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Research Article

COMPARATIVE STUDY OF NATURAL SUPERDISINTEGRATING AGENTS IN THE FORMULATION OF ROSUVASTATIN MOUTH DISSOLVING TABLETS

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ABSTRACT

The present work concerned with formulation and evaluation of Mouth dissolving tabletsof Rosuvastatin by using natural superdisintegrants like dehydrated banana powder, plantago ovata mucilage powder and orange peel powder. Rosuvastatin is an anti-hyperlipidemic drug a BCS-II drug. The solubility of the dug was increased by complexation. Inclusion complexes of Rosuvastatin with β-cyclodextrin have been prepared in the ratio of 1:1, 1:3 and 1:5. Preformulation studies like solubility, Melting point, drug- excipient interaction studies (FTIR) were conducted. Dissolution study with β-cyclodextrin- Rosuvastatin complex (1:3), has shown faster drug release. Hence 1:3 ratio was selected for formulating Rosuvastatin mouth dissolving tablets. Nine formulations were prepared using different concentrations of superdisintegrants by direct compression method. FTIR studies revealed that no interaction between drug and carrier. All the formulations were evaluated for precompression parameters and all the parameters were found to be within the pharmacopoeial limits. Post compression parameters like hardness, thickness, disintegration time, water absorption ratio, Dispersion time, Swelling Index and *in-vitro* drug release studies were performed. The formulation F6 containing 7.5% w/w of plantago ovata mucilage shown disintegration time of 15 sec and 97% of drug release within 30 minutes.Rapid disintegration of the Plantago ovata is due to its mucilaginous swelling activity (85.1%v/v) that creates enough hydrodynamic pressure for quick and complete disintegration of the tablet. An accelerated stability study on optimised formulation was performed and it was found to be stable. It can be concluded that Plantago ovata as Superdisintegrant showed better release than Banana and orange peel powder.

Key words: Inclusion complexes, Plantago ovata, Banana powder, orange peel powder

INTRODUCTION

The oral route of drug administration is the most popular and successfully route used for conventional delivery of drugs[1]. The tablet is the most widely used dosage form because of its convenience in terms of self-administration, low cost and ease in manufacturing[2]. However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets[3], which leads to poor patient compliance. "Fast Disintegrating Tablets (FDT)" tablets are novel types of tablets that disintegrate/ dissolve/disperse within 15 to 60 seconds. This characteristic advantage leads to their suitability for geriatric and pediatric patients at anytime, anywhere. It may be absorbed from the mouth, pharynx and esophagus as the saliva passes into the stomach and may produce rapid onset of action. Their growing importance was underlined recently when the European Pharmacopoeia adopted the term Fast disintegrating tablet. As a tablet that is to be placed in the mouth where it disperse rapidly before swallowing. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability and good stability make these tablets popular as a dosage form of choice in the current market.

Rosuvastatin ((E, 3R, 5S)-7-[4-(4-fluorophenyl)-2-[methyl (methyl sulfonyl) amino]-6-propan-2-ylpyrimidin-5-yl]-3, 5-dihydroxyhept-6-enoic acid) is an anti-hyperlipidemic drug which is a HMG CoA reductase competitive inhibitor. Rosuvastatin has 20.1% oral bio availability and not extensively metabolized. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing a dispersed drug that passes down into the stomach[4]. Banana and orange peel powder are considered to be good for treatment of gastric ulcer and diarrhea because they contain vitamin A[5]. Present day researches are looking for natural excipients as they believe that anything natural will be more safe and devoid of side effects. Advantage of natural excipients are low cost and natural origin free from side effects, biocompatibility & bio acceptance, renewable source, environment friendly processing, local availability, better patient tolerance as well as public acceptance, they comprise the natural economy by providing inexpensive formulation to people[6]. In the present work an attempt was made to formulate Mouth dissolving tablets of Rosuvastatin by using different natural superdisintegrants.

MATERIALS AND METHODS

Rosuvastatin obtained as gift sample from Aurobindo pharmaceutical Ltd. Hyderabad. β-cyclodextrin, methanol, Avicel l01 purchased in SD fine chemicals Mumbai, Bananas, plantago ovata, oranges purchased in local market of Ananatapuramu.

