Research Article

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Solid dispersion preparation by different methods to improve solubility & dissolution simvastatin

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Abstract

The improvement of a pure drug's solubility and dissolution rate in the treatment of hyperlipidemia. Simvastatin is a 5-percent absolute bioavailability selective competitive inhibitor of HMG Co-A reductase. For the selection of the carrier, a preliminary solubility investigation of solid dispersion was performed, and solid dispersion was made using Hydroxy Propyl Methyl Cellulose (HPMC) and gum acacia. Solid dispersion of medication with polymer was created and studied for solubility and in-vitro dissolution profile. Solid dispersion of drug with polymer has shown an increase in solubility and improved dissolution rate. On the obtained formulations, further FTIR, X-Ray, Scanning electron microscopy, and Differential scanning calorimetry experiments were conducted. The existence of amorphous form in a solid dispersion made with polymer in a 1:5 ratio is verified by characterization research. The research also showed that using a solid dispersion approach with Polymer, the dissolving rate of a pure medication may be significantly increased.

Keywords: Simvastatin, Hydroxy Propyl Methyl Cellulose, gum acacia, Solubility, Dissolution rate.

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Introduction

The novel chemical entities have a high permeability and are absorbed in the upper small intestine, but absorption drops dramatically beyond the ileum, indicating a short absorption window. Furthermore, these medications have limited bioavailability, solubility, dissolution, and absorption rates in this part of the gastrointestinal system. Inadequate bioavailability is commonly caused by the poor dissolution rate and solubility of medicinal compounds in water in aqueous G.I.T fluid. Various strategies for improving the dissolution rate of medications that are poorly water soluble have been documented. Solid dispersions are defined as molecular mixtures of poorly water soluble drugs in hydrophilic carriers that present a drug release profile that is driven by the polymer properties, and are one of the most successful methodologies for improving drug release and dissolution rate of water insoluble drugs. One of the ways is dispersion, which involves integrating the medication into a hydrophilic carrier material to produce solid dispersions. Simvastatin (BCS II medication) comes in the shape of a white crystalline powder (1S,3R,7S,8S,8aR) -1,2,3,7,8,8a–hexahydro–3,7–dimethyl–8 -[2-[(2R,4R)-tetrahydro–4–hydroxy–6–oxo–2H-pyran–2yl]ethyl] -1–naphthalenyl ester is a kind of naphthalenyl ester. SMS, an inert lactone, is hydrolyzed to the equivalent -hydroxyacid form after oral intake. This is a major metabolite and inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme-A (HMG Co-A) reductase, which catalyses an early and rate-limiting step in cholesterol production. It's a hypolipidemic medicine that works by inhibiting HMG-CoA reductase. It's used to treat hypercholesterolemia, dyslipidemia, and coronary heart disease. HPMC (1-6-hydroxypropyl methyl ether) is a 2-hydroxypropyl methyl ether that is soluble in ethanol, methanol, and propanol. Methyl

Cellulose (MC) is a Methyl Ether of Cellulose that is soluble in water, glacial acetic acid, and both of these polymers are used to improve the dissolving rate of water insoluble drugs. Gum Acaia is a white or yellowish-white thin flakes, spheroidal tears, granules, and powder that is utilised as a viscosity agent, suspending agent, emulsifying agent, and tablet binder. Water, glycerin, and propylene glycol are all extremely soluble in it [7].

Material & Methods

Materials

Dr. Reddys' Pharmaceuticals Ltd. in Hyderabad provided the Simvastatin gift sample. Signet Chemicals Pvt. Ltd and Loba Chem Pvt. Ltd Mumbai provided the hydroxy propyl methyl cellulose (HPMC) and gum acaia polymers. The remaining chemicals were acquired from Loba Chemicals in Mumbai, India, and include ethanol, methanol, magnesium state, talc, lactose, disodium hydrogen orthophosphate, and potassium dihydrogen orthophosphate.

Methods

Physiochemical Characterisation of Pure Drug

To confirm the legitimacy of the medicine sample (Simvastatin), several methods such as colour, odour, and texture were used to examine it.

Determine the Solubility of Pure Drug by using UV Spectroscopic Method

Determination Absorption Maxima of the Drug (λ_{max})

The medication's UV absorption maximum was established by scanning a 10g/ml methanol solution of the drug between 200 and 400nm.

Determine the Solubility of Pure Drug by using UV Spectroscopic Method

Simvastatin solubility tests were performed in a variety of solvent systems. In screw-capped vials, the extra medication was mixed with 10ml of each solvent. The vials were shaken for 24 hours in a water bath shaker at 372oC until equilibrium was reached. The saturated solution was filtered and the UV spectrophotometer was used to analyse it.

Preparation of Standard plots in different solvents

A.Calibration Curve Preparation in Phosphate Buffer (pH 6.8)

Simvastatin (10 mg) was dissolved in a tiny quantity of methanol (as a cosolvent) and diluted in 100 mL of phosphate buffer (pH6.8). A stock solution of 250g/ml was prepared by diluting 50ml of this solution to 100ml with phosphate buffer (pH6.8) to make a stock solution. Aliquots of 2, 4, 6, 8, 10, and 12 were transferred from this stock solution to a 10ml volumetric flask, and the volume was brought up to 10ml using phosphate buffer. Using phosphate buffer as a blank, the absorbance of these solutions was measured at 239.5nm.

B Calibration Curve Preparation in Distilled Water

Simvastatin 10 mg was dissolved in a little quantity of methanol (used as a cosolvent) and diluted in 100ml distilled water. A stock solution with a concentration of 250g/ml was prepared by diluting 50ml of this solution to 100ml with distilled water. Aliquots of 2, 4, 6, 8, 10, and 12 were transferred from this stock solution to a 10ml volumetric flask, and the volume was brought up to 10ml with distilled water. Using distilled water as a blank, the absorbance of these solutions was measured at 239nm.

C Calibration Curve Preparation in 0.1N Hydrochloric Acid (HCL)

Simvastatin was dissolved in a little quantity of methanol (as a cosolvent) and then diluted in 100ml of 0.1N hydrochloric acid. A stock solution of 250g/ml was prepared by diluting 50ml of this solution to 100ml with 0.1N hydrochloric acid to make a stock solution. Aliquots of 2, 4, 6, 8, 10, and 12 were transferred from this stock solution to a 10ml volumetric flask, and the volume was brought up to 10ml with 0.1N hydrochloric acid. These solutions' absorbance was measured at 238nm using 0.1N HCL as a blank.

D Calibration Curve Preparation in Methanol

10 mg Simvastatin was dissolved in 100 mL methanol, and 50 mL of this solution was collected and diluted to 100 mL with methanol again to make a stock solution of 250 g/mL. Aliquots of 2, 4, 6, 8, 10, and 12 were transferred to a 10ml volumetric flask from this stock solution, and the volume was brought up to 10ml with methanol. Using methanol as a blank, the absorbance of these solutions was measured at 238nm.

Simvastatin Solid Dispersions Preparation

Method of Melting

The melt technique is another name for the fusion procedure. To produce a solidified mass, the polymer HPMC was melted at 60°C, then the medication was added, well mixed, and chilled in an ice bath. The hardened mixture was crushed and then sieved using a number 60 sieve. The solid dispersion that resulted was kept in desiccators until it could be tested further.

