Asian Journal of Chemistry; Vol. 25, No. 10 (2013), 5340-5346

ASIAN JOURNAL OF CHEMISTRY

http://dx.doi.org/10.14233/ajchem.2013.14180

Formulation and Evaluation of Rosuvastatin Fast Dissolving Tablets

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(*Received*: 7 June 2012; *Accepted*: 3 April 2013) AJC-13201

Rosuvastatin calcium (RST) is a selective and competitive inhibitor of HMG-CoA reductase, mainly used in the treatment of hypercholesterolemia, hyper triglyceridemia and atherosclerosis. In this work a new attempt was made to enhance the solubility, dissolution rate and oral bioavailability of poorly soluble rosuvastatin by formulating it as solid dispersions using various techniques with polyethylene glycol (PEG) 6000 as a carrier. Fast dissolving tablets of rosuvastatin were prepared with super disintegrants like sodium starch glycolate, croscarmellose sodium, pregelatinized starch and mannitol from the optimized solid dispersions. Tablets were evaluated for physical parameters and drug release by *in vitro* dissolution studies. Surface characteristics, drug-excipient interactions and crystal morphology of optimized solid dispersions were evaluated by SEM analysis, DSC and XRD studies, respectively.

Key Words: Rosuvastatin calcium, PEG 6000, Sodium starch glycolate, Croscarmellose sodium, Pregelatinized starch, Mannitol.

INTRODUCTION

The oral route of drug administration is the most common and preferred method of delivery due to convenience and ease of ingestion. From a patient's perspective, swallowing a dosage form is a comfortable and a familiar means of taking medication[1,2]. Although the oral route of administration is preferred, for many drugs it can be a problematic and inefficient mode of delivery for a number of reasons. Limited drug absorption resulting in poor bioavailability is paramount amongst the potential problems that can be encountered when delivering an active agent *via* the oral route[3-5].

Drug absorption from the gastrointestinal (GI) tract can be limited by a variety of factors with the most significant contributors being poor aqueous solubility and/or poor membrane permeability of the drug molecule. When delivering an active agent orally, it must first dissolve in gastric and/or intestinal fluids before it can then permeate the membranes of the gastrointestinal tract to reach systemic circulation[6-8]. Therefore, a drug with poor aqueous solubility will typically exhibit dissolution rate limited absorption and a drug with poor membrane permeability will typically exhibit permeation rate limited absorption[9,10]. Hence, two areas of pharmaceutical research that focus on improving the oral bioavailability of active agents include: (i) enhancing solubility and dissolution rate of poorly water-soluble drugs and (ii) enhancing permeability of poorly permeable drugs. So, a solid dispersion technology is used to improve the dissolution characteristics of poorly water-soluble drugs and in turn their oral bioavailability[11-13].

In the present investigation the drug such as rosuvastatin was selected for the enhancement of solubility and bioavailability by improving its dissolution rate by preparing it in solid dispersion form.

Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) to mevalonate, a precursor of cholesterol. rosuvastatin calcium is a white amorphous powder that is sparingly soluble in water and methanol. rosuvastatin calcium after oral administration is well absorbed from gastrointestinal tract. Peak plasma concentration was reached 3-5 h following oral dosing. It has got elimination half life of 19 h and *ca.* 88 % of rosuvastatin calcium has the tendency to protein binding.

Based on the above physicochemical and biopharmaceutical properties, rosuvastatin was selected for developing solid dispersions formulations for improving its solubility and dissolution rate.

EXPERIMENTAL

Rosuvastatin calcium was a gift sample from Matrix Pharma Ltd., Hyderabad and croscarmellose sodium, sodium starch glycolate, Pregelatinized starch, mannitol were gift samples obtained from M/s. NATCO Pharma Ltd, Hyderabad.

Polyethylene glycol 6000, potassium dihydrogen phosphate, sodium hydroxide, lactose, magnesium stearate (SD Fine Chem, Ltd., Mumbai) and methanol (High-Pure fine Chem., Chennai) was procured from commercial sources. All other materials used were of pharmacopoeial grade.

Saturated solubility studies: 500 mg of rosuvastatin calcium was weighed and transferred into different conical flask. 50 mL of different dissolution media were transferred into individual conical flask and were closed appropriately. All the conical flasks were placed in a REMI incubator shaker. The shaker was allowed to operate at 50 rpm at 37 ± 1 ºC for 24 h. Then the conical flasks were removed from the incubator shaker and the samples were filtered by using Whatman filter paper. The clear solution obtained by filteration was suitably diluted with appropriate dissolution media and the absorbance values were noted at 248 nm by using corresponding dissolution media as blank solutions.

Preparation of solid dispersions: Poorly soluble rosuvastatin was incorporated into the polymer polyethylene glycol 6000 by four different techniques such as (1) physical mixing method (2) fusion method (3) solvent evaporation method (4) lyophilization technique.

