoparticles, Chitosan, Zeta potential and Ionotropic gelation method

INTRODUCTION

Nanoparticles are tiny particles ranging from 1 to 100 nanometres in size, exhibiting unique properties due to quantum effects at the nanoscale. These properties, such as increased surface area, enhanced chemical reactivity, and unique optical or

mechanical behavior, differ significantly from those of bulk materials. Because of these characteristics, nanoparticles are highly valuable across various fields. In medicine, they are used for targeted drug delivery, helping to reduce side effects and improve treatment outcomes. In electronics, nanoparticles enable the creation of smaller, more efficient components like transistors, batteries, and solar cells. Their optical properties, especially in metals like gold and silver, make them ideal for use in sensors and imaging technologies **[1]**. Nanoparticles also vary widely in shape, size, and structure, and can be categorized as zero-dimensional (0D), one-dimensional (1D), two-dimensional (2D), or three-dimensional (3D) depending on their physical form. They can take shapes such as spheres, tubes, or cones, and have either smooth or irregular surfaces. Produced through various synthesis methods, nanoparticles are applied across sectors like healthcare, electronics, energy, and environmental science. Despite their advantages, there are concerns about the health and environmental risks associated with their use, as their small size allows them to interact with biological systems in unpredictable ways. Hence, ongoing research is focused on their safe and sustainable application. Notably, their high reactivity makes them effective in water treatment and pollution control **[2]**. Based on their composition, nanoparticles are generally classified into three categories: organic, carbon-based, and inorganic. Organic nanoparticles include materials made from proteins, lipids, carbohydrates, or polymers, such as liposomes, micelles, and dendrimers. These are biodegradable, non-toxic, and widely used in drug delivery and cancer treatment. Carbon-based nanoparticles, like fullerenes, carbon black, and carbon quantum dots, possess excellent electrical, thermal, and optical properties, making them useful in energy storage, bioimaging, and environmental sensing. Inorganic nanoparticles consist of metals, semiconductors, and ceramics **[3]**. Metal nanoparticles have unique optical and magnetic properties useful in medical and technological applications. Semiconductor nanoparticles are important in photocatalysis and electronics due to their tunable bandgaps, while ceramic nanoparticles are valued for their stability and are used in biomedicine, catalysis, and photonics **[4]**. Nanoparticles offer several advantages. Their high surface area increases reactivity and functionality, while their enhanced physical properties improve the performance of materials in various applications. They can be engineered for specific tasks, such as targeted drug delivery in medicine, and contribute to improved efficiency in electronics, catalysis, and energy systems. However, there are also notable disadvantages. Nanoparticles can

pose toxicity risks to humans and the environment, are sometimes difficult to dispose of safely, and may be costly to produce. Some types are unstable under certain conditions, and there is a lack of clear regulations to ensure their safe use **[5]**. The poor solubility of Rosuvastatin calcium affects its dissolution rate and, in turn, its bioavailability. The present aim was to develop Rosuvastatin loaded nanoparticles and to evaluate it. The main aim of designing nanoparticles as a drug delivery system is due to reduction in particle size and thereby increases surface area, solubility and dissolution rate **[6, 7]**.

MATERIALS AND METHODS

Rosuvastatin Calcium, (Aurobindo Pharma Ltd, HYD), HPMC K4M (SD Fine chemicals, Mumbai) Gelatin (Merck Specialities Pvt Ltd, Mumbai), Chitosan (Research-Lab Fine Chem Industry, Mumbai), Sodium tripolyphosphate (Research-Lab Fine Chem Industry, Mumbai), and Tween 80 (Aceto Pharma Pvt Ltd, Gujarat).

Methodology

Determination of Absorption Maxima of Rosuvastatin Calcium

Rosuvastatin calcium (100 mg) was weighed and dissolved in phosphate buffer pH 7.4 to prepare a 1000 µg/ml solution. A 2 ml sample was transferred to a 10 ml flask, diluted to 10 ml, resulting in a 20 µg/ml standard solution. The solution was scanned between 200-400 nm using a UV-visible spectrophotometer to determine the maximum absorption wavelength (λ max).