Method of Solvent Evaporation

In a round bottom flask, an accurately weighed quantity of drug and carriers in varied ratios were dissolved in ethanol and the solvent was evaporated at 45 °C

temperature. The solid dispersions were then kept for 48 hours at room temperature in a vacuum oven to eliminate any remaining solvent. The dried solid dispersions were ground in a mortar and pestle and sieved no. 60 before being kept in desiccators for subsequent analysis.

Solid Dispersion and Characterization of Physical Mixtures

The percentage yield, drug content, solubility studies, Fourier transform infrared (FTIR), Differential scanning calorimetry (DSC), X-ray diffraction (XRD), Scanning Electron Microscopy (SEM), in vitro drug release, and dissolution efficiency of the prepared physical mixtures and solid dispersions were all evaluated.

Drug Content Determination

10mg of Simvastatin solid dispersions were carefully weighed and dissolved in 10ml of methanol. The solution was filtered, diluted appropriately, and the drug concentration was determined using a UV Spectrophotometer at 238 nm.

Studies on saturation solubility

Excess quantities of solid dispersions were added to water and biorelevant medium at 37oC 0.5°C to assess saturation solubility. To get a clear solution, the solutions were equilibrated under continuous agitation for 24 hours and then filtered using Whatman filter paper. A UV spectrophotometer was used to determine the absorbance of the samples.

X-Ray Diffraction (XRD) Analysis of Powder

XRPD was used to analyse the crystallinity of materials using a Bruker diffractometer (WI 1140, Japan) and Cu-K radiation. The diffractograms were produced at a temperature of 2.5 degrees Celsius per minute and a chart speed of 2 degrees/2 centimetres per second.

Drug Release in Vitro

In 900 ml of dissolving medium (6.8 phosphate buffer) placed in USP dissolution apparatus II, accurately weighed solid dispersion corresponding to 10 mg of pure medication were introduced and agitated at a speed of 50 rpm at 370.5 C. At 10, 20, 30, 40, 50, and 60 minutes, 5 ml aliquots were removed and replaced with 5 ml of new dissolving medium (37°C). The obtained samples were examined using a UV-visible spectrophotometer at 239.5 nm against a blank, and the in vitro investigation of pure medication was done in the same way.

FTIR Spectroscopy (Fourier Transform Infrared Spectroscopy)

FT-IR was used to better characterise simvastatin and solid dispersions. On an FTIR- 8400S, CE (Shimadzu, Japan) equipment, samples produced on KBr discs were recorded (SEM). Data was gathered in the 4000 to 400 cm-1 spectral region.

Calorimetry via Differential Scanning (DSC)

In a nitrogen atmosphere, DSC analysis of Simvastatin and solid dispersion was carried out as follows: samples were kept in hermetically sealed aluminium pans and heated at a scan speed of 10o min-1 over a temperature range of 160-280oC in a differential scanning calorimeter (Perkin Elmer, DSC – 7, calibrated with indium) at a chart speed of 10mm.

SEM (Scanning Electron Microscopy)

This is a kind of microscopy that uses electron Simvastatin and their final solid dispersion were scanned using a scanning electron microscope stub attached with double-sided carbon tape and viewed using a 370701-14, S-3700, scanning electron microscope. The samples were gently strewn on a double-sided adhesive tape that was adhered to an aluminium stub. Under an argon environment, the stubs were coated with platinum to a thickness of roughly 10 microns. The coated samples were then put on stubs and placed in the scanning electron microscopy chamber.

Results

Melting point and physical appearance

Organoleptic qualities were used to evaluate the drug's physical appearance. Simvastatin sample had the same colour, odour, texture, and taste as described in the literature. The substance was white and crystalline in appearance. The melting point of the drug sample was determined using the Capillary technique to be 135° to 138°C, which is consistent with published values.

DSC

As shown in Figure 1, the DSC of the medication sample Simvastatin reveals a distinct endothermic peak at 139.91oC, indicating the sample's purity and legitimacy.

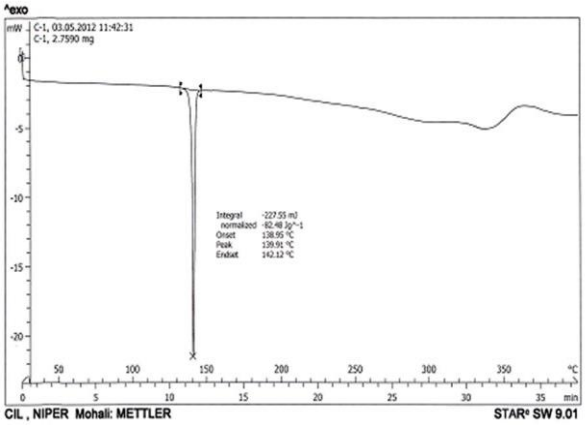

Figure 1: DSC thermogram of Simvastatin

FTIR

The FT-IR spectrum of pure drug was found similar with that given in Clarkes' Analysis.[50] IR spectra of pure drug have been performed and no major differences were observed in characteristic absorption peaks of the IR spectra of the reference spectra given in literature and pure sample drug. The FT-IR spectra of reference and pure sample, as shown in Figure 6.2(A) and 6.2(B).

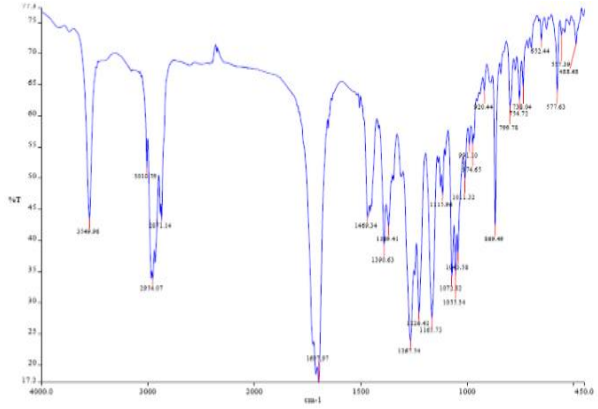

Figure 2(A): IR Spectra of Simvastatin Given in literature

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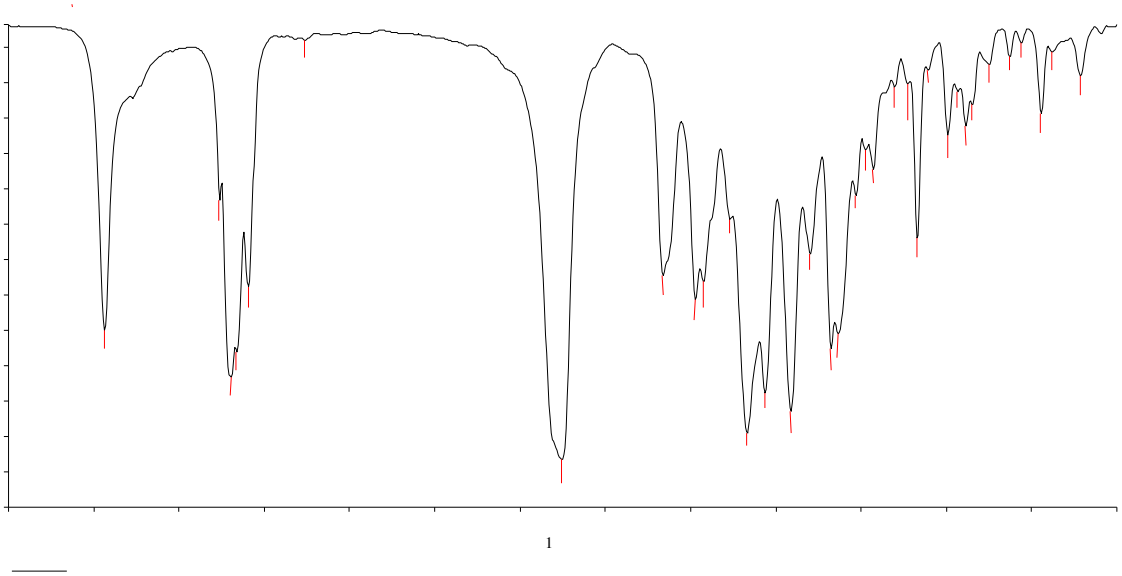