Physical mixing method: Known quantity of drug and PEG 6000 were weighed separately and passed through sieve No. 80. The materials passed through sieve No. 80 were collected and transferred into a clean and dry glass motor. Rosuvastatin and PEG 6000 were triturated together for 5 min and again screened through sieve No. 80. The mixture passed through sieve No. 80 is collected and packed in a wide mouthed amber coloured glass container and was hermetically sealed.

Fusion method: Specified quantity of PEG-6000 was taken in a china dish and it was heated at 50 ºC on a mantle until molten solution was formed. To the molten solution add specified quantity of drug and triturated vigorously at room temperature. Grind the mass if necessary and screen through sieve No. 100. Then the mixture was collected, packed and was hermatically sealed and was stored at an ambient condition.

Solvent evaporation method: Rosuvastatin was taken in a china dish and was dissolved in few mL of methanol. To the methanolic solution, specified amount of PEG 6000 was added and the mixture was heated at 50 ºC on a mantle with continuous stirring until the solvent is evaporated. Then the mixture was collected and packed in an amber coloured glass containers and was hermetically sealed. Then the mixture was stored at ambient conditions.

Lyophilization: Specified quantity of rosuvastatin and PEG-6000 were weighed and added with minimum amount of water. This dispersion was rapidly solidified by freezing in a lyophilizer [Il Shin Freeze drier (Shin Lab Co., Ltd)]. The solvent in the dispersion was sublimed under a pressure of 10 M torr and condensed onto a -40 ºC condenser. After the solvent was completely removed, the powder residue appeared as a porous, light and pluffy mass. The lyophilized preparations were stored in a dessicator at room temperature. Various compositions of solid dispersions were shown in Table-1.

Characterization and evaluation of solid dispersions: The solid dispersions prepared by various methods were characterized by particle size determination and flow properties such as angle of repose and Carr's index. Surface characteristics, drug-excipient interactions and crystal morphology of optimized solid dispersions were evaluated by SEM analysis, DSC and XRD studies, respectively.

TABLE-1
COMPOSITION OF VARIOUS SOLID DISPERSIONS OF ROSUVASTATIN

S. No.	Composition	Ratio
	Physical mixing method	Drug: Polymer*
1	RST + PEG-6000 (RP1)	1:0.5
2	RST + PEG-6000 (RP 2)	1:1
3	RST + PEG-6000 (RP 3)	1:1.5
4	RST + PEG-6000 (RP 4)	1:2
	Solvent evaporation	
5	RST + PEG-6000 (RS 1)	1:0.5
6	RST + PEG-6000 (RS 2)	1:1
7	RST + PEG-6000 (RS 3)	1:1.5
8	RST + PEG-6000 (RS 4)	1:2
	Fusion method	
9	RST + PEG-6000 (RF 1)	1:0.5
10	RST + PEG-6000 (RF 2)	1:1
11	RST + PEG-6000 (RF 3)	1:1.5
12	RST + PEG-6000 (RF 4)	1:2
	Lyophilization technique	
13	RST + PEG-6000 (RLP)	1:2

Note: 1 part is equivalent to 10 mg.

TABLE-2
FLOW PROPERTIES AND DRUG CONTENT OF ROSUVASTATIN SOLID DISPERSIONS

S. No.	Solid dispersions	Angle of repose (º)	Carr's index (%)	Particle size (µ)	Drug content (mg)
1	RP 1	25	19	178 ± 5	9.9 ± 0.2
2	RP 2	23	16	175 ± 4	9.8 ± 0.3
3	RP 3	26	14	176 ± 6	11.2 ± 0.3
4	RP 4	28	17	174 ± 5	10.5 ± 0.2
5	RF 1	23	18	176 ± 6	9.8 ± 0.3
6	RF 2	24	16	179 ± 4	9.9 ± 0.2
7	RF 3	21	18	175 ± 5	9.7 ± 0.3
8	RF 4	24	17	173 ± 6	9.8 ± 0.2
9	RS 1	25	19	176 ± 4	9.7 ± 0.3
10	RS 2	22	15	178 ± 5	10.5 ± 0.3
11	RS 3	26	13	176 ± 4	9.7 ± 0.2
12	RS 4	20	12	174 ± 6	9.9 ± 0.2

TABLE-3
DISSOLUTION PARAMETERS OF ROSUVASTATIN SOLID DISPERSIONS

S. No.	Solid dispersions	T_{50} (min)	T_{90} (min)	DE_{30} (%)	First order K (min^{-1})	First order R^2
1	PD	>90	>90	17	0.013	0.885
2	RLP	6	45	73.3	0.225	0.991
3	RP1	37	>90	31.8	0.014	0.953
4	RP2	24	>90	36.4	0.016	0.915
5	RP3	16	>90	40	0.017	0.966
6	RP4	13	>90	45.03	0.019	0.975
7	RF1	18	>90	36.6	0.017	0.981
8	RF2	13	>90	41.16	0.021	0.957
9	RF3	11	60	45.3	0.026	0.964
10	RF4	8	56	51.6	0.038	0.989
11	RS1	26	>90	35.3	0.014	0.959
12	RS2	14	>90	43.2	0.015	0.965
13	RS3	12	>90	45	0.025	0.982
14	RS4	11	79	49.6	0.027	0.984

