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FORMULATION AND *IN-VITRO* EVALUATION OF TASTE MASKED FAST DISINTEGRATING TABLET OF ROSUVASTATIN CALCIUM

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ABSTRACT

Rosuvastatin calcium (RCa), an extensively studied antihyperlipidemic agent, has concerns regarding its oral bioavailability because it belongs to BCS class II. To overcome this problem the objective was set as to formulate a taste masked FDT of Rosuvastatin calcium. Taste masking was achieved using β-cyclodextrin in different ratios (1:0.5, 1:1, 1:1.5) with the drug. The tablets were made from the direct compression method. From the FTIR spectra of the developed formulation and the pure drug, there were no chemical interactions between the drug and the excipients. The optimal taste-masked formulation was achieved with a 1:1 calculated that Rosuvastatin calcium to β-cyclodextrin ratio should be 1, thus formulation F6 is found to be most effective because it successfully leap frog the taste problem. This formulation had an *in vitro* disintegration time of 22 seconds seemed to be tablet disintegration satisfactory for oral administration. When F6 formulation was tested in pH 6.8 buffer, the drug release *in vitro* amounts to 96.23% in 30 minutes. The result of the stability studies, done following ICH guidelines for six months, indicated that the formulation was stable. In conclusion, it can be seen that all the taste masked FDTs of Rosuvastatin calcium prepared and optimized in this study can be deemed as a hopeful methodology of enhancing the oral bioavailability of the drug.

Keywords: Hyperlipidemia, Rosuvastatin calcium, Statin, β-cyclodextrin, Bioavailability.

1) INTRODUCTION

Fast-dissolving tablets (FDTs) are designed to dissolve within seconds upon contact with the tongue, making them a convenient form of solid oral medication. Their unique structure characterized by high porosity, low density, and low hardness allows them to quickly break down, disperse, or dissolve in the mouth without the need for water. When saliva interacts with the tablet, it rapidly dissolves the outer layer, activating the ingredients and triggering the disintegration of the core, aided by super disintegrants. This process accelerates the release of the drug into the body.

FDTs are available in various formulations tailored to different groups, including children, adults, the elderly, and individuals with active lifestyles who may not have access to water while on the go. They are especially beneficial for patients who struggle with swallowing traditional tablets or capsules due to conditions like dysphagia or hand tremors. Additionally, FDTs offer pharmaceutical companies an opportunity to expand their product lines.

One of the key challenges with FDTs is managing the taste of bitter drugs, which can lead to poor patient compliance. Effective taste masking by minimizing or eliminating bitterness plays a crucial role in improving the palatability and overall acceptance of these oral dosage forms.

Rosuvastatin calcium, a member of the statin class of drugs, works by inhibiting the HMG-CoA reductase enzyme involved in cholesterol production. It helps lower levels of harmful LDL cholesterol and triglycerides while increasing beneficial HDL cholesterol. Typically used alongside dietary changes, rosuvastatin helps reduce the risk of cardiovascular events such as heart attacks and strokes.

2) MATERIALS AND METHODS :

Rosuvastatin calcium (cipla Ltd), Cros-povidon , croscarmellose sodium, sodium starch glycolate (JRS Parma Pvt Ltd), β-cyclodextrin (Signet Chemicals Co Ltd), Methanol (S.D. Fine chem. Ltd), Magnesium sterate (Emcure Pvt Ltd), Aerosils (S.D. Fine chem. Ltd), Sodium saccharin (S.D. Fine chem. Ltd), Microcrystalline cellulose (Signet excipient company Pvt Ltd).

Pre-formulation Studies

Organoleptic Properties: Straight descriptions of the drug's color, smell and flavors were made.

Solubility Studies: The solvents that were used are distilled water, phosphate buffer at 6.8pH, 0.1N hydrochloric acid and methanol. The extent of binding was determined by absorbance using a UV spectrophotometer at a particular λmax.