Preparation of for Rosuvastatin

100 mg of Rosuvastatin calcium was accurately weighed and transferred into a 100 ml standard flask and then volume was made up to 100 ml with phosphate buffer of pH 7.4 (Primary stock 1000µg/ml concentration). Pipette out 1 ml and transferred into 10ml standard flask and then diluted to 10 ml with phosphate buffer of pH 7.2 (Secondary stock 100µg/ml). Pipette out 0.5 ml, 1.0 ml, 1.5 ml, 2.0 ml and 2.5 ml from above solution and transferred into a 10 ml standard flask and then diluted to 10 ml with phosphate buffer of pH 7.4 to get 5 µg ml, 10 µg/ ml, 15 µg/ ml, 20 µg/ ml and 25 µg/ ml. Absorbance of the prepared solutions was determined spectro-photometrically at 243 nm. Phosphate buffer of pH 7.4 was used as blank solution.

FTIR Study

The drug and polymer must be compatible with one another to produce a stable product. Drug and polymer interactions were studied by using FTIR. IR spectral analysis of pure rosuvastatin, rosuvastatin with polymers was carried out. The peaks produced by the pure drug were compared with combination of polymer and pure drug **[8]**.

Preparation of Rosuvastatin calcium nanoparticles

Rosuvastatin calcium nanoparticles were formulated using the ionotropic gelation method. Initially, the polymer solution was prepared in 2% (v/v) glacial acetic acid and left undisturbed overnight to stabilize. A 0.2% (w/v) tripolyphosphate (TPP) solution was prepared in distilled water. Rosuvastatin calcium (50 mg) was dissolved in an ethanol/water mixture (1:1 v/v) containing 1 ml of Tween 80. The nanoparticles were formulated by stirring the 1% (w/v) polymer in a clean beaker on a hot plate using a magnetic bead at a constant speed of 2000 rpm at 60°C for 90 minutes. During the formulation process, Rosuvastatin calcium (0.1%, w/v) and 0.2% (w/v) TPP were added at predetermined time intervals using a syringe with a needle size of 0.45 mm. The nanoparticles were then collected by centrifugation **[9, 12]**.

Table 1: Composition of different formulations of Rosuvastatin calcium nanoparticles

Ingredients (mg)	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Rosuvastatin calcium	50	50	50	50	50	50	50	50	50
Chitosan	50	100	150	-	-	-	-	-	-
Gelatin	-	-	-	50	100	150	-	-	-
HPMC K4M	-	-	-	-	-	-	50	100	150
Glacial Acetic Acid (ml, 2% v/v)	30	30	30	30	30	30	30	30	30
Sodium tripolyphosphate	20	20	20	20	20	20	20	20	20
Tween 80(ml)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

Evaluation of Nanoparticles

Percentage Yield

Fixed volumes of Rosuvastatin calcium nanosuspension were centrifuged at 9000 rpm for 30 min at 15 °C. The obtained sediment was dried and weighed. The percentage yield was calculated by below formula **[10]**.

$$\% \, Yield = \frac{Actual \, Yield}{Theoretical \, Yield} \times 100\%$$

Entrapment Efficiency

The Entrapment efficiency of nanoparticles was determined by the separation of drug loaded Nanoparticles from the aqueous medium containing non-associated Rosuvastatin calcium by ultracentrifugation at 12,000 rpm at 4 °C for 1 hr. The quantity of rosuvastatin calcium loaded into the nanoparticles was calculated as the difference between the total amount used to prepare the nanoparticles and also the amount that was found within the supernatant. The quantity of free rosuvastatin calcium within the supernatant was measured by UV Spectrophotometer. Entrapment efficiency was then calculated as follows; Entrapment efficiency was calculated by **[11]**.

$$\mathbf{EE} = \frac{\mathbf{Total\ amount\ of\ drug - non\ bound\ drug}}{\mathbf{Total\ amount\ of\ drug\ added}} \times \mathbf{100}$$