Estimation of rosuvastatin in solid dispersions: Solid dispersions of rosuvastatin from a batch were taken at random and were transferred into a 100 mL volumetric flask and 70 mL of methanol was added. It was shaken occasionally for *ca.* 0.5 h and the volume was made up to 100 mL by adding methanol. About 10 mL of the solution from the volumetric flask was taken and centrifuged. The supernatant solution from the centrifuge tube was collected and again filtered by using Whatman filter paper. Then the filtrate was subsequently diluted with 6.8 pH phosphate buffer and the absorbance was measured at 248 nm.

Dissolution rate studies on rosuvastatin solid dispersions and rosuvastatin tablets: Dissolution studies on each solid dispersions rosuvastatin tablets were performed in a calibrated 8 station dissolution test apparatus (LAB INDIA) equipped with paddles (USP apparatus II method) employing 900 mL of 6.8 pH phosphate buffer as a medium. The paddles were operated at 50 rpm and temperature was maintained at 37 ± 1 ºC through out the experiment. 5 mL samples were with drawn upto 90 min and replaced with equal volume of same dissolution medium to maintain the constant volume through out the experiment. Samples with drawn at various time intervals were suitably diluted with same dissolution medium and the amount of the drug dissolved was estimated by ELICO double beam UV spectrophotometer at 248 nm. The dissolution studies on each formulation were conducted in triplicate. From the dissolution profiles various parameters like T_{50}, T_{90} and $DE_{30\%}$ were calculated.

Preparation of rosuvastatin tablets with solid dispersions: Among the solid dispersions prepared and based upon the dissolution studies performed, optimized dispersions were selected for further preparation as tablets. The solid dispersions prepared by fusion, solvent evaporation and lyophilization method with drug to polymer in the ratio of 1:2 (RF4, RS4 and RLP) were further compressed as tablets. The tablets were prepared by direct compression process. The tablet formulations consisted of drug, polymer and diluents. The ratio of drug and polymer were maintained constant while the superdisintegrant concentration was varied. The weights of all the tablet formulations were maintained uniformly by using directly compressible lactose as diluent. The materials were individually weighed, passed through sieve No: 80 and blended for 15 min by using double cone blender. The powder mixture was then lubricated with 1 % talc and magnesium stearate and directly compressed as matrix tablets using Elite 10 station mini press. Compositions of various tablet formulations were given in Tables 4 and 5.

Estimation of physical parameters of rosuvastatin tablets: The physical parameters such as weight uniformity, hardness, friability, wetting time, dispersion time and drug content were evaluated for the prepared tablets as per the Indian pharmacopoeial standards.

RESULTS AND DISCUSSION

Saturated solubility studies revealed that rosuvastatin showed maximum solubility in 6.8 pH phosphate buffer as medium among the different media used. Hence 6.8 pH phosphate buffer was used as dissolution medium for further studies. The drug concentration was measured at 248 nm using UV spectrophotometer for all the dissolution media. Solid dispersions were prepared by incorporating poorly soluble Rosuvastatin into PEG 6000 by physical mixing, fusion, solvent evaporation and lyophilization methods as per the composition shown in Table-1. All dispersions were prepared

TABLE-4
COMPOSITION OF VARIOUS ROSUVASTATIN FAST DISSOLVING TABLETS

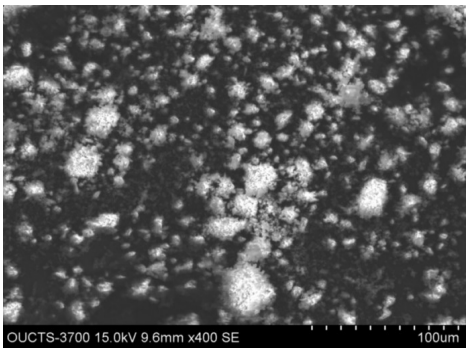
S. No.	Ingredient (mg/tablet)	Formulations								
		RLP_1	RFF_1	RFF_2	RFF_3	RFF_4	RFF_5	RFF_6	RFF_7	RFF_8
1	RF 4	–	30	30	30	30	30	30	30	30
2	RLP	30	–	–	–	–	–	–	–	-
3	Directly compressible lactose	102.5	102.5	102.5	102.5	102.5	102.5	102.5	102.5	102.5
4	CCS	30	15	30	–	–	–	–	–	-
5	SSG	–	–	–	15	30	–	–	–	-
6	PGS	–	–	–	–	–	15	30	–	-
7	Mannitol	–	–	–	–	–	–	–	15	30
8	Talc	5	5	5	5	5	5	5	5	5
9	Magnesium stearate	5	5	5	5	5	5	5	5	5
Total weight of tablet (mg)		150	150	150	150	150	150	150	150	150