Melting Point: In the identification, the melting point of Rosuvastatin calcium was analyzed through the capillary method on a melting point apparatus.

Determination of λmax: Rosuvastatin calcium standard stock solution was prepared by dissolving 10 mg of Rosuvastatin calcium in 10 ml of methanol to obtain a concentration of 1,000 µg/mL. The solution was analyzed in a Shimadzu UV Visible spectrophotometer in the wavelength of range of 200-400 nm.

Preparation of Calibration Curve:

Standard Solution: An accurately weighed 100 mg of Rosuvastatin calcium was diluted to a total volume of 100 mL giving a concentration of 1,000 µg/mL in pH 6.8 phosphate buffer.

Stock Solution: From the standard solution a 1 mL was mixed with methanol to making a 10 µg/mL stock solution. For preparation of standard curve aliquots of 2, 4, 6, 8, and 10 mL from stock solution 50 µg/mL were taken on to 10 mL volumetric flask diluted up to mark in methanol to give concentration of 2, 4, 6, 8 and 10 µg/mL.

Absorbance Measurement: The absorbance of these solutions was then recorded at wavelength of 244 nm using UV spectrophotometer Shimadzu UV 3101, with methanol as blank.

Drug-Excipients Compatibility Studies (FTIR): About 0.1-1.0% of the sample was mixed with KBr powder to make a pellet for analysis between 4000 cm^{-1} and 400 cm^{-1} for compatibility study.

Synthesis of Drug H + β-Cyclodextrin Inclusion Compound

Different molar ratios of Rosuvastatin calcium and β-cyclodextrin (1:0.5, 1:1, 1:1.5) were used. A weighed portion of the physical mixture was further ground in a mortar and pestle. An agglomerated paste with the use of the kneading technique was prepared and the produced mass was dried, milled and classified to 44 mesh.

Table 1: Composition of various Inclusion Complexes:-

S.NO	Composition (Drug : β-Cyclodextrin)	Molar Ratio
1.	Rosuvastatin calcium+β-Cyclodextrin	1:0.5
2.	Rosuvastatin calcium+β-Cyclodextrin	1:1
3.	Rosuvastatin calcium+β-Cyclodextrin	1:1.5

Drug polymer complex of ratio 1:1 is having better taste masking enhancement.

Evaluation of the Drug + β-CD complex

Percentage Yield

Percentage yield is the amount of product formed as a particular percentage of the theoretical value. They decided for all batches of it.

Drug Content

For determination of drug content in the prepared complex, 100mg of the drug complex was accurately weighed and dissolved in 100 mL of methanol. The solution was then filtered and diluted as and when necessary and the amount of the drug was quantified by a Uv spectro photometer.

Investigating the Solubilization of a Drug & β-Cyclodextrin Inclusion Complex

The solubility of the drug was assessed using a 100 mL conical flask filled with water, incorporating different ratios of the drug and β-cyclodextrin (pure drug, 1:0.5, 1:1, and 1:1.5). The flasks were incubated at 50 rpm for 24 hrs in a rotary shaker. At these intervals samples were withdrawn, filtered and diluted with the same solvent. The amount of drug that was absorbed was subsequently determined through the use of a UV spectrophotometer.

Evaluation of taste masked ratio's: Taste masking techniques are applied to mask or overcome the bitter or unpleasant taste of active pharmaceutical ingredients/drug to achieve patient acceptability and compliance. Different volunteers are taken and asked to give the different taste of inclusion complex.