In-Vitro analysis

The in vitro release study was performed using a dialysis membrane (HiMedia). An appropriate amount of nanoparticles was taken containing a drug equivalent to 10 mg in the dialysis bag and sealed at both ends. A dialysis bag is placed in the receptor chamber (beaker) containing 100ml of phosphate buffer pH 7. 4. The temperature was maintained at 37°C±2°C and was magnetically stirred at 100rpm. Samples were taken from the receptor chamber at regular intervals time from the receptor chamber (beaker) and replaced with an equal amount of the fresh phosphate buffer solution to maintain the sink condition. Sampling was determined by a UV spectrophotometer (LABINDIA) at243nm. All experiments were conducted in 3 times. The graph was drawn between the percentage cumulative of drug release versus time (hours).The results obtained from the in vitro release studies in nanoparticles have been fit into many kinetic equations such as zero order (percentage cumulative release vs. time), the first order (log percentage remaining vs. time), Higuchi (cumulative release of drugs vs. square), and Korsmeyer Peppas (log cumulative percentage drug release vs. log time). The correlation coefficients (R) and K were determined **[12]**.

Determination of particle size and polydispersity index

The particle size of the formulation was determined by photo correlation spectroscopy with a zeta master (Malvern Instruments, UK) equipped with the Malvern PCS software. Determining the Polydispersity Index (PDI) is a critical process in characterizing materials like nanoparticles. Polydispersity index is a parameter to define the particle size distribution of nanoparticles obtained from photon correlation spectroscopic analysis. It is a dimensionless number extrapolated from the autocorrelation function and ranges from a value of 0.01 for mono dispersed particles and up to values of 0.5-0.7. Samples with very broad size distribution have polydispersity index values > 0.7 **[13]**.

Zeta potential

The surface charge (Zeta potential) was determined by measuring the electrophoretic mobility of the nanoparticles using a Malvern zeta sizer (Malvern Instruments, UK) **[14]**.

Scanning electron Microscopy

Scanning electron microscopy was used to characterize the particle morphology of the unprocessed drug as well as the fabricated

drug nanoparticles. A small fraction of each drug powder sample was fixed on a double-sided conductive carbon tape and sputtercoated with 5 nanometers of a Pt–Pd alloy. Micrographs were obtained on a Zeiss Field Emission Gun Scanning Electron Microscope (Carl Zeiss AG, Germany) **[15]**.

RESULTS AND DISCUSSION

The maximum absorption (λ_{max}) was found to be 243 nm from UV spectrum of Rosuvastatin calcium. In the present study, analytical method obeyed the Beer-lamberts law in the concentration range of 5-25 µg/ml and was suitable for the estimation of Rosuvastatin calcium using phosphate buffer of pH 7.4. The value of r (correlation coefficient) for the linear regression equation was found to be more than 0.99 which indicates a positive correlation between the concentration of drug and the corresponding absorbance values **(Figure 1, 2)**.

Drug- excipient compatibility investigations

FT-IR spectra of Rosuvastatin calcium and Rosuvastatin calcium with Polymers were given in **Table 2**. Pure Rosuvastatin showed principal absorption peaks at 962.22 cm^{-1}(O-H Bending), 1150.69 cm^{-1} (C-F stretching), 1544.68 cm^{-1} (C=C stretching), 3369.90 cm^{-1} (N-H stretching) and 3563.30 cm^{-1} (O-H stretching). The identical peaks of O-H Bending, C-F stretching, C=C stretching, N-H stretching and O-H stretching vibrations were also noticed in the spectra of drug with polymers. FT-IR spectra revealed that there was no interaction between the drug and the polymers used for Nanoparticles formulation.

Percentage yield was found to be 71.58 % to 91.95 % for formulation F1 to F9 as shown in **Table 3**. Percentage practical yield depends on the concentration of polymer added, as the concentration of polymer increases, there is increases in the % yield. Highest % yield obtained is 91.95% for formulation F3. The entrapment efficiency of the nanoparticles was found to vary between 76.82±0.55 to 91.02±0.11, which are shown in **Table 3**. Formulation F3 shows 91.02±0.11 maximum entrapment efficiency. The entrapment efficiency depends on the polymer concentration, so that sufficient quantity of polymer will be available to entrap the drug. Results shown in the **Table 3** revealed there was no significant loss of the drug during the preparation and all the formulations exhibited fairly uniform drug entrapment.