TABLE-5
COMPOSITION OF VARIOUS ROSUVASTATIN FAST DISSOLVING TABLETS

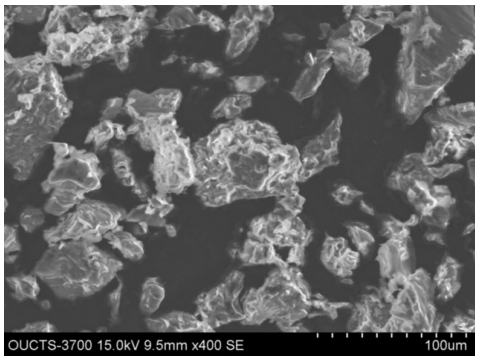
S. No.	Ingredient (mg/tablet)	Formulations							
		RSF_1	RSF_2	RSF_3	RSF_4	RSF_5	RSF_6	RSF_7	RSF_8
1	RS 4	30	30	30	30	30	30	30	30
2	Directly compressible lactose	102.5	102.5	102.5	102.5	102.5	102.5	102.5	102.5
3	CCS	15	30	–	–	–	–	–	-
4	SSG	–	–	15	30	–	–	–	-
5	PGS	–	–	–	–	15	30	–	-
6	Mannitol	–	–	–	–	–	–	15	30
7	Talc	5	5	5	5	5	5	5	5
8	Magnesium stearate	5	5	5	5	5	5	5	5
Total weight of tablet (mg)		150	150	150	150	150	150	150	150

under similar conditions to avoid batch to batch variations. The dispersions were found to be uniform in their characteristics. All the solid dispersions were in the size range of 173-179 ± 5 µm. The angle of repose and Carr's index values for all the dispersions prepared indicated good and free flowing characteristics (Table-2). The drug content estimated in all the solid dispersions were in the range of 9.7-11.2 ± 0.3 mg (Table-3).

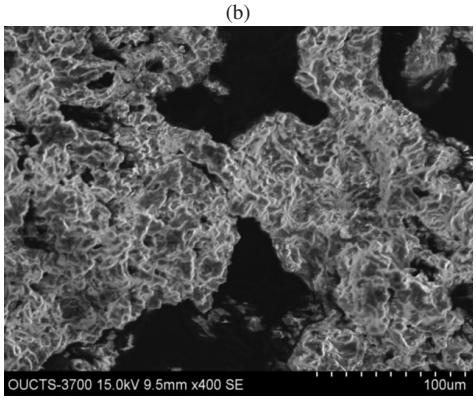
The SEM photographs were taken for RF4, RS4 and RLP and were shown in Fig. 1. The formulation RF4 (Fig. a) in SEM photograph showed that the dispersions are in a micronized state with tiny particulate system. Solid dispersion RS4 (Fig. b) prepared by solvent evaporation method was observed as finely divided almost amorphous form of the dispersion. The formulation RLP (Fig. c) prepared by lyophilization was observed that the dispersions were highly porous, loosely networked, friable and low dense solid form.



(a)



(b)



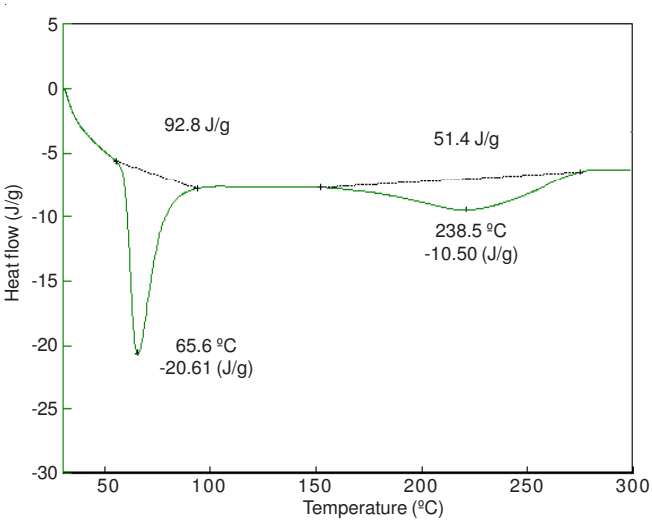
(c)

Fig. 1. Scanning electron microscope photographs of rosuvastatin solid dispersions prepared by various methods. (a) Solid dispersions prepared by fusion method, (b) solid dispersions prepared by solvent evaporation method, (c) solid dispersions prepared by lyophilisation technique