Following scale was used for the indicating taste masking values:

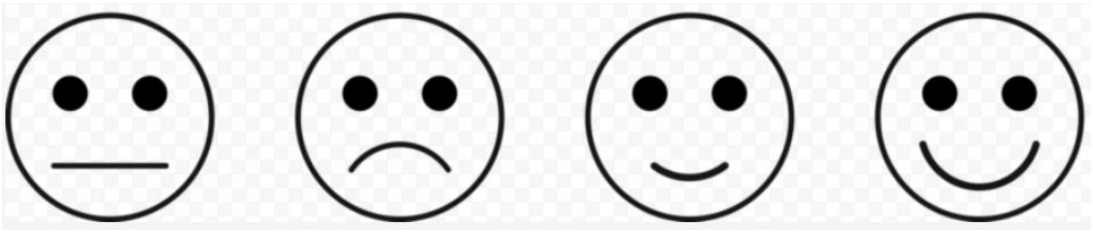

Figure 1: Taste masking scale

+ = very bitter,
++ = moderate to bitter,
+++ = slightly bitter,
++++ = tasteless/taste masked.

Pre compression parameters of fast dissolving tablets:

Angle of repose (θ) : The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

Angle of repose= $\tan^{-1}$ (h/r)

Where,

h = height of a pile (2 cm)

r = radius of pile base.

Bulk and Tapped density: The accurately weighed amount of sample was taken and recorded the volume of packing and tapped 100 times on a plane hard wooden surface and tapped volume of packing was recorded.

Bulk density=Weight of sample in gram/ volume occupied by the sample

Tapped density= Wt of sample in gram/Tapped volume

Carr's compressibility index (%) : The Carr's index is frequently used as an indication of the flowability of a powder. Percent compressibility of powder mix was determined by Carr's compressibility index.

% Compressibility = Tapped density-Bulk density/Tapped density×100

Hausner Ratio : Hausner Ratio is a number that is correlated to the flowability of a powder or granular material. Compressibility index has been defined by Hausner.

Hausner ratio= tapped density/ bulk density

Table 2: Pre compression parameters of FDTs Rosuvastatin

Batch	Angle of repose(θ)	Bulk density(gm/cm³)	Tapped density(gm/cm³)	Car's index(%)	Hausner ratio
RF1	23.08± 0.65	0.41±0.01	0.64±0.02	13.04±0.09	1.12±0.02
RF2	28.29± 0.42	0.43±0.14	0.73±0.34	12.71±0.52	1.28±0.03
RF3	27.55± 0.63	0.42±0.02	0.71±0.02	15.33±0.41	1.37±0.07
RF4	28.01± 0.9	0.45±0.18	0.59±0.41	14.37±0.25	1.42±0.02
RF5	25.12± 0.29	0.44±0.02	0.66±0.02	19.27±0.31	1.44±0.03
RF6	**24.74± 0.27**	**0.48±0.08**	**0.72±0.19**	**20.03±0.18**	**1.88±0.19**
RF7	29.28±0.73	0.45±0.4	0.58±0.06	16.02±0.34	1.50±0.6
RF8	30.08±0.41	0.46±0.21	0.62±0.2	18.48±0.5	1.63±0.03
RF9	36.68±0.13	0.46±0.7	0.70±0.18	19.52±0.71	1.71±0.6

Formulation Planning

A 5mg equivalent of the Drug + β-cyclodextrin inclusion complex was accurately weighed and placed in a mortar and pestle. Superdisintegrants were then added and blending was done. Lubricating property of the resultant product was achieved through the addition of magnesium stearate while aerosils were added as an antidust agent. Microcrystalline cellulose was used in this formulation to act as diluent meanwhile sodium saccharin was used for sweetening the formulation. In this study, the compressed tablets were made on direct compression using 9 mm round flat punches of optimized weight 150 mg.

Table 3: Formulation for Fast Dissolving Tablet of Rosuvastatin calcium.