All the formulations except F4, F5 and F7 showed sustained release up to 6hrs. This may be due to less concentration of polymer. The developed nanoparticles can be used as an important platform for sustained drug release which would contribute to lower dosing frequency. The formulations shows the biphasic releasing pattern with an initial burst or abrupt release of the drug followed

early few hours and later sustained release. The dissolution of the formulations showed cumulative increase in drug release with increase in polymer concentration. From the results it was revealed that Rosuvastatin calcium nanoparticles prepared with chitosan (F3) showed better drug release than Rosuvastatin calcium nanoparticles prepared with gelatin and HPMC K4M because of the interaction between the negatively charged of the sodium tripolyphosphate (STPP) and the positively charged amino groups of chitosan **(Table 4)**.

Particle size and Polydispersity index

The particle size of optimized formulation (F3) is 130.9 nm. From the above data it is clear that nanoparticles prepared by using chitosan exhibited reduction in mean nanoparticulate diameter. The Polydispersity Index (PDI) is a measure of the particle size distribution in a sample, specifically for nanoparticles, and indicates the degree of uniformity or homogeneity of the sample. A PDI value closer to 0 suggests a narrow, more uniform distribution, while a higher PDI value indicates a broader, more heterogeneous distribution. The PDI for the optimized formulation of Rosuvastatin calcium nanoparticles is 0.204 which indicates a highly monodisperse sample with a very narrow size distribution **(Figure 3)**.

Zeta potential

The zeta potential provides the essential information in finding the physical stability of nanoparticles. The zeta potential higher than + 30 mV or lower than – 30mV are found to have acceptable stability. Particles having large zeta potential possess repulsive forces which makes the particles to prevent aggregation. The optimized formulation of Rosuvastatin calcium nanoparticles (F3) has the zeta potential of -25.3 mV, the result suggest that the optimized formulation was found to be physically stable. Drug leakage can be prevented in nanoparticles that are physical stable, so that formulated carrier show better efficacy and activity **(Figure 4)**.

Scanning electron microscopy

The surface morphology was evaluated using scanning electron microscopy. The data exhibited from the SEM of Rosuvastatin calcium pure drug consisted of a mixture of large crystals, indicating its crystalline nature. The SEM image of Rosuvastatin calcium NPs appeared as smooth-surfaced, and irregularly shaped. However, the prepared Rosuvastatin calcium-loaded chitosan NP's of batch F3 had no drug crystals were present, which were shown in SEM images **(Figure 6)**.