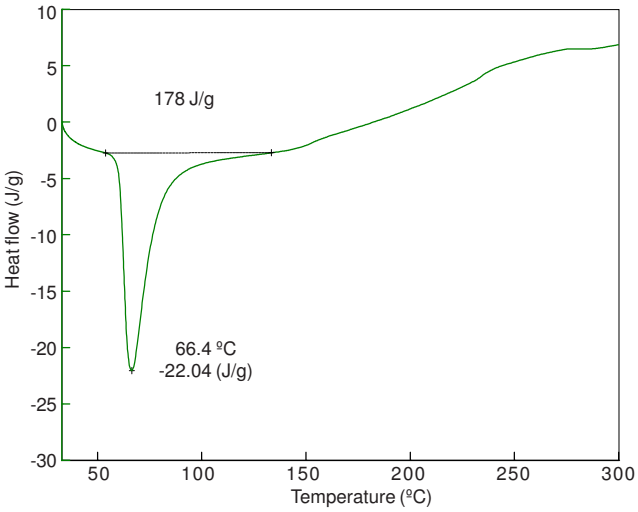
The DSC results (Fig. 2) showed that a broad endothermic peak for rosuvastatin was observed at 223.1 ºC. Sharp endothermic peak for PEG-6000 was observed at 66.4 ºC. Broad endothermic peak for rosuvastatin solid dispersions prepared by solvent evaporation method was observed at 228.1 ºC (Fig. 2a). Broad endothermic peak for rosuvastatin SDs prepared by fusion method was observed at 223.1 ºC (Fig. 2b). Sharp endothermic peak for rosuvastatin SDs prepared by lyophilization method was observed at 200.2 ºC (Fig. 2c). From the spectra it was observed that a little change in melting isotherm of rosuvastatin was observed indicating that there was no major interaction between drug and polymer.

The crystalline nature of rosuvastatin, PEG-6000 and solid dispersions prepared by fusion, solvent evaporation and lyophilization methods were determined by powder XRD and the results are given in Fig. 3. In diffractograms, all diffraction peaks were due to carrier crystals and no diffraction peaks of rosuvastatin calcium in the solid dispersions was observed. This indicates that the amorphous state of rosuvastatin calcium was formed in the solid dispersion system.

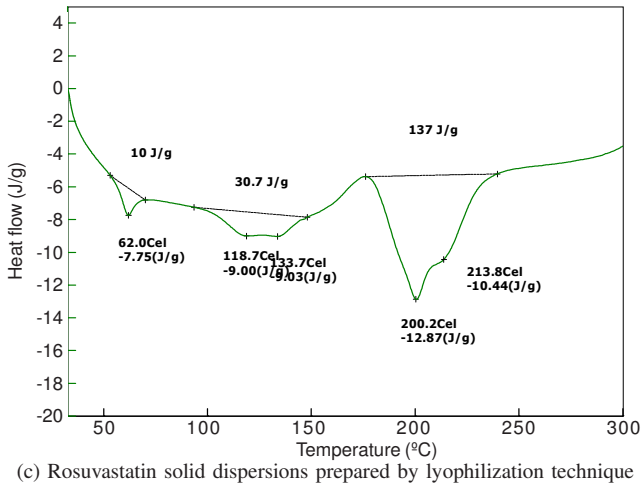
The dissolution studies of rosuvastatin as pure drug and its solid dispersions were performed in 6.8 pH phosphate buffer by using paddle method. The dissolution rate of all the solid



