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Formulation and In-Vitro Evaluation of Taste Masked Fast Disintegrating Tablet Rosuvastatin Calcium

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A B S T R A C T
The present study was aimed at developing oral disintegrating tablets (ODTs) of Rosuvastatin with enhanced solubility and rapid disintegration using a simple and cost-effective method. A suitable UV-Visible spectrophotometric method was established for drug analysis, with λmax identified at 220 nm in phosphate buffer pH 6.8. ODTs were successfully formulated by direct compression technique utilizing pregelatinized starch, banana powder, and corn starch as natural and conventional excipients. All prepared formulations were evaluated for hardness, friability, weight variation, and drug content, and the values were found to be within acceptable limits, confirming good quality and reproducibility. In vitro drug release studies indicated that formulation F3 exhibited the best performance, showing superior release characteristics compared to other batches. Notably, formulations containing banana powder demonstrated enhanced drug release compared to those with other excipients. Overall, the study successfully achieved its objective of formulating Rosuvastatin ODTs using minimal excipients and a simple manufacturing approach, ensuring improved solubility and patient compliance.
Keywords: Rosuvastatin, hardness, friability, weight variation, ODTs

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

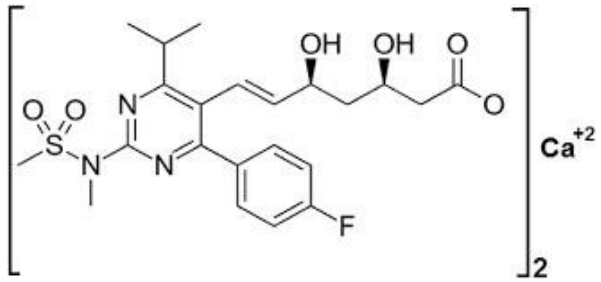

Fig.1: Rosuvastatin Calcium

Molecular Formula: $C_{22}H_{28}FN_3O_6S{\cdot}Ca$
Molecular Weight: 1001.14 g/mol (as calcium salt)
IUPAC Name: bis[(E)-7-4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethanesulfonamido)pyrimidin-5-yl-3,5-dihydroxyhept-6-enoic acid] calcium salt
ChemSpider ID: 24593361
Density: Not readily available
Melting Point: ~122 °C
Boiling Point / Vapour Pressure / Flash Point: Not typically applicable for pharmaceutical solids
Refractive Index: Not applicable
Polar Surface Area: ~151 Å²

LogP (Octanol/Water): ~2.0
Generic Name: Rosuvastatin calcium
Brand Names: Crestor, Rosulip, Rosuvas, among others
Drug Category: HMG-CoA reductase inhibitor (statin)
Indications: Hypercholesterolemia, mixed dyslipidemia, prevention of cardiovascular disease
Pharmacology: Inhibits HMG-CoA reductase, reducing cholesterol synthesis in the liver
Potency: One of the most potent statins; 10–40 mg/day can reduce LDL by 45–55%
Tolerability: Generally well tolerated; fewer drug interactions compared to some other statins
Contraindications: Active liver disease, pregnancy, breastfeeding
Adverse Effects: Myalgia, headache, abdominal pain, rare risk of rhabdomyolysis
Availability: Widely available globally in tablet form

2. Materils and Methods

Table 1: List of Materials Used

S.N	Materials	Source
1	Rosuvastatin	Supplied By Pharma Train
2	Banana powder	S.D. Fine Chemicals Limited, Mumbai
3	Pregelatinised starch	S.D. Fine Chemicals Limited, Mumbai
4	Corn starch	S.D. Fine Chemicals Limited, Mumbai
5	MCC	S.D. Fine Chemicals Limited, Mumbai
6	Pippermint flavour	S.D. Fine Chemicals Limited, Mumbai
7	Magnesium Stearate	S.D. Fine Chemicals Limited, Mumbai
8	Purified Talc	S.D. Fine Chemicals Limited, Mumbai