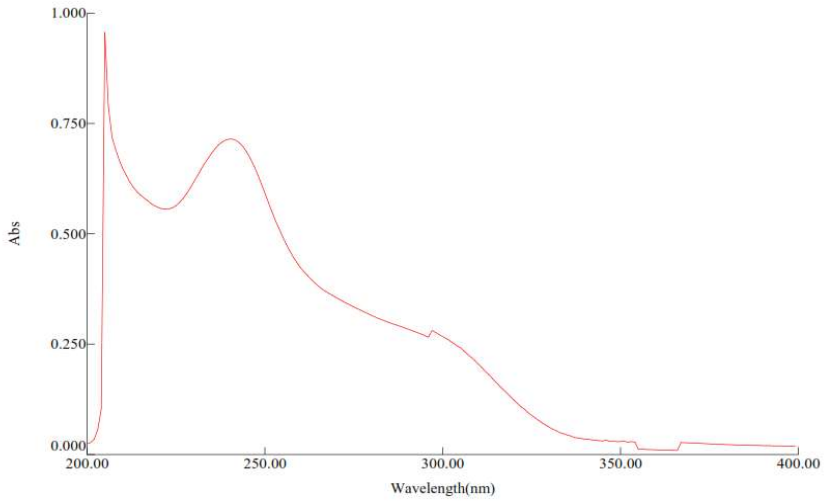

Figure 1: Absorption maxima of Rosuvastatin calcium

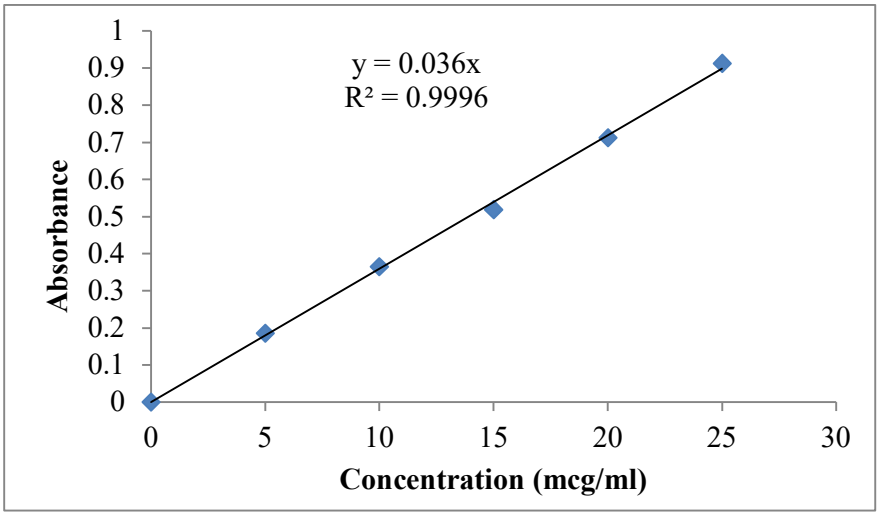

Figure 2: Standard curve of Rosuvastatin calcium using phosphate buffer of pH 7.4

Table 2: FT-IR interpretations of pure drug (Rosuvastatin calcium) and excipients

Functional group	Characteristic Peaks	Observed peaks			
		Rosuvastatin calcium	Rosuvastatin : Chitosan	Rosuvastatin : Gelatin	Rosuvastatin : HPMC K4M
O-H (stretching)	3600-3200 cm^{-1}	3563.30	3564.07	3565.38	3564.07
N-H (stretching)	3500-3300 cm^{-1}	3369.90	3369.39	3369.64	3369.90
C=C (stretching)	1700-1500 cm^{-1}	1544.68	1546.42	1545.66	1544.07
C-F (stretching)	1400-1000 cm^{-1}	1150.69	1152.22	1151.42	1149.93
O-H (bending)	970-910 cm^{-1}	962.22	963.27	962.31	961.94

Table 3: Percentage Yield of Rosuvastatin calcium nanoparticles

Formulation code	Percentage Yield	Entrapment Efficiency
F1	75.42	80.94 ± 0.11
F2	84.65	85.03 ± 0.17
F3	91.95	91.02 ± 0.11
F4	72.92	76.82 ± 0.55
F5	78.12	79.92 ± 0.28
F6	88.41	84.56 ± 0.22
F7	71.58	78.97 ± 0.29
F8	80.53	81.82 ± 0.33
F9	88.59	87.84 ± 0.22

n= 3

Table 4: Comparative dissolution data of Rosuvastatin calcium nanoparticles

S. No.	Time (hrs)	% Cumulative drug release (mean± S.D.)								
		Formulation containing chitosan			Formulation containing gelatin			Formulation containing HPMC K4M		
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0.5	19.94±0.42	16.98±0.28	13.88±0.42	24.47±0.28	21.93±0.79	20.31±0.37	20.63±0.94	20.36±0.35	16.98±0.28
2	1	30.58±0.28	28.08±0.28	26.00±0.42	40.15±0.50	38.72±0.42	30.72±0.50	37.98±1.12	30.72±0.50	28.45±0.64
3	2	40.98±0.37	38.72±0.42	34.14±0.49	67.25±0.16	61.01±0.63	41.44±0.79	60.27±0.69	41.26±0.77	38.90±0.28
4	3	52.68±0.58	46.58±0.42	43.62±0.73	81.12±0.35	72.71±0.49	53.05±0.73	71.78±1.23	52.77±0.73	46.81±0.24
5	4	66.74±0.29	61.15±0.66	58.00±0.45	96.48±0.37	86.95±0.81	67.34±0.60	86.02±1.61	66.97±0.68	61.51±1.05
6	5	81.08±0.73	71.74±0.58	69.15±0.24		94.95±0.73	81.26±0.66	94.35±0.76	81.03±0.66	72.01±0.85
7	6	95.23±0.50	85.98±0.16	75.94±2.77			96.15±0.92		95.50±0.97	86.16±0.42
8	7		96.06±0.28	88.71±0.64						97.03±0.64
9	8			98.09±0.29						