(a) Rosuvastatin solid dispersions prepared by solvent evaporation method

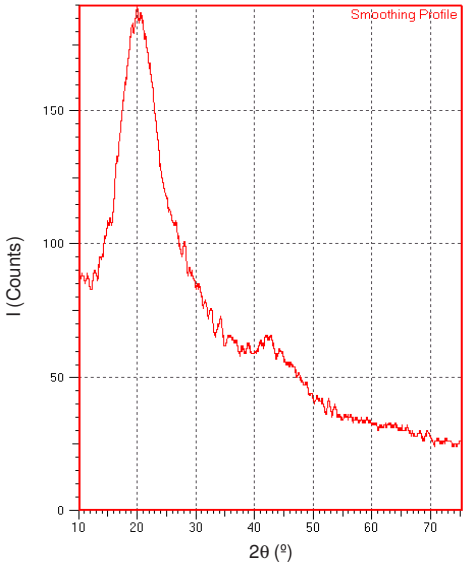


(b) rosuvastatin calcium solid dispersions prepared by fusion method

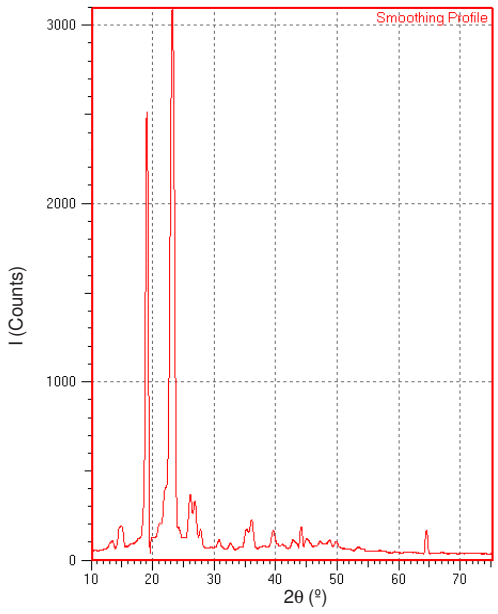


(c) Rosuvastatin solid dispersions prepared by lyophilization technique

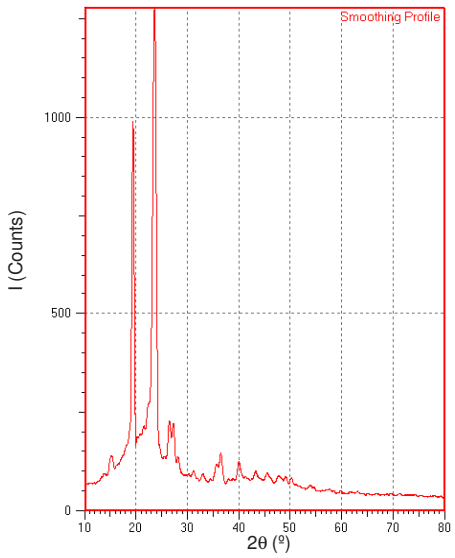
Fig. 2. Differential scanning calorimetry curves for rosuvastatin pure drug, PEG 6000 and solid dispersions prepared by various methods



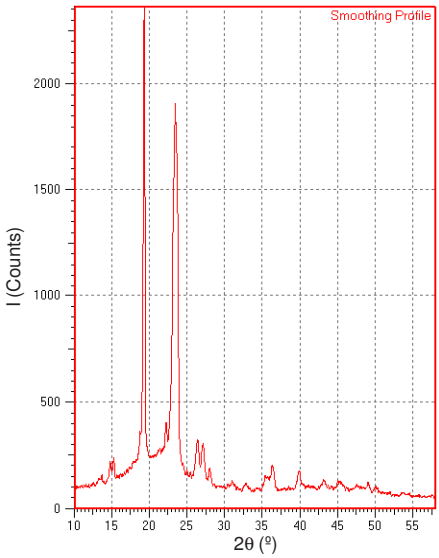
(a) Rosuvastatin calcium



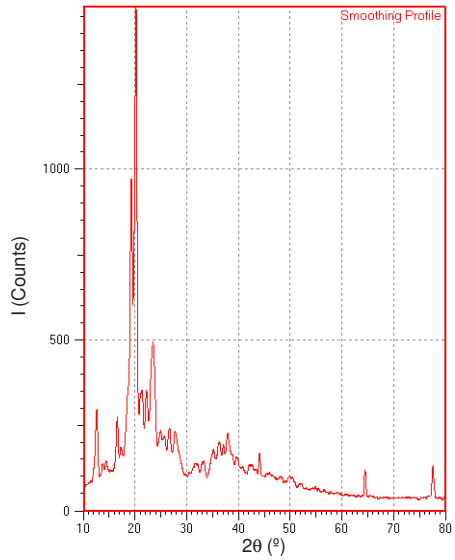
(b) PEG-6000



(c) Rosuvastatin solid dispersions prepared by solvent evaporation method



(d) Rosuvastatin solid dispersions prepared by fusion method



(e) Rosuvastatin solid dispersions prepared by lyophilization technique

Fig. 3. Powder X-ray diffraction (PXRD) patterns for rosuvastatin pure drug, PEG 6000 and solid dispersions prepared by various methods

dispersions were found to be rapid than compared to its pure drug rosuvastatin. The kinetics of drug release from all the dispersions followed first order. The R^2 values obtained for all the dispersions were linear for the first order plots (Table-3). Formulations RF4 and RS4 prepared by fusion method and solvent evaporation in drug to polymer ratio 1:2 was found to release the drug rapidly than the other solid dispersions prepared by physical mixing. Formulation RLP prepared by lyophilization method in drug to polymer ratio 1:2 was found to release the drug rapidly than the all solid dispersions. It was found that as polymer concentration increases the drug release was increased. The drug released from the formulation RLP was nine times greater than the pure drug which was due to porous and pluffy formation of dispersions by lyophilization.

The solid dispersions were further directly compressed as tablets. All the tablets were compressed under identical conditions to avoid processing variables. The ratio of drug and polymer were maintained constant while the superdisintegrant concentration was varied. The physical parameters such as weight uniformity, hardness, friability, drug content, dispersion time and wetting time were evaluated for prepared tablets as per the standards of official compendium (Tables 6 and 7).