Figure 2(B): IR Spectra of Simvastatin Determined Practically

The FT-IR spectrum of simvastatin is presented in Figure 6.2(B). The spectrum of simvastatin shows a broad band at 3551.24 cm^{-1}, 2930.21cm^{-1}, 2956.18cm^{-1}, 2874.31cm^{-1}, 1702.6 cm^{-1},1465.32cm^{-1}, 1389.29cm^{-1}, 1268.10 cm^{-1}, 1165.13 cm^{-1}, 1071.22cm^{-1}. This co-relates with the peaks of standard simvastatin FTIR.

Absorption maxima (λ max) of drug:

The absorption maxima of pure drug were prepared in different solvent.

Table 1 Absorption maxima (λmax) of the Simvastatin in different solvents

S.No.	Solvent	λ max (nm)
1.	Methanol	238nm
2.	Phosphate buffer (pH 6.8)	239.5nm
3.	Water	239nm

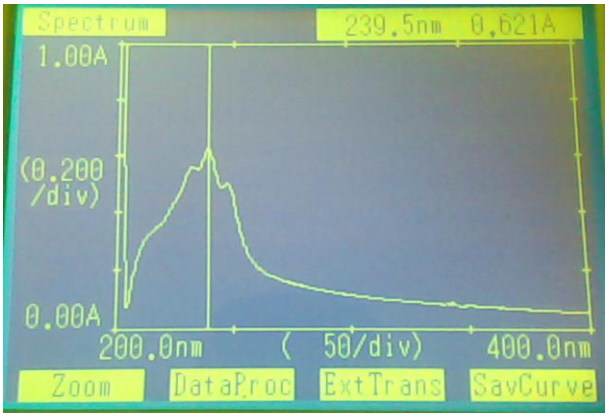


Figure 3 Scan graph of Simvastatin in phosphate buffer pH 6.8

Solubility:

The solubility studies of Simvastatin were determined in different solvents as shown in given Table 6.3 respectively.

Table 2 Solubility of Simvastatin in different solvents

S.No.	Solvent	Solubility(mg/ml)
1.	Methanol	2.036±0.705
2.	Phosphate buffer (pH 6.8)	3.953±0.585
3.	Water	1.826±0.511
4.	0.1N HCL	1.283±0.170

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

The solubility of Simvastatin is more in Phosphate buffer pH (6.8) than HCL and which indicates the weakly acidic nature of drug.

Drug compatibility studies

Excipient testing revealed no discoloration or liquefaction between the medication and the polymer. There was no physical contact between the drug and the polymer utilised, according to the FTIR spectra of the physical combination of drug and polymer. There was no substantial movement in the peak, indicating that both the medication and the polymer are compatible.The FTIR spectrum of drug and various excipients are shown in the figure 6.4 and 6.5 respectively.

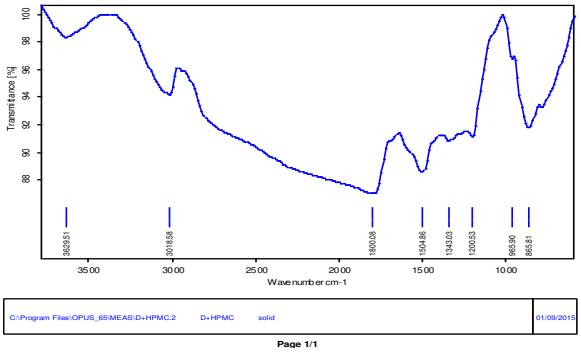


Figure 4: IR Spectra of Physical Mixture of Drug & HPMC

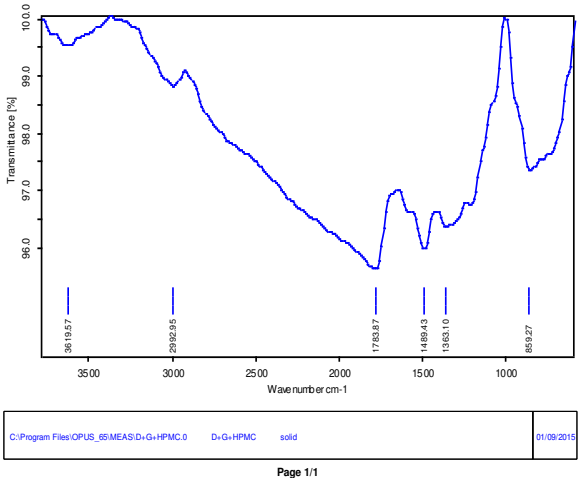


Figure 5: IR Spectra of Physical Mixture of Drug, HPMC and Acacia Gum

Standard plot

Simvastatin's standard curve in Phosphate buffer (pH 6.8), methanol, 0.1N HCl, and water was shown to be linear in the concentration range of 2-12 g/ml and fulfil Beer's Lambert Law. Table 6.1-6.4 shows the absorbance at various concentrations. And graph is represented in figure 6.2-6.5 respectively. Data are expressed as mean ± S.D. (n=3)

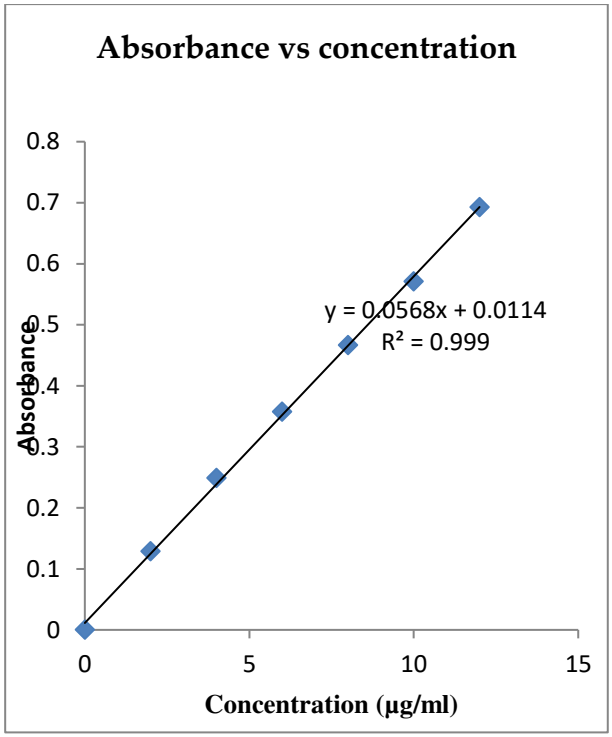


Figure 6: Standard plot of Simvastatin in Phosphate Buffer (pH6.8) Data are expressed as mean ± S.D. (n=3)