INGREDIENTS	F1	F2	F3	F4	F5	**F6**	F7	F8	F9
Drug +β-CD Inclusion Complex equivalent to 5mg of drug	20	20	20	20	20	**20**	20	20	20
Cros-povidone	5	10	15	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	5	10	**15**	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	5	10	15
Magnesium stearate	1	1	1	1	1	**1**	1	1	1
Aerosils	0.5	0.5	0.5	0.5	0.5	**0.5**	0.5	0.5	0.5
Micro crystalline cellulose	119	114	109	119	114	**109**	119	114	109

Sodium saccharin	4.5	4.5	4.5	4.5	4.5	**4.5**	4.5	4.5	4.5
Total	150	150	150	150	150	**150**	150	150	150

Direct Compression Method The tablets were directly compressed by placing the formulated powder blend comprising the active ingredients and suitable excipients.

General Appearance: organoleptic evaluation included the evaluation of color, odour, taste and texture or shape as appropriate.

Weight Variation: Measuring known volume of mass according to IP standards, 20 tablets were weighed in bulk and the average weight calculated, with individual weights then being checked to see how far they deviated from the mean.

Table 4: limits of Average weight of filled tablet.

Average weight of the tablet	Percentage deviation
80mg or less	10
More than 80mg but less than 250mg	7.5
250mg or more	5

 Tablet Hardness: Using a Monsanto hardness tester, the hardness of three randomly selected tablets was measured and expressed in kg/cm².

 Tablet Thickness: Ten tablets from each batch were randomly selected, and their thickness was measured with a vernier caliper.

 Friability: A Roche friabilator was used to evaluate tablet friability. Pre-weighed tablets were subjected to 100 revolutions, and the percentage weight loss was calculated using the formula:

Friability (%)=(W1−W2W1)×100\text{Friability (\%)} = \left(\frac{W_1 - W_2}{W_1} \right) \times 100Friability (%)=(W1W1−W2)×100

Where:

W1W_1W1 = Weight of tablets before the test

W2W_2W2 = Weight of tablets after the test

Tablets should not lose more than 1% of their original weight.

 Estimation of Drug Content: Ten tablets were ground into a powder. A portion equivalent to one tablet was dissolved in methanol, diluted to 100 mL, filtered, and further diluted for analysis. The drug content was measured spectrophotometrically at 244 nm.

 In Vitro Disintegration Time: Measured using a disintegration test apparatus. One tablet was placed in each of the six tubes of the basket, which was immersed in a 37 ± 2°C water bath containing pH 6.8 phosphate buffer. Disintegration time was recorded in seconds.

 Wetting Time: A piece of folded tissue paper in a 5 cm petri dish containing 6 mL of water was used. The tablet was placed on the paper, and the time taken for complete wetting was recorded.

 In Vitro Dispersion Time: Three randomly selected tablets from each batch were evaluated for dispersion time by observing the time taken to uniformly disperse in pH 6.8 buffer.

 Water Absorption Ratio: A tablet was placed on a paper, and the time for complete wetting was measured. The wetted tablet was then weighed to calculate the water absorption ratio.

 In Vitro Drug Release Studies: Conducted using a USP type-II dissolution apparatus in a 900 mL 6.8 phosphate buffer. The apparatus operated at 50 RPM, maintained at 37 ± 0.5°C. Samples were collected at various intervals (1, 2, 5, 8, 10, 15, 20, 25, and 30 minutes), filtered through a 0.45 µm Whatman filter paper, and analyzed spectrophotometrically at 244 nm. Drug concentration was determined from the standard calibration curve and expressed as cumulative percent drug dissolved.

Medium : 6.8 phosphate buffer

Type of Apparatus : USP- XXIV (paddle type)

RPM : 50

Volume : 900ml

Run time ; 30 minutes

Temperature : 37±0.5°C

Time intervals : 1,2,5,8,10,15,20,25,30 minutes

 Stability Studies: Stability tests were conducted under different temperature conditions according to ICH guidelines for a duration of six months. The formulation was assessed for drug content and in vitro dissolution during this period.