The rate of dissolution of tablet formulations was rapid when compared to the marketed tablet of rosuvastatin. The rate of release from all the tablets followed first order kinetics (Tables 8 and 9). Formulations RFF2 and RSF2 prepared by fusion method and solvent evaporation with 20 % CCS was found to release the drug rapidly than the other tablet formulations. Formulation RLP1 prepared by lyophilization method with 20 % CCS was found to release drug instantly *i.e.*, 90 % of the drug released in less than 5 min was suitable as fast dissolving tablet. The drug release of tablet formulations in the presence of various superdisintegrants were in the order of CCS > SSG > PGS > mannitol.

TABLE-8
DISSOLUTION PARAMETERS OF ROSUVASTATIN TABLET FORMULATIONS

S. No.	Tablets	T_{50} (min)	T_{90} (min)	$DE_{30\%}$	First order K (min^{-1})	First order R^2
1	MF	28	>90	36.2	0.0124	0.945
2	RLP1	2.5	4	83.33	0.097	0.721
3	RFF_1	11	60	54.1	0.048	0.910
4	RFF_2	6	28	70	0.126	0.992
5	RFF_3	12	>90	46.2	0.026	0.973
6	RFF_4	9	56	55.8	0.046	0.991
7	RFF_5	28	>90	48.3	0.014	0.996
8	RFF_6	10	68	51.3	0.047	0.983
9	RFF_7	46	>90	23.8	0.006	0.965
10	RFF_8	28	>90	35.4	0.025	0.949

TABLE-9
DISSOLUTION PARAMETERS OF ROSUVASTATIN TABLET FORMULATIONS

S. No.	Tablets	T_{50} (min)	T_{90} (min)	$DE_{30\%}$	First order K (min^{-1})	First order R^2
1	MF	28	>90	36.2	0.012	0.965
2	RSF_1	9	60	53	0.074	0.922
3	RSF_2	7	39	68.3	0.050	0.994
4	RSF_3	13	>90	45.2	0.043	0.980
5	RSF_4	9	56	62.4	0.035	0.989
6	RSF_5	14	>90	32.6	0.018	0.991
7	RSF_6	9	72	44.4	0.033	0.992
8	RSF_7	57	>90	21.4	0.013	0.964
9	RSF_8	36	>90	30.5	0.014	0.950

The dissolution profiles of rosuvastatin pure drug and solid dispersions prepared by various techniques are given in Fig. 4, while the dissolution profiles of rosuvastatin marketed formulations and tablet formulations prepared by fusion, solvent evaporation and lyophilization methods are given in Fig. 5. Comparison of dissolution profiles of rosuvastatin tablets prepared from fusion method (RF 4), solvent evaporation

TABLE-6
PHYSICAL PARAMETERS OF ROSUVASTATIN TABLET FORMULATIONS

S. No.	Tablet	Weight uniformity (mg/tablet)	Friability loss %)	Hardness (kg/cm^2)	Drug content (mg)	Wetting time (s)	Dispersion time (min)
1	RLP1	149 ± 2	0.17	3.0	9.9 ± 0.1	10	1
2	RFF_1	146 ± 3	0.18	3.5	9.7 ± 0.3	20	2
3	RFF_2	148 ± 2	0.20	3.5	9.8 ± 0.2	14	2
4	RFF_3	149 ± 1	0.17	3.0	9.9 ± 0.1	23	3
5	RFF_4	148 ± 3	0.19	3.0	9.8 ± 0.2	17	2
6	RFF_5	151 ± 2	0.17	3.5	11 ± 0.2	34	3
7	RFF_6	147 ± 4	0.20	3.5	9.7 ± 0.3	21	2
8	RFF_7	148 ± 2	0.16	3.0	9.8 ± 0.2	31	3
9	RFF_8	147 ± 3	0.20	3.0	9.7 ± 0.3	27	3

TABLE-7
PHYSICAL PARAMETERS OF ROSUVASTATIN TABLET FORMULATIONS

S. No.	Tablet	Weight uniformity (mg/tablet)	Friability loss (%)	Hardness (kg/cm^2)	Drug content (mg)	Wetting time (s)	Dispersion time (min)
1	RSF_1	147 ± 3	0.14	3.0	9.7 ± 0.3	26	3
2	RSF_2	151 ± 3	0.20	3.0	11 ± 0.2	18	2
3	RSF_3	149 ± 1	0.20	3.5	9.9 ± 0.1	34	3
4	RSF_4	148 ± 2	0.20	3.5	9.8 ± 0.2	16	2
5	RSF_5	146 ± 4	0.20	3.0	9.7 ± 0.3	28	3
6	RSF_6	151 ± 2	0.15	3.0	11 ± 0.2	23	2
7	RSF_7	149 ± 2	0.20	3.5	9.9 ± 0.1	35	3
8	RSF_8	147 ± 3	0.20	3.5	9.7 ± 0.3	29	3

method (RS 4) using various superdisintegrants are given in Figs. 6 and 7, respectively.