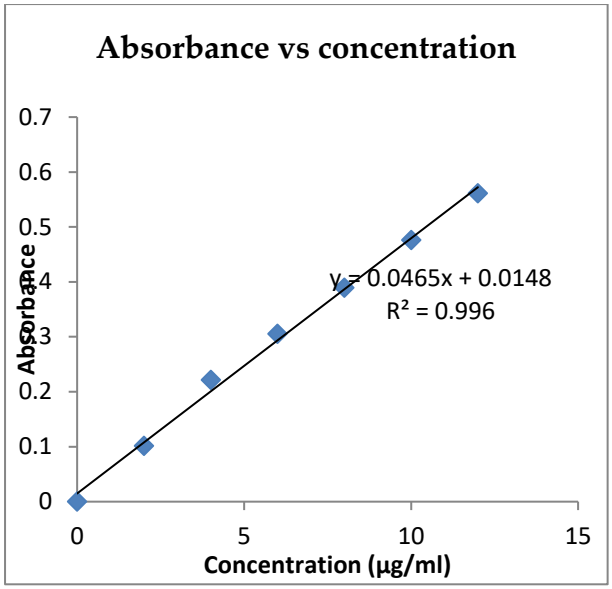


Figure 7: Standard plot of Simvastatin in Methanol
Data are expressed as mean ± S.D. (n=3)

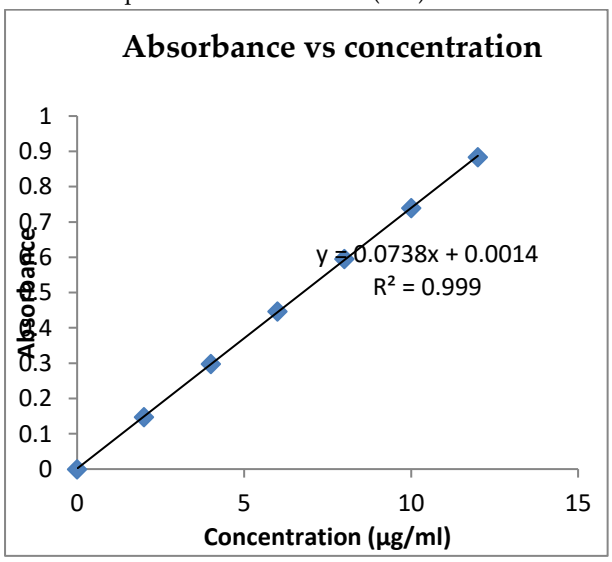


Figure 8: Standard Plot of Simvastatin in 0.1N HCL
Data are expressed as mean ± S.D. (n=3)

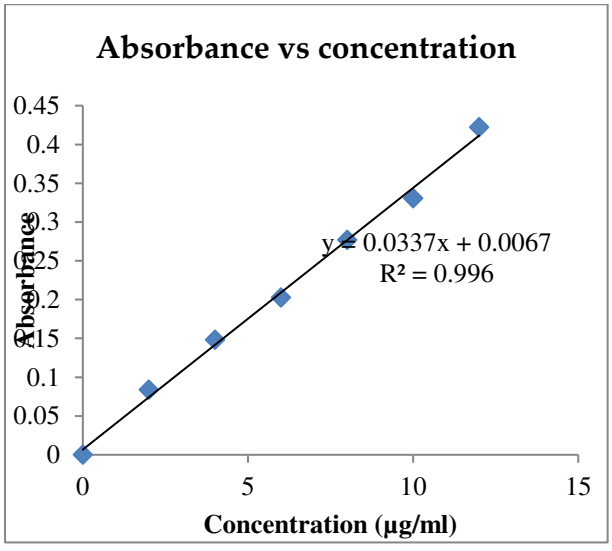


Figure 9: Standard plot of Simvastatin in Water

Table 3: Characteristics of Gum and HPMC

Parameter	HPMC	GUM ACACIA
Loss on drying	≥10.0%	≥15%
Apparent viscosity	75 to 140%	-
Swelling index	-	5.68±0.05
pH	5.0-8.0	4.5-5.0
Apparent density	0.25~0.70g/cm^3	-
Surface tension	42 to 56 mN/m	42.6 mN/m

Percent yield and drug content

We calculated the % yield and drug content of pure drug and various solid dispersions. Tables 6.10 and 6.11 demonstrate the percentage yield and drug content of various solid dispersions, respectively. The percent yields fell as the polymer and surfactant concentrations increased, owing to the difficulties of sieving at higher concentrations. Low standard deviations in percent yield and drug content suggested that the drug was evenly distributed in all solid dispersions and that the findings were consistent and repeatable across all formulations.

Table 4: Percentage yield and drug content of Solid dispersion of Simvastatin and HPMC

Formulation code	Percentage yield	Drug content
SIM 1	93.16±0.763	91.33±0.003
SIM 2	92.82±0.184	90.22±0.005
SIM 3	90.31±0.548	92.22±0.003

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

Table 5: Percentage yield and drug content of Solid dispersion of Simvastatin, HPMC and Gum Acacia

Formulation code	Percentage yield	Drug content
SIM 4	90.46±0.591	92.44±0.001
SIM 5	87.15±0.259	96.22±0.057
SIM 6	88.66±0.577	93.55±0.012

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

Solubility study

Data on the solubility of a pure medication and various solid dispersions. The solubility of the medication increased as the polymer ratio rose.

Table 4: Solubility of pure drug and solid dispersion (Drug: HPMC)

Formulation code	Solubility(mg/ml)
Pure drug	3.953±0.585
SIM 1	4.483±0.646
SIM 2	6.456±0.011
SIM 3	8.706±0.742

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

Table 5: Solubility of pure drug and solid dispersion (Drug: Gum+HPMC)

Formulation code	Solubility(mg/ml)
Pure drug	3.953±0.585
SIM 4	5.766±0.565
SIM 5	6.736±0.586
SIM 6	9.263±0.704

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

Dissolution studies

The In vitro release of pure drug and different solid dispersions and plotted the graph between % drug released vs time

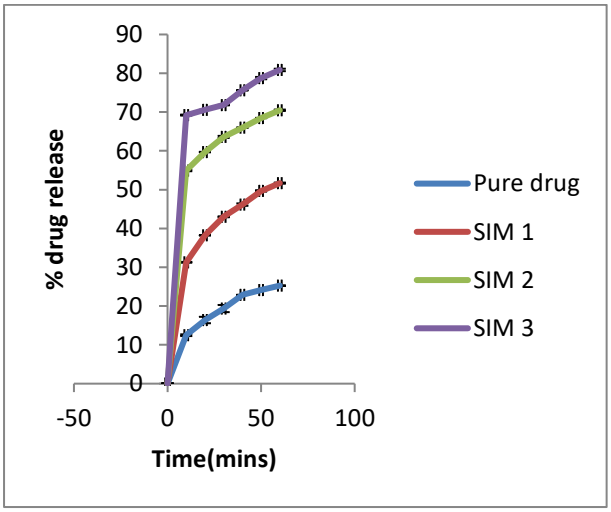


Figure 10: In vitro dissolution profile of %pure drug released vs time solid dispersions with HPMC