Table 5: Post compression parameters of FDTs

Batch	Weight variation(mg)	Hardness(Kg/cm³)	Thicknes(mm)	Friability(%)	Drug content
RF1	0.52±0.66	3.29±0.07	4.41±0.03	0.21±0.25	89.04±0.05
RF2	0.57±0.41	2.72±0.15	4.21±0.02	0.26±0.02	90.23±0.03
RF3	0.60±0.02	4.20±0.08	4.49±0.08	0.72±0.22	92.30±0.09
RF4	0.61±0.04	3.23±0.16	4.34±0.02	0.51±0.04	91.88±0.39
RF5	0.73±0.19	4.14±0.02	4.32±0.15	0.43±0.66	94.27±0.34
RF6	**0.16±0.18**	**3.55±0.07**	**4.44±0.06**	**0.47±0.05**	**98.77±0.23**
RF7	0.44±0.67	3.50±0.11	4.01±0.09	0.62±0.08	92.14±0.21
RF8	0.53±0.54	3.77±0.05	4.00±0.05	0.55±0.48	90.47±0.42
RF9	0.75±0.59	4.34±0.08	4.50±0.18	0.59±0.34	95.12±0.16

TABLE 6: Post compression parameters of FDTs

Batch	In vitro disintegration time (sec)	Wetting time (sec)	In vitro dispersion time (sec)	Water absorption ratio (%)
RF1	32.11±0.22	22.33±0.03	66.05±0.02	78.08±0.12
RF2	35.32±0.79	32.34±0.12	50.12±0.04	80.02±0.08
RF3	40.10±0.12	20.97±0.34	74.03±0.08	82.21±0.15
RF4	33.15±0.28	35.18±0.05	61.34±0.04	79.21±0.18
RF5	42.09±0.36	34.33±0.06	55.21±0.06	84.02±0.11
RF6	**22.13±0.19**	**16.20±0.14**	**42.57±0.08**	**90.13±0.10**
RF7	44.08±0.27	24.75±0.41	59.45±0.06	71.50±0.06
RF8	54.35±0.61	23.80±0.44	70.21±0.05	81.53±0.07
RF9	61.04±0.18	34.99±0.50	81.04±0.09	80.92±0.14

Table 7: *In vitro* drug release studies

TIME IN MINUTES	RF1	RF2	RF3	RF4	RF5	RF6	RF7	RF8	RF9
0	0	0	0	0	0	0	0	0	0
1	20.15±0.14	26.38±0.13	32.15±0.11	22.37±0.15	26.34±0.05	**34.28±0.026**	15.26±0.20	24.56±0.29	21.14±0.15
2	30.24±0.28	33.49±0.17	30.2±0.03	32.48±0.09	31.22±0.23	**44.24±0.19**	20.33±0.12	30.74±0.41	34.27±0.29
5	35.29±0.8	44.28±0.26	52.14±0.15	39.52±0.60	39.27±0.2	**52.26±0.30**	29.25±0.19	43.27±0.34	40.78±0.22
8	49.26±0.04	53.26±0.5	62.45±0.21	44.26±0.27	49.12±0.20	**60.42±0.59**	42.25±0.77	56.42±0.45	48.26±0.27
10	51.41±0.31	65.32±0.03	69.28±0.45	51.48±0.53	53.3±0.44	**65.32±0.63**	49.02±0.54	61.87±0.87	53.86±0.92
15	58.55±0.75	68.21±0.49	75.65±0.57	59.21±0.48	65.47±0.78	**71.67±0.25**	54.66±0.68	69.89±0.10	59.24±0.07
20	61.27±0.06	70.28±0.09	79.37±0.12	60.48±0.23	70.35±0.50	**78.29±0.87**	58.05±0.56	72.37±0.20	65.26±0.33
25	78.24±0.05	81.19±0.05	87.42±0.43	76.24±0.08	81.26±0.63	**89.27±0.75**	72.34±0.98	82.18±0.76	82.48±0.52
30	91.24±0.57	94.28±0.43	92.11±0.41	90.25±0.39	92.48±0.21	**96.23±0.88**	87.26±0.92	91.27±0.96	95.28±0.98