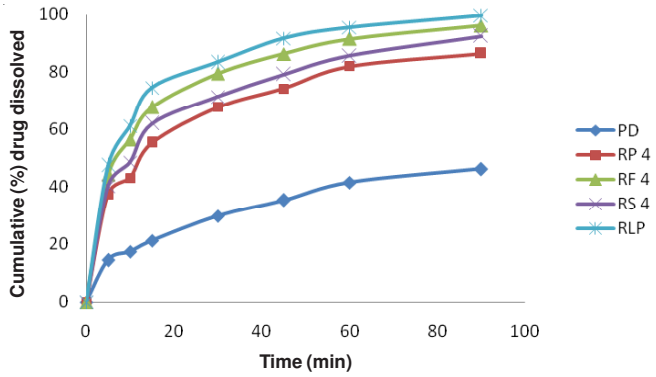


Fig.4. Dissolution profile of rosuvastatin pure drug and solid dispersions prepared by various techniques

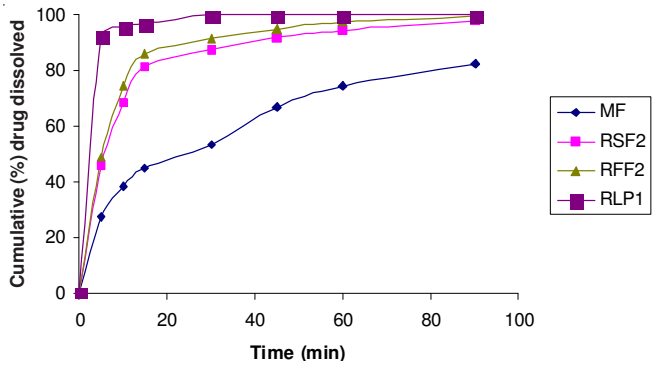


Fig. 5. Dissolution profiles of rosuvastatin fast dissolving tablets

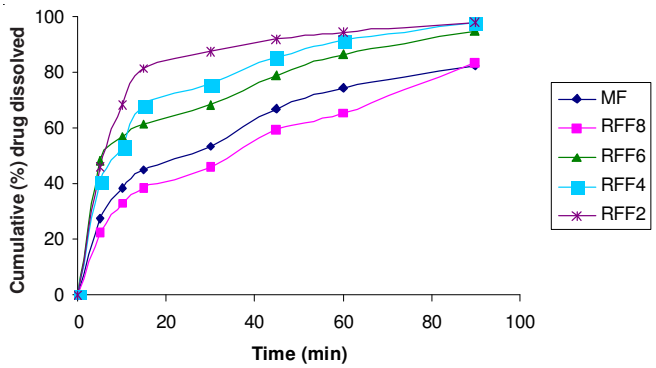


Fig. 6. Dissolution profiles of rosuvastatin fast dissolving tablets

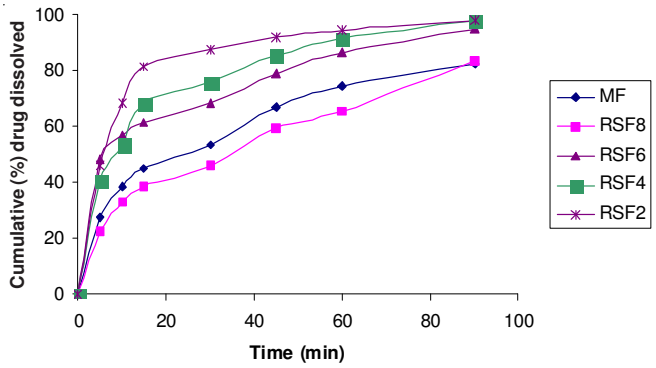


Fig. 7. Dissolution profiles of rosuvastatin fast dissolving tablets

Conclusion

The present study has shown that it is possible to increase the dissolution rate of poorly water soluble drug rosuvastatin by preparing solid dispersions with superdisintegrants like croscarmellose sodium, sodium starch glycolate, pregelatinized starch and mannitol. The solid dispersions exhibit faster dissolution characteristics as compared to plain drug. This was due to solubilizing effect of the carrier or crystallization of drug entrapped in molecular state by the carrier. Solid dispersions in the drug to polymer ratio 1:2 prepared by lyophilization (RLP) released the drug rapidly than the pure drug and other dispersions. Based on the study it may be concluded that rosuvastatin tablets (RFF2, RSF2 and RLP1) prepared with 20 % croscarmellose sodium as superdisintegrant showed rapid drug release when compared to marketed and other tablet formulations. The drug release of tablet formulations in the presence of various superdisintegrants were in the order of CCS > SSG > PGS > mannitol.

ACKNOWLEDGEMENTS

The authors express their gratitude to Matrix Pharma Ltd., Natco Pharma Ltd., Hyderabad for providing the gift samples. The authors are thankful to the management of Chebrolu Hanumaiah Institute of Pharmaceutical Sciences, Guntur for providing the facilities to carry out the research work.

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