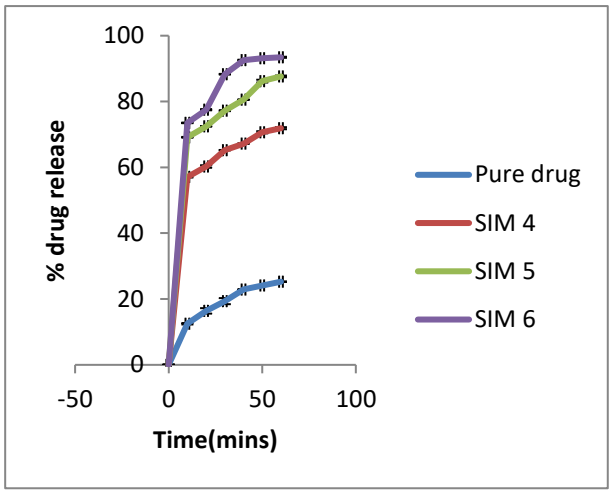


Figure 11: In vitro dissolution profile of %pure drug released vs time solid dispersions with HPMC and Acacia Gum

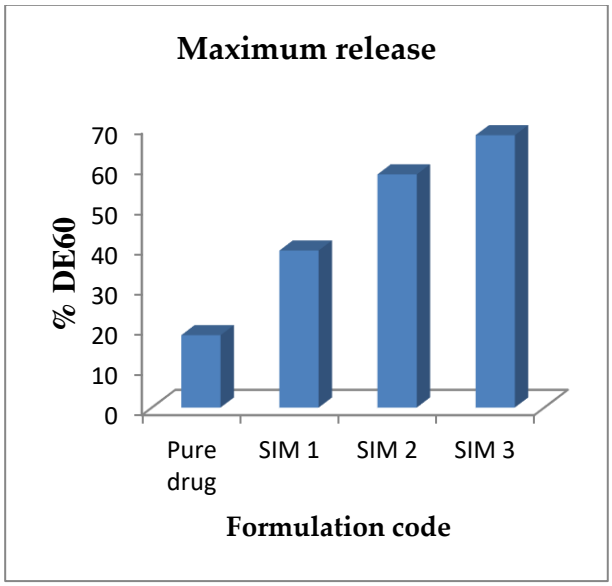


Figure 12 Comparison of %DE60 of pure drug and different formulations with HPMC

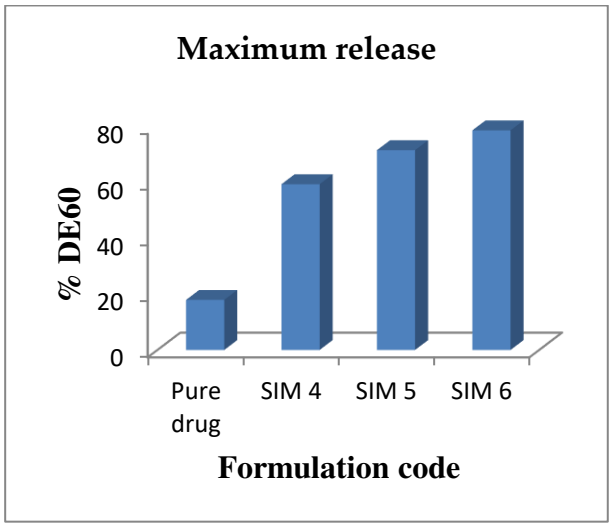


Figure 13: Comparison of %DE60 of pure drug and different formulations with HPMC and Acacia gum

Table 4: Dissolution efficiency and percentage yield of optimized formulations

Optimized formulations	%DE 60	% of yield
SIM 6	78.63±1.08	88.66±0.577

Differential scanning calorimetry

As illustrated in Fig.6.14 to 6.15, DSC of Simvastatin and optimum solid dispersions. Simvastatin's DSC curve revealed a strong melting peak at 139.9 degrees Celsius, indicating its crystalline structure. In the optimised produced solid dispersions, however, the distinctive endothermic peak related to drug melting was expanded and moved toward lower temperature, with decreased intensity (i.e. HPMC and Acacia Gum). This might be owing to a greater polymer concentration and homogeneous drug dispersion in the polymer crust, resulting in total molten drug miscibility in the polymer. The lack of a drug peak shows that the drug is dispersed uniformly in an amorphous nature condition inside the solid dispersions, with no interaction.

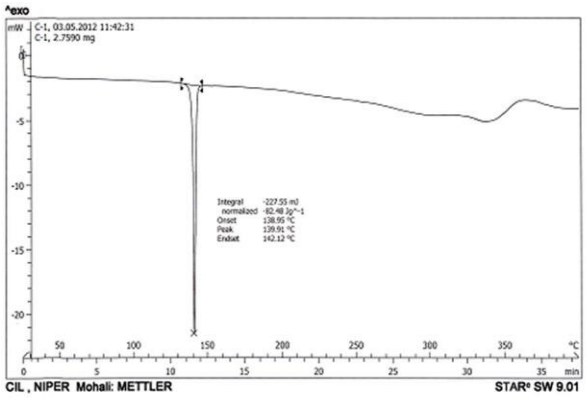


Figure 14: DSC Thermogram of Simvastatin

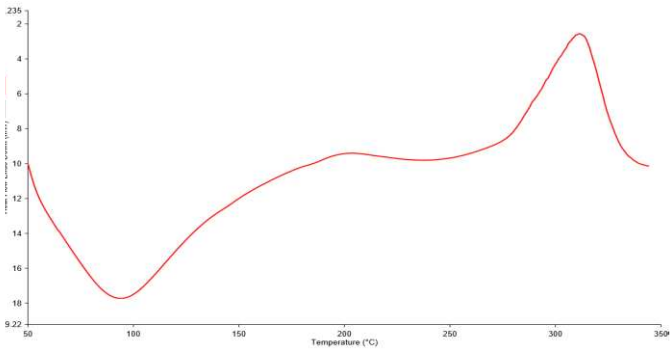


Figure 15: DSC Thermogram of optimized formulation with HPMC and Acacia Gum

Infrared spectroscopy

Figures 6.16 to 6.18 show the infrared spectra of simvastatin and optimal solid dispersions. There was no physical contact between the drug and the polymer utilised, according to the FTIR spectra of the physical combination of drug and polymer. There was no substantial movement in the peak, indicating that both the medication and the polymer are compatible. The strength of O-H stretching vibrations in the spectrum of solid dispersions decreased significantly, perhaps owing to intermolecular hydrogen bonding.