Table 2: List of Equipment's used

S.N	Equipment	Model/ Source
1	UV-spectrophotometer	LabindiaUv 3000+
2	Digital Balance	Scale-Tec
3	Digital pH meter	Systronic Electronics, Mumbai
4	Dissolution apparatus	Electrolab TDT-08L
5	Hot air oven	Tempo Instruments &Equipments, Mumbai
6	Hardness tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche Friabilator Electrolab, Mumbai
8	Tablet punching machine	Cadmach, Ahmedabad

Analytical Method Development
Preparation of 6.8 phosphate buffer:
27.22g of monobasic potassium phosphate was weighed and diluted up to 1000 ml to get stock solution of monobasic potassium phosphate. 8g Sodium hydroxide was weighed and diluted up to 1000ml to get 0.2M sodium hydroxide solution. 50 ml of the monobasic potassium phosphate solution was taken from the stock solution in a 200-mL volumetric flask and 22.4 ml of sodium hydroxide solution from stock solution of 0.2M sodium hydroxide solution was added and then water was used to make up the volume.
Determination of λ_{max} of Rosuvastatin in 6.8 phosphate buffer
Working standard: 100mg of Rosuvastatin was weighed and dissolved in 10ml Methanol and then make up to a volume of 100ml with 6.8 phosphate buffer it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 100µg/ml concentrated solution.
Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer it will give 10µg/ml concentrated solution.
This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as $\lambda_{max.}$
Standard Calibration curve of Rosuvastatin in phosphate buffer pH 6.8 solution:
Working standard:
100mg of Rosuvastatin was weighed and dissolved in 10ml Methanol and then make up to a volume of 100ml with 6.8 phosphate buffer it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 100µg/ml concentrated solution. From the dilution 1, Aliquots of 0.5, 1, 1.5, 2 and 2.5ml of solution were pipette out in to 10ml volumetric flask. The volume was made up to the mark with phosphate buffer pH 6.8. These dilutions gives 5,10,15,20, 25µg/ml concentrations of Rosuvastatin respectively. The absorbance was measured in the UV-visible spectrophotometer at 217 nm using distilled water as blank and graph of concentration versus absorbance was plotted. The absorbance data for standard calibration curves are given in the results table.
Preparation of Rosuvastatin Fast Disintegrating Tablets
Direct compression method:
Oral disintegrating tablets of Rosuvastatin were prepared by direct compression method. All the ingredients were powdered separately and passed through # 40 mesh sieve separately. The drug and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Then the other ingredients were mixed in geometrical order, in an inflated polyethylene pouch magnesium stearate and talc were added last and mixed for further two minutes and the tablets were compressed using 6-8mm flat round punches to get tablets of 150 mg weight.

***In vitro* dispersion time**

Tablet was added to 10 ml of pH 6.8 phosphate buffer solution at 37 ± 0.5° C. Time required for complete dispersion of a tablet was measured.

Dissolution study

In vitro dissolution of Rosuvastatin oral fast disintegrating tablets was studied in USP XXIII type-II dissolution apparatus (LABINDIA) employing a paddle stirrer at 50 rpm. 900ml of 6.8 phosphate buffer was used as dissolution medium. The temperature of dissolution medium was maintained at 37±0.5° C throughout the experiment. One tablet was used in each test. Samples of dissolution medium (5ml) were withdrawn by means of syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 217 nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Cumulative percent Rosuvastatin released was calculated and plotted against time.

3. Results and Discussion

Construction of Standard calibration curve of Rosuvastatin in 6.8 phosphate buffer: The absorbance of the solution was measured at 220 nm, using UV spectrometer with 6.8phosphate buffer as blank. The values are shown in table no 5. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 5 to 25 µg/ml.