n= 3

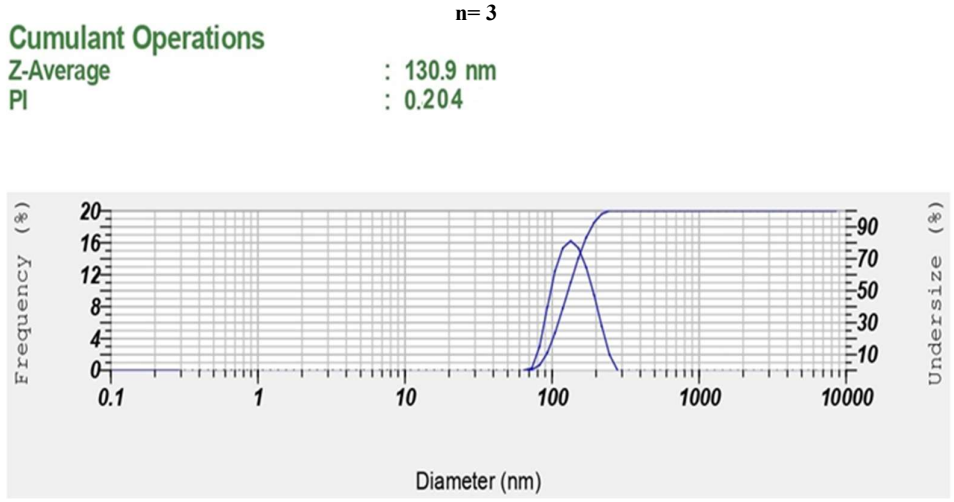

Figure 3: Particle size and Polydispersity index of Rosuvastatin calcium nanoparticles optimized formulation (F3)

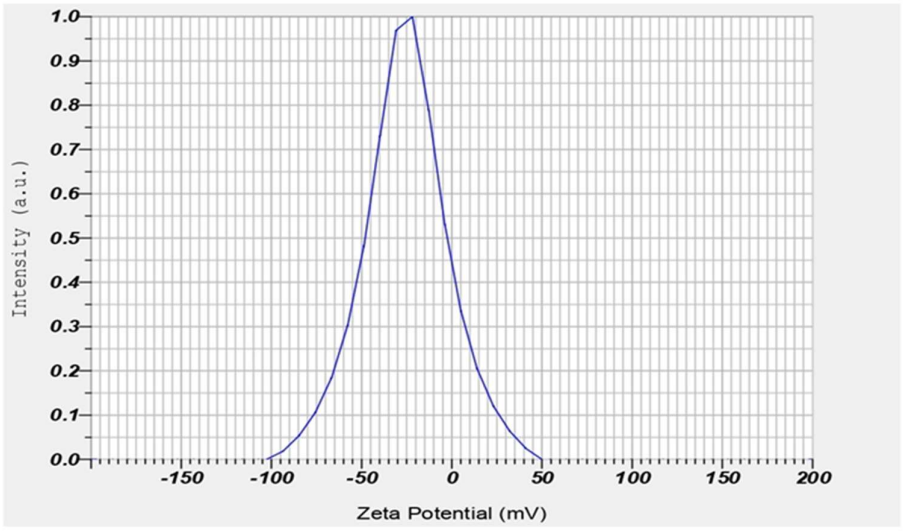

Figure 4: Zeta potential of Rosuvastatin calcium nanoparticles optimized formulation (F3)