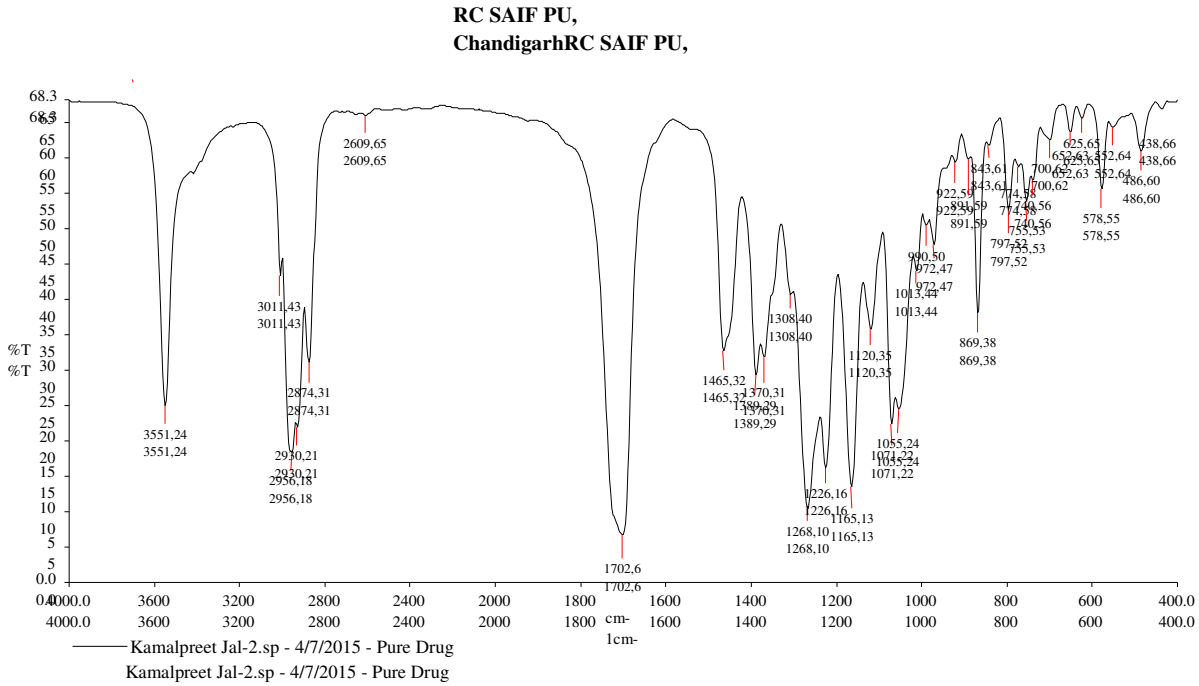


Figure 16: FTIR spectra of Simvastatin

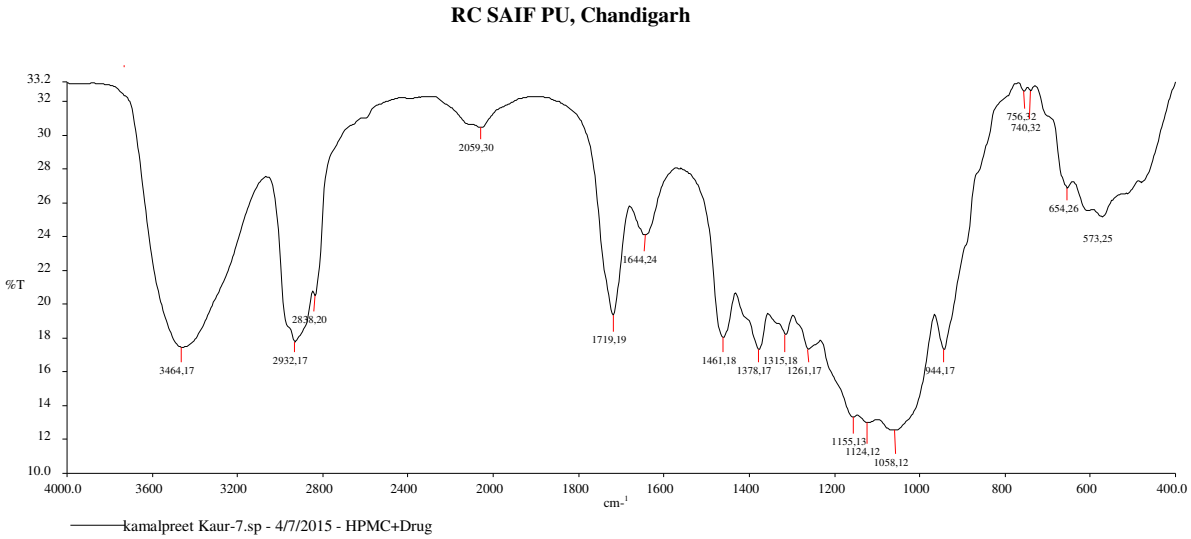


Figure 17: FTIR spectra of optimized formulation with HPMC

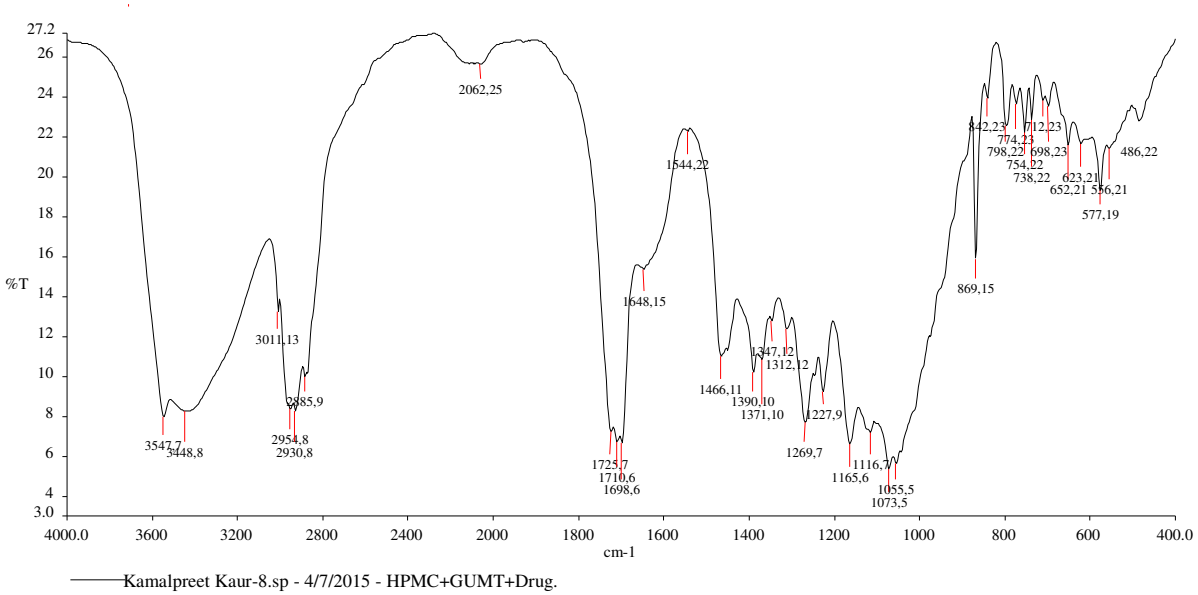
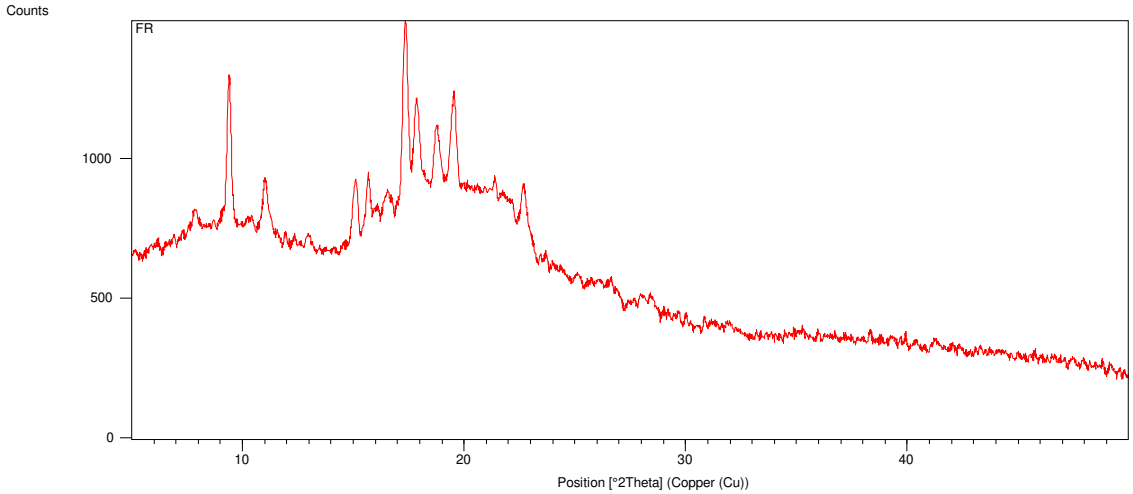