3) RESULT AND DISCUSSION

3.1) Preformulation studies

A. **Organoleptic properties**

Table 8: Organoleptic properties of Rosuvatatin calcium

Particulate	Description
State	Crystalline
Colour	white
Odour	Odourless
Taste	Bitter

B. Melting point determination

Table 9: Melting point values of Rosuvastatin calcium

Reference Melting point	155- 160^{0}C
Observed Melting point	157^{0}C

Observation: The observed melting point for Rosuvastatin was 157ºC. This indicates the purity of drug sample.

c. Solubility results

Table 10: Solubility profile of Rosuvastatin calcium in different solvents.

SOLVENT	SOLUBILITY (µg/ml)
water	8±0.2
Methanol	983±0.97
HCL (0.1N)	510±0.5
Buffer (pH 6.8)	360±0.8

Observation: Rosuvastatin was found to be freely soluble in methanol, sparingly soluble in HCL, phosphate buffer (6.8) and poorly soluble in water

D. UV-Spectroscopy Analysis of Drug

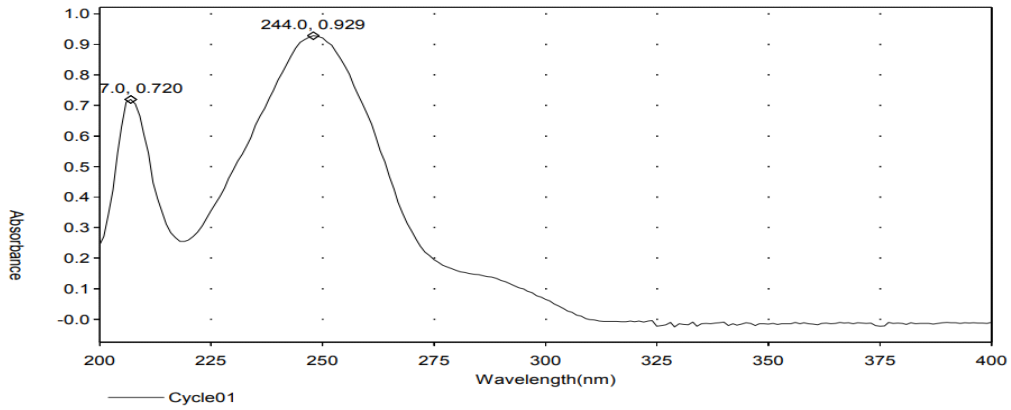

Figure 2: Determination of λmax

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Observation: Solution of rosuvastatin concentration of 10 ug/ml was scanned in the range of wavelength 200-400 nm. The absorption spectrum was found to be sharp and maximum at wavelength of 244nm.

E. Calibration curve

Table 11: Calibration curve data of rosuvastatin calcium

Concentration	Absorbance at 244nm
0	0
2	0.385±0.003
4	0.498±0.004
6	0.684±0.005
8	0.858±0.002
10	0.926±0.006

The data is presented as mean value ± S.D (n=3)