Table 3: Standard Calibration graph values of Rosuvastatin in 6.8phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
5	0.139
10	0.275
15	0.432
20	0.553
25	0.702

Standard plot of Rosuvastatin by taking absorbance on Y – axis and concentration (µg/ml) on X – axis, the plot is shown fig No.3

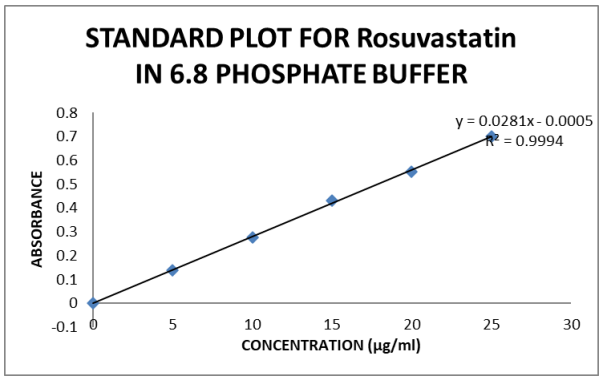

Fig.2: Standard calibration curve of Rosuvastatin in 6.8 phosphate buffer

Inference: The standard calibration curve of Rosuvastatin in 6.8 phosphate buffer showed good correlation with regression value of 0.999

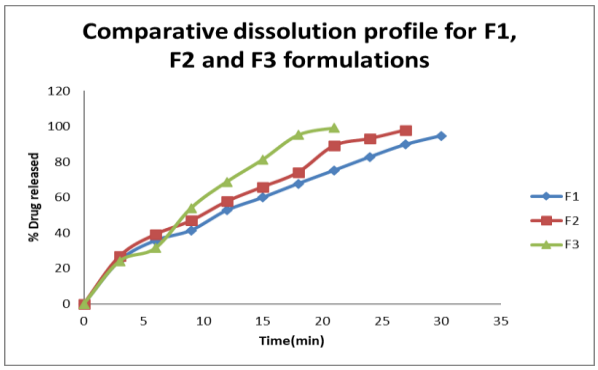

Fig.3: Comparative dissolution profiles for Banana powder used formulations

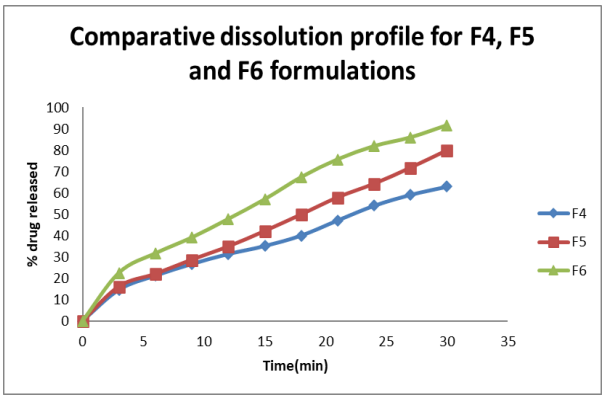

Fig.4: Comparative dissolution profiles for Pre gelatinized starch used formulations