Figure 18: FTIR spectra of optimized formulation with HPMC and Acacia Gum

X-ray diffraction studies

Pure simvastatin and optimal solid dispersions X-ray diffraction investigations As a result, simvastatin's distinctive diffraction peaks at (2) 9.63o, 11.24o, 15.90o, 16.889o, 17.56o, 18.04o, 19.74o, 22.84o, 28.68o, 33.51o, 35.17o, and 38.73o reveal the drug's crystalline form. As can be seen in Figure 19, the lower peak height area suggests a reduction in the crystallinity nature of the simvastatin as part of the medication transitioned to the amorphous form in the solid dispersions.



20: X-ray diffraction of optimized formulation with HPMC and Acacia gum

Scanning electron microscopy (SEM)

Photographs of simvastatin taken using a scanning electron microscope (SEM) and optimum solid dispersions. It was discovered that simvastatin was a highly crystalline substance with needle-shaped crystals. It was discovered that the crystals of solid dispersions of drug did not show any needle-shaped crystals and that uniform dispersion of the drug in the polymeric matrix of the polymer and surfactant was observed in the solid dispersions, indicating that the drug's crystallinity nature is reduced and the drug becomes amorphous.

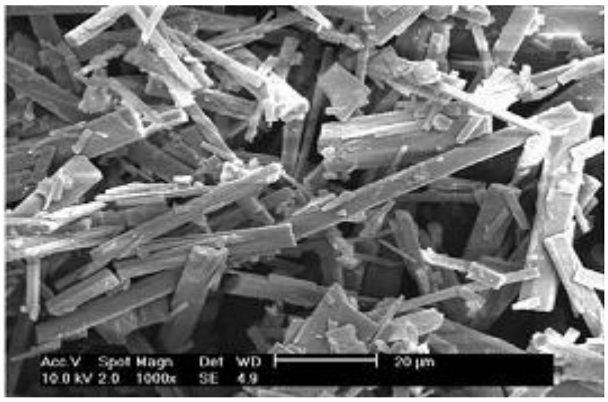


Figure 21: Scanning electron photomicrographs of Simvastatin

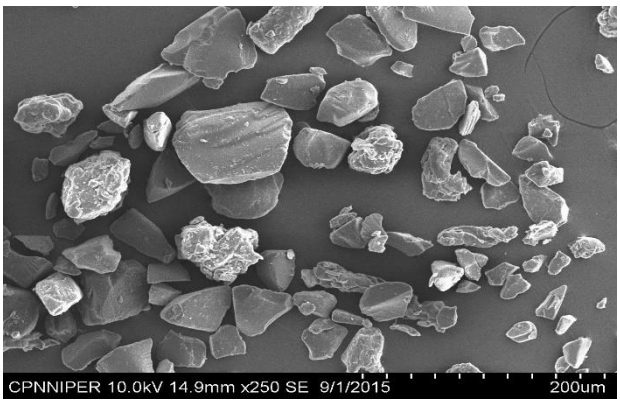


Figure 22: Scanning electron photomicrograph of optimized solid dispersion at 250 X

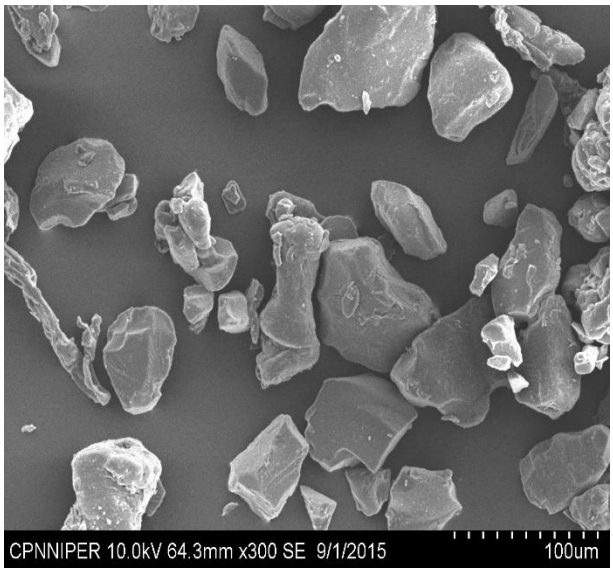


Figure 23: Scanning electron photomicrograph of optimized solid dispersion at 300 X

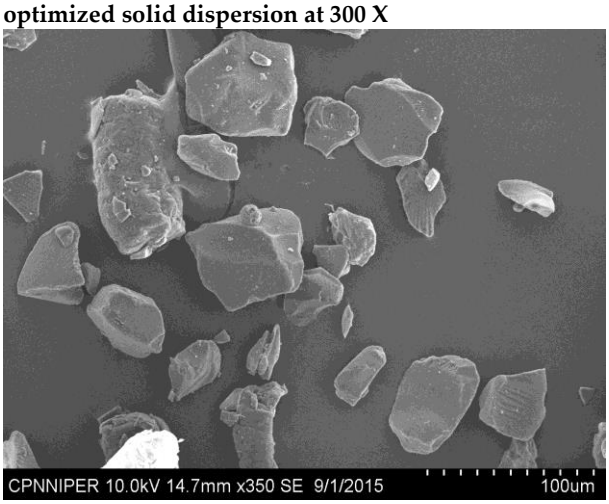


Figure 24: Scanning electron photomicrograph of optimized solid dispersion at 350 X

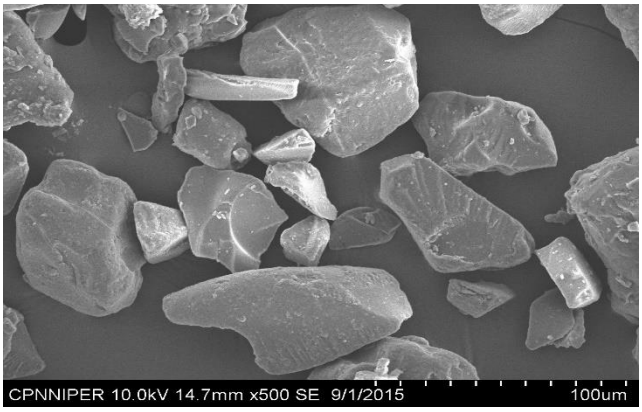


Figure 25: Scanning electron photomicrograph of optimized solid dispersion at 500 X

The final capsule dosage forms were created and labelled as SIMC after the optimum solid dispersion was inserted into the "0" firm gelatine capsule shell.