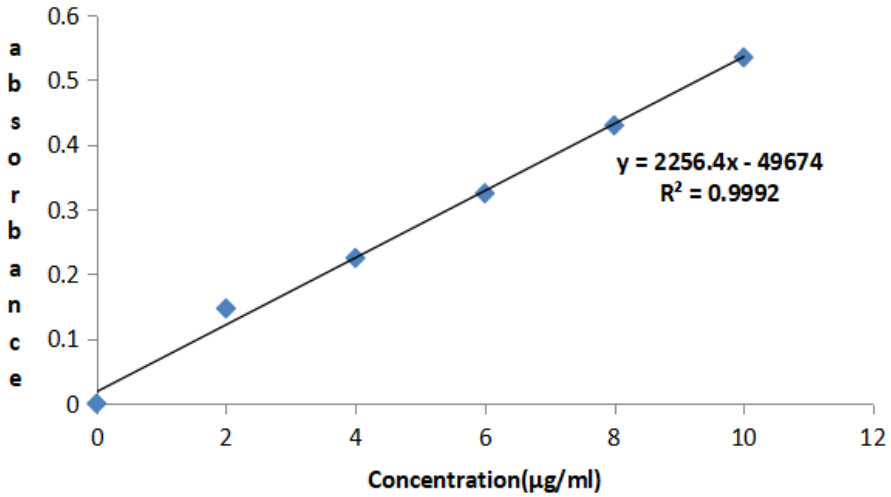

Figure 3: Calibration curve data of Rosuvatsatin

Observation: R2 value of rosuvastatin was found to be 0.9992 and indicate that it obeys beer's lambert's law in concentration range of 2-10 µg/ml. The standard graph of rosuvastatin showed good linearity with R2 of 0.9992, which indicates that it obeys "Beer- Lamberts" law.

F. Drug excipient interaction studies (compatibility studies) by FTIR spectroscopy

FTIR spectra for Rosuvastatin Calcium and excipients were observed in the transmission mode with the wave number region 4000- 500 cm^{-1}