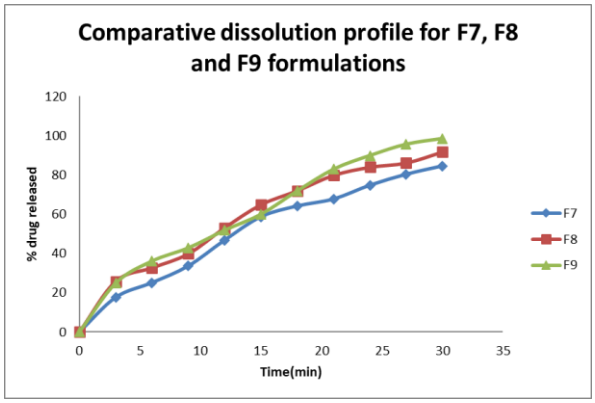

Fig.5: Comparative dissolution profiles for Corn starch used formulations

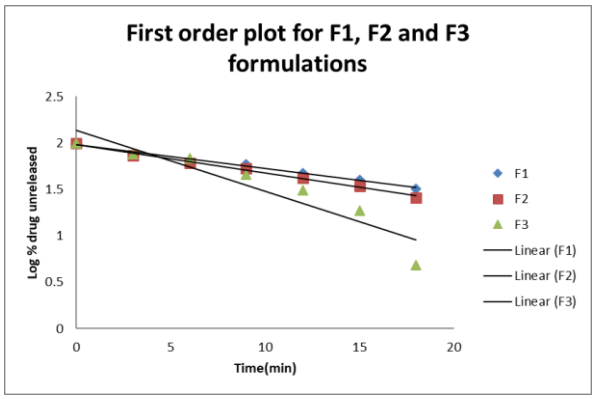

Fig.6: First order plot for Banana powder used formulations

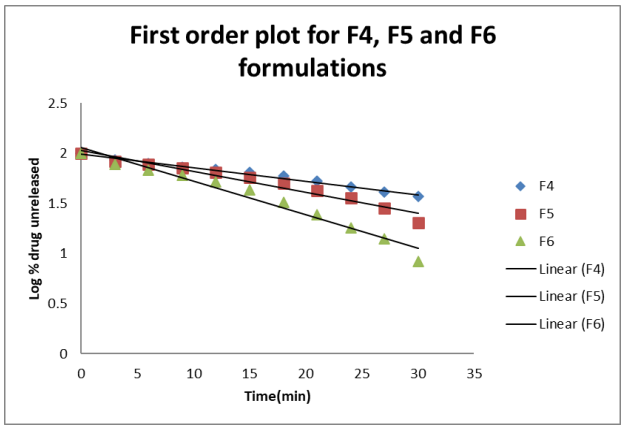

Fig.7: First order plot for Pre gelatinized starch used formulations

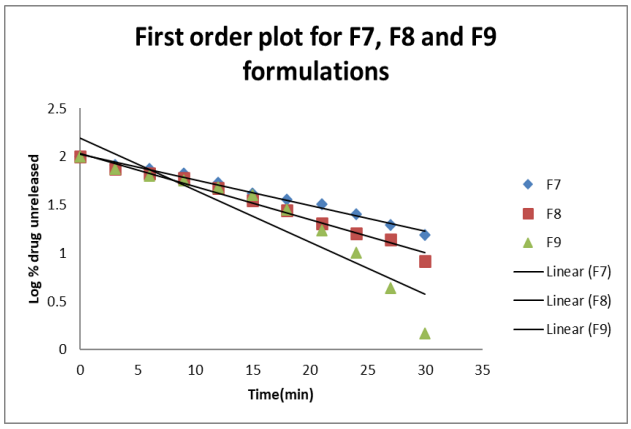

Fig.8: First order plot for Corn starch used formulations

Table 4: Formulae of Rosuvastatin Oral Disintegrating Tablets

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Rosuvastatin	20	20	20	20	20	20	20	20	20
Banana powder	10	20	30	-	-	-	-	-	-
Pregelatinised Starch	-	-	-	10	20	30			
Corn starch	-	-	-	-	-	-	10	20	30
MCC	115.5	105.5	95.5	115.5	105.5	95.5	115.5	105.5	95.5
Pipperment flavor	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Mg.Stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Total wt (mg)	150	150	150	150	150	150	150	150	150

Table 5: Pre compression studies of Rosuvastatin oral disintegrating tablets

Formulation Code	Bulk density (Kg/cm^3)	Tapped density (Kg/cm^3)	Cars index	Hausners ratio	Angle of repose (˚)
F1	0.43	0.50	14	1.16	33.12
F2	0.46	0.55	16.36	1.19	36.38
F3	0.48	0.53	9.43	1.10	29.12
F4	0.40	0.49	18.36	1.22	38.28
F5	0.44	0.51	13.72	1.15	33.87
F6	0.48	0.56	14.28	1.16	34.21
F7	0.45	0.49	8.16	1.08	37.91
F8	0.39	0.47	17.02	1.20	37.37
F9	0.43	0.51	15.68	1.18	34.67