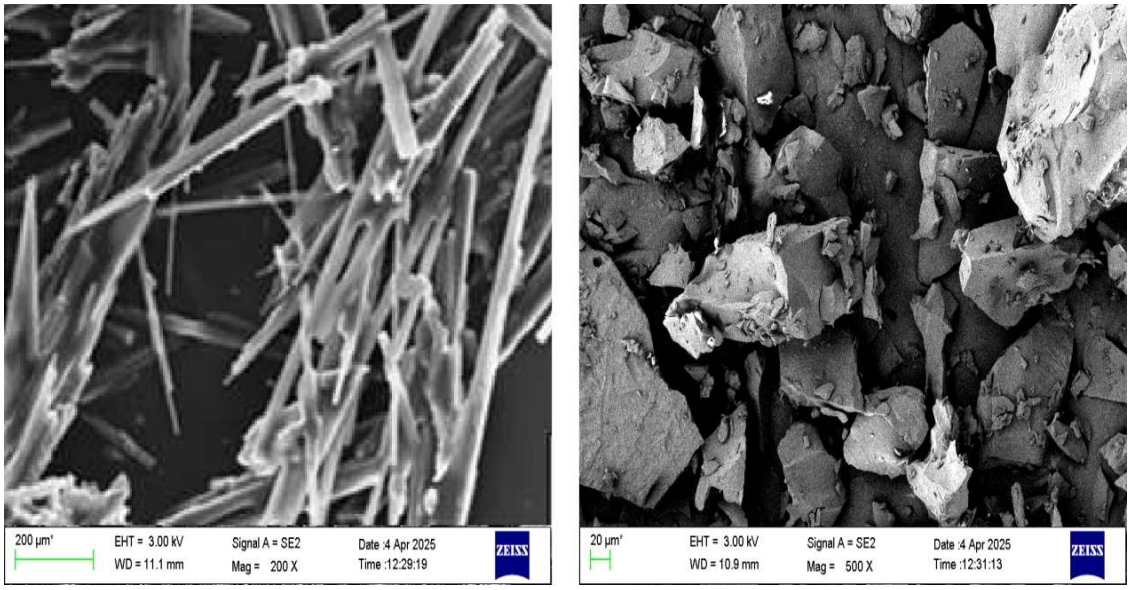

Figure 5: SEM image of Rosuvastatin calcium

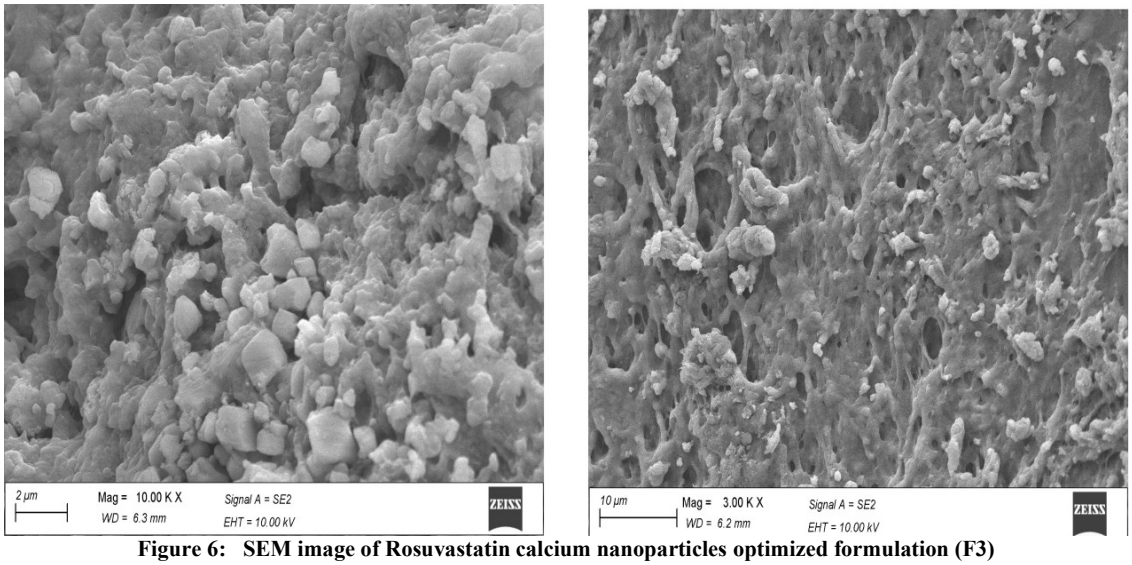

Figure 6: SEM image of Rosuvastatin calcium nanoparticles optimized formulation (F3)