Preformulation studies[5]

FT-IR Studies: Fourier transform Infrared spectroscopy (FT IR Spectrometer Bruker ALPHA) was employed to determine the compatibility of drug with the excipients. About 2 mg of pure drug and formulation were dispersed in potassium bromide powder and pellets were prepared by applying 6 tons pressure.

The positions of FT-IR bands of important functional groups were identified and were mapped with FT-IR of drugs with formulation. The individual drug and the final formulation containing excipients were selected and scanned separately. Both the spectra were compared for confirmation of common peaks.

API characterization

Organoleptic properties: The drug sample was observed visually for the determination of its color using white and dark backgrounds and then the results were compared with official books and pharmacopoeias. The odor and taste of the drug sample results were compared with the official books and pharmacopoeias.

Determination of Melting point: The melting point of the drug was determined using capillary tube. One end of the capillary tube was sealed. The sample was filled and placed in the melting point apparatus[7,15]. The melting point of the drug was noted and the obtained observed value was compared with the literature value.

Solubility analysis: The solubility of API was determined by dissolving the highest unit dose of the drug in 250 mL of buffer adjusted between pH 1.0 and 8.0. 0.1N HCl, pH 4.6 buffer, pH 6.8 buffer and purified water were used for determination of solubility. Highest dose of the drug i.e., 400mg was dissolved in 250 mL of medium and was kept untouched for 6 hrs. Later on the insoluble drug was filtered off and the solution was analyzed by UV Spectroscopic technique.

Analytical method -Standard Calibration curve by Ultraviolet Visible Spectroscopy[8,16,17]: An accurately weighed amount of 100 mg of drug was transferred separately into 100 ml volumetric flask and then the volume was made up to the mark with 6.8 pH phosphate buffer.From the stock solution 0.6, 0.8, 1.0 ,1.2, 1.4, and 1.6 ml of sample was taken diluted up to 100 ml using 6.8 pH phosphate buffer in a 100 ml volumetric flask resulting in concentrations of 6, 8, 10, 12, 14, 16µg/ml solutions. These were analyzed at 242 nm and calibration curve was plotted taking concentration in µg/ml on X-axis and absorbance units on Y-axis.

FORMULATION

Preparation of Dehydrated Banana Powder[9,18,19,20]: Bananas were purchased from local market of Ananthapuramu. Peels were removed and fruits were sliced. Sliced pulp was washed with distilled water to remove water soluble contents. 0.2% w/w methyl paraben was added as preservative. Sliced pulp was ground in domestic mixer and dried in oven at 45°C for 24 hours to get constant weight and sieved through Sieve No. 80.

Preparation of plantago ovata mucilage[10]: Plantago ovate husk was purchased from local market of Anantapuramu. Husk was added to water and boiled for few minutes. This mixture was taken in eight folded muslin cloth and squeezed. Obtained mucilage dried in hot air oven at 45-50^{o}C. and passed through Sieve No. 80 stored indesiccators for further use.

Preparation of Orange peel powder[11]: Ripped orange peel was obtained from was purchased from local market of Anantapuramu.Peel was carefully washed and dried under shade for 24 h,further dried at 60 °C in a hot air oven.Dried fruit peel was cut into pieces and powdered byelectric grater. Powdered peel was further passed from sieveNo. 20.Peel powder, 200 g of was dissolved in 1 L of water and 1 g of citric acid was added to maintain acidic pH 2.This solution was subjected to reflux condensation at70 ºC for 6 h to extract pectin. The extractor thimble was a whatman cellulose thimble with 33 mm internal and 80 mmexternal length.Hot acid extract was pressed in a cheese cloth bag andthe concentrated juice was cooled to 4 ºC. Pectin wasprecipitated by ethanol: water (2:1 v/v) treatment followedby continuous stirring for 15 min and allowed to stand for 2h.Pectin coagulate was filtered through cheese cloth,washed with 95 % alcohol and pressed. Pressed pectin wasfurther dried to constant weight at 35 – 45 ºC. Hard pectincake was ground and passed through sieve No.60, stored indesiccators for further use.

Preparation of Inclusion Complex[12]: Inclusion complexes of rosuvastatin were prepared in the ratios, drug: β cyclodextrin (1:1, 1:3, 1:5) using solvent evaporation method. βcyclodextrin was used as a carrier to enhance the solubility of the dug. The accurately weighed quantity of