Table 5 Evaluation parameters of Capsule dosage form SIMC with HPMC and Acacia Gum

Formulation code SIMC	Weight variation (mg)	Disintegration time (min)	Content uniformity
1	0.111±0.001	27	96.96 ± 0.04
2	0.108±0.002	26	98.21±0.05
3	0.107±0.002	25	99.67±0.03
4	0.107±0.005	30	99.96 ± 0.04
5	0.110±0.001	26	95.51±0.24
6	0.106±0.004	29	98.90±0.02
7	0.109±0.001	27	97.25±0.51
8	0.108±0.001	31	96.32±0.03
9	0.109±0.004	25	97.58 ± 0.02
10	0.103±0.002	28	96.90 ± 0.06

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

Table 6 Dissolution profile of pure drug and Capsules dosage forms

Time (min)	Pure drug	SIMC
10	12.68±0.92	90.86±0.01
20	16.39±0.82	93.91±0.11
30	19.35±0.92	96.68±0.19
40	22.12±0.91	98.49±0.01
50	24.21±0.97	99.44±0.15
60	25.17±1.03	99.63±0.11

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

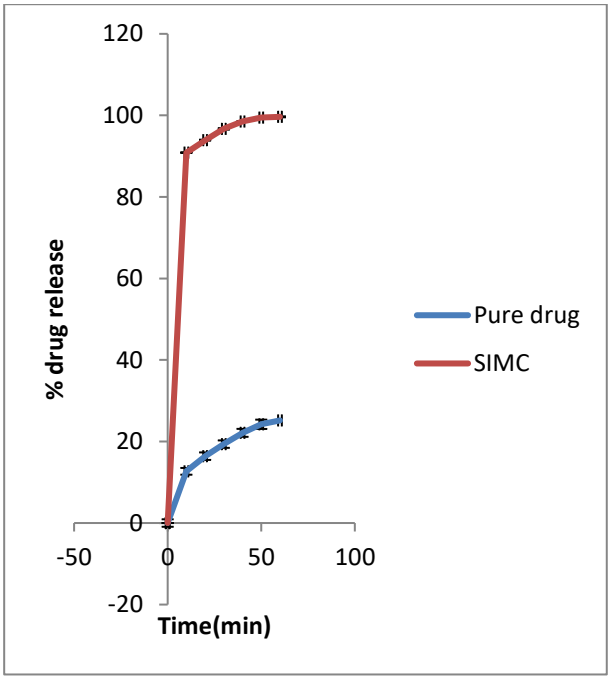


Figure 26: In vitro dissolution profile of %drug released vs time of pure drug and Capsule dosage form

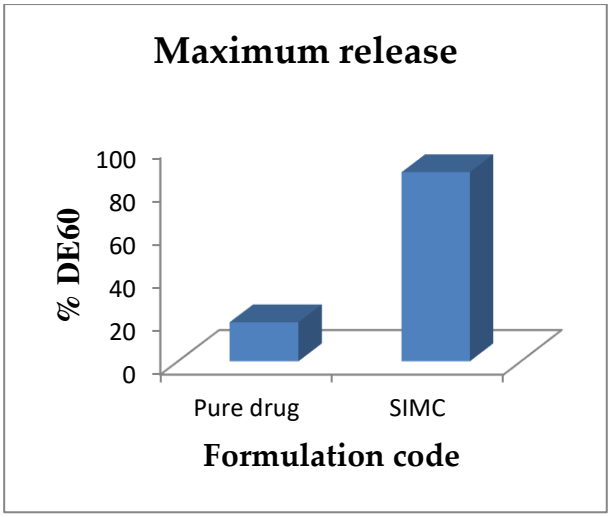


Figure 27: Comparison of % DE60 with pure drug and capsules dosage formulations

Table 6.21: Dissolution efficiency of pure drug and Capsules dosage formulations

Formulation codes	Dissolution efficiency (% DE60)
Pure drug	17.98±2.94
SIMC	87.36±1.34

Stability studies

Any three produced capsule dosage formulations preserved for stability tests revealed no significant fluctuation in all parameters during the test period at varying temperatures and relative humidity (402oC and 755% RH). Table 7 summarises the findings.

Table 7 Evaluation of Capsule formulation C after stability studies

Time period (days)	0	7	14	21	30
Colour appearance	No change in colour	No change in colour	No change in colour	No change in colour	No change in colour
Content uniformity	97.20	99.27	91.62	93.35	94.51

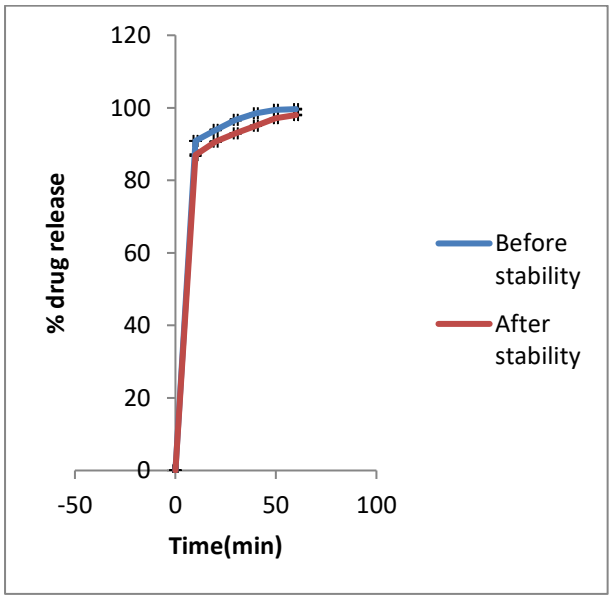


Figure 28: In vitro dissolution profile of %drug released vs time of pure drug and Capsule dosage forms SIMC

Conclusion

The goal of this research was to create a solid dispersion of simvastatin loaded with a mixture of HPMC and Acacia Gum that would give sustained release effects for cholesterol patients. Because of the effect of cholesterol, lipid and lipoprotein abnormalities are exceedingly frequent in the general population and are recognised as a highly modifiable risk factor for cardiovascular illnesses. They are particularly prevalent in aged people. Simvastatin inhibits HMG CoA reductase in a selective manner. Simvastatin is classified as a BCS class 2 drug because of its poor solubility and hence limited oral bioavailability (5 percent). Melt and Solvent evaporation methods were used to make solid dispersions with varying drug carrier ratios (HPMC and Acacia Gum). To boost the drug's solubility, a solid dispersion was created. The % yield, drug content, solubility, SEM, XRD, DSC, and in-vitro dissolution profile of these solid dispersions were all examined. Simvastatin's dissolving rate has increased, according to a research on solid dispersion dissolution. The formulations have been tested for stability in a stability chamber according to ICH guideline Q1A under moderate and accelerated circumstances and have been shown to be stable throughout a broad variety of storage conditions.

Disclosure Statement

There are no conflicts of interest.

Acknowledgment

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