CONCLUSION

The Rosuvastatin calcium nanoparticles were prepared by ionotropic gelation method. Chitosan, Gelatin and HPMC K4M were used as polymers in different concentration. Tween 80 is used as solubilizer. The prepared Rosuvastatin calcium nanoparticles were evaluated for Percentage yield, Entrapment efficiency and the in vitro release studies were performed. F3 formulation containing chitosan 150 mg shows the release of 98.09% in 8hrs was considered as optimum formulation. FTIR studies revealed no interaction between drug and polymers. The optimized formulation (F3) was subjected to determine of particle size, polydispersity index, zeta potential and

Scanning electron microscopy (SEM) studies. All the studies showed good results.

REFERENCES

[1] Konwar Ranjit and Ahmed Abdul Baquee, Nanoparticle: an over review of preparation, characterization and application, Journal of pharmacy, 4(4), 2013, 1 to 11.

[2] Khadijah A. Altammar, A review on nanoparticles: characteristics, synthesis, applications, and challenges. Journal of microbiology, 14(3), 2023, 1 to 20.

[3] Satoshi Horikoshi, Introduction to Nanoparticles. Journal of microwave technology. oct; 139(45), 2022, 1 to 24.

[4] Sushila Kaura, Pros and Cons of Nanotechnology, International journal of scientific research, 1(7), 2023, 1 to 22.

[5] Khaji Mohammad Anees, Ch. Lalitha, Angilicam Avinash, Dr. M. Sreenivasulu. A Comprahensive Review on Nanotechnology. International Journal of Chemistry and Pharmaceutical Sciences. 2016, 4(12):692–696.

[6] Aziz M, Pathogenesis of Atherosclerosis, Journal of medical and clinical med. review. 2016; 2(3); 1 to 6.

[7] Peter Libby, Targeting Inflammation in Atherosclerosis: The Role of Anti-inflammatory Medications. 2019; 16(5); 316-327.

[8] S.Madhu & M. Komala & P. Pandian, Formulation Development and Characterization of Withaferin-A Loaded Polymeric Nanoparticles for Alzheimer's Disease, Bio Nano Science, 2020.

[9] Muhammad Abdullah, Azra Rafiq, Nariman Shahid, Muhammad Nasir Kalam, Yusra Munir, Muhammad Daoud Butt and Hamid Saeed. Synthesis, characterization and in-vitro cytotoxic potential of sitagliptin phosphate nanoparticles against advanced breast cancer cell line - MCF-7.2023; 36(6); 1849-1858.

[10] Angilicam Avinash, Rajesh Kaza. Design and Characterization of Atenolol Floating Microcapsules. International Journal of Pharmaceutical Research, 2016; 8(1):20-24.

[11] Suvarna G. Bhokare, Rajendra P. Marathe, Rosuvastatin loaded chitosan nanoparticles: preparation evaluation and in vitro release studies, International Journal of Applied Pharmaceutics, 12(5), 2020, 95-102.

[12] Harjeet Singh, Ram Dayal Gupta and Girendra Gautam, Formulation Development, Characterization, and In Vitro-In Vivo Study of Antihyperlipidemic Drug Rosuvastatin Calcium - Solid Lipid Nanoparticles, Asian Journal of Pharmaceutical and Clinical Research, 11(7), 2018, 436-443.

[13] Surendranath Betala, M. Mohan Varma, K. Abbulu, Formulation and evaluation of polymeric nanoparticles of an

antihypetensive drug for gastroretention, Journal of Drug Delivery & Therapeutics, 8(6), 2018, 82-86.

[14] Gautham U., Anasuya Patil, Hemanth G. Formulation and Evaluation of Nanoparticle Drug Delivery System for Treatment of Hypertension. International Journal of Applied Pharmaceutics, 15(6), 2023, 90-97.

[15] V. Swapna, K. Siva Divya, NB. Pati, B. Ravindra Babu and A. Lakshmana Rao, Preparation and Evaluation of Lamivudine Nanoparticles, International Journal of Research in Pharmacy and Chemistry, 9(3), 2019, 154-160.