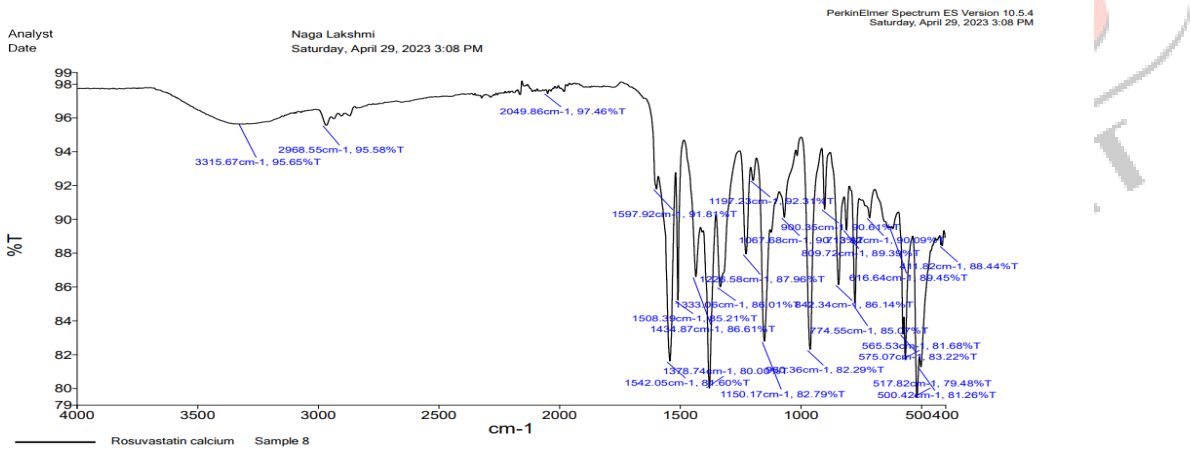

Figure 4: FTIR spectra of rosuvastatin calcium pure drug

Source Spectra Results	
Spectrum Name	Number of Peaks
Rosuvastatin Calcium	25

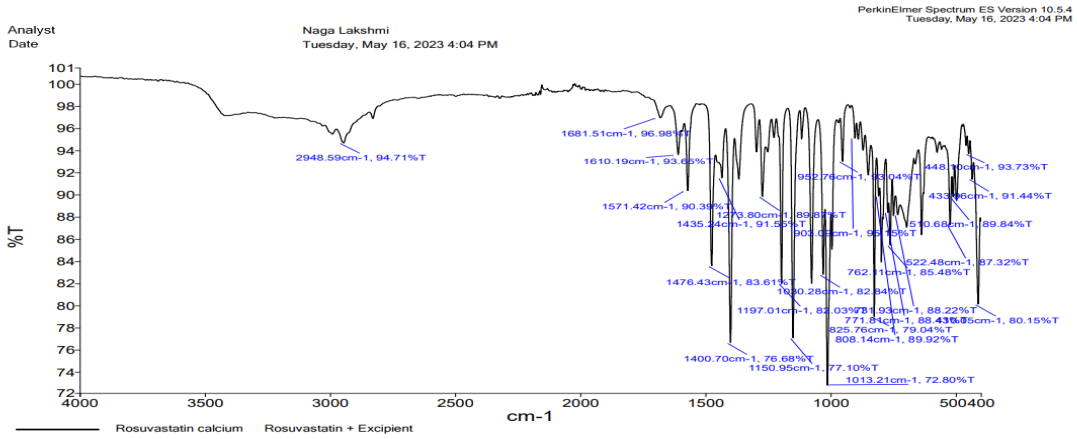

Figure 5: FTIR spectra of rosuvastatin calcium and excipients

Table 12: list of peak areas

List of Peak/Area Height		
Peak Number	**X (cm-1)**	**Y (%T)**
1	3315.67	95.65
2	2968.55	95.58
3	2049.86	97.46
4	1597.92	91.81
5	1542.05	81.6
6	1508.39	85.21
7	1434.87	86.61
8	1378.74	80
9	1333.06	86.01
10	1226.58	87.92
11	1197.23	92.31
12	1150.17	82.79
13	1067.68	90.13
14	960.36	82.29
15	900.35	90.61
16	842.34	86.14
17	809.72	89.39
18	774.55	85.07
19	713.82	90.09
20	616.64	89.45
21	575.07	83.22
22	565.53	81.68
23	517.82	79.48
24	500.42	81.26
25	411.82	88.44

Observation: The spectra of the drug and excipient revealed all of the RSV's distinctive peaks. There was no drug-lipid interactions and RSV crystallinity was retained.

Table 13: Evaluation of taste masked β-Cyclodextrin Inclusion Complex

Formula code	Polymer	Drug-polymer ratio	% drug content ±IC
IC1	β-cyclodextrin	1:0.5	5.23±0.19
IC2		1:1	6.49±0.36
IC3		1:1.5	7.52±0.49

Table 14: Solubility of β-cd complex

Solvent	Ratio	Solubility (µg/ml)
Water	Pure drug	7.9±0.6
	1:0.5	57±0.9
	1:1	90±0.57
	1:1.5	86±0.5

Figure 6 : In vitro dissolution profile of optimized FDTs

Table 15: Stability Data of optimized RF6 Rosuvastatin calcium Fast Dissolving tablet.

S.NO.	TESTS	Initial 0 months	After 6 months
1.	Dissolution Profile (Cumulative % drug release)	5 min- 52.26 10 min-65.32 30 min-96.23	5 min- 51.19 10 min- 64.21 30 min- 95.14
2.	Assay	98.77%	98.72%

Stability studies: There is no change in drug content and % drug release for the period of 6 months.

CONCLUSION

This study was conducted to prepare and optimized taste masked Rosuvastatin calcium fast disintegrating tablets. Taste masking was done by using β-cyclodextrin in different ratios (1:0.5,1:1,1:1.5). Inclusion complex in the ratio of 1:1 was shown better masking of taste. FTIR spectrum shows that drug has no interaction with the excipients. A total of nine formulations using three different superdisintegrants in three different ratios were designed and prepared by direct compression method.

Out of nine formulations RF6 was considered as optimized. As it exhibited rapid disintegration time (22 secs) and dissolution percentage drug release was found to be (96.23%) in 30 mints. Stability studies indicated that Rosuvatatin calcium was stable for 6 months. Hence the optimized taste masked Rosuvastatin calcium fast disintegrating tablets could be a better viable dosage form in the future.

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