Table 6: Post compression studies of Rosuvastatin oral disintegrating tablets

Formulation Code	% weight variation	Thickness (mm)	% friability	% Drug Content	Hardness (Kg/cm^2)	Disintegration time(Sec)	Dispersion time(Sec)	Water absorption ratio
F1	pass	3.93	0.15	99.83	3.2	46.3	32	78.65
F2	pass	4.21	0.23	101.42	3.4	39.5	27.3	81.34
F3	pass	3.86	0.17	98.99	2.9	30	23	84.43
F4	pass	4.12	0.32	99.35	3.6	60.83	42.6	87.11
F5	pass	3.94	0.44	100.28	3.2	53.6	36.1	89.56
F6	pass	3.79	0.14	99.94	3.4	23.8	17.3	91.57
F7	pass	4.02	0.26	101.62	3.3	40.3	28.1	92.76
F8	pass	4.10	0.35	98.86	3.5	30.8	23.5	93.96
F9	pass	3.97	0.22	100.32	2.8	24.5	16.3	98.01

Table 7: Dissolution profile

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1 N HCL
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	3, 6, 9, 12, 15, 18, 21, 24, 27 and 30minutes
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	220 nm

Note: 5 ml of sample was with draw at each time point & replace the same volume of 6.8 phosphate buffer preheated to 37± 0.5 ºC

Table 8: Dissolution data of various oral dissolving tablets of Rosuvastatin

TIME (min)	% Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
3	24.32	26.83	24.08	14.63	16.18	22.57	17.63	25.83	24.87
6	35.67	39.12	31.38	21.24	22.03	31.65	25.14	32.72	36.12
9	41.38	46.87	53.97	26.71	28.67	39.05	33.62	39.86	42.87
12	52.67	57.71	68.78	31.38	34.85	47.74	46.74	53.12	51.83
15	59.83	65.87	81.23	35.13	42.09	56.93	58.65	64.89	59.97
18	67.74	74.14	95.17	40.05	49.84	67.33	64.13	72.01	71.86
21	75.13	89.12	99.12	47.13	57.83	75.65	67.67	79.86	82.93
24	82.71	93.14		54.02	64.18	81.83	74.68	83.98	89.87
27	89.73	97.98		59.13	71.71	85.90	80.25	86.18	95.63
30	94.68			62.95	79.84	91.62	84.47	91.74	98.54

Table 9: Correlation Coefficient (r) Values in the Analysis of dissolution data as per Zero order and First order Models

Formulation Code	R^2 values	
	Zero order	First order
F1	0.967	0.989
F2	0.964	0.991
F3	0.979	0.875
F4	0.980	0.984
F5	0.992	0.955
F6	0.972	0.964
F7	0.965	0.99
F8	0.947	0.982
F9	0.970	0.876

4. Conclusion

Suitable analytical method based on UV-Visible spectrophotometer was developed for Rosuvastatin. λ_{max} of 220 nm was identified in 6.8phosphate buffer. Direct compression method was established to manufacture oral disintegrating tablets of Rosuvastatin. Oral disintegrating tablets of Rosuvastatin were successfully prepared using pregelatinized starch, banana powder and Corn starch. In the present study, oral disintegrating tablets were prepared by direct compression method. Evaluation parameters like hardness, friability, weight variation and drug content indicate that values were within permissible limit for all formulations. *In vitro* drug release study was carried out and based on the results; F-3 was identified as the best formulation among all the other formulations. The banana powder used formulation has shown better release profile than compared with other formulations. Thus, we are able to achieve our objective of preparing oral disintegrating tablets of Rosuvastatin with minimum excipients and simple method of manufacture and enhance the solubility of the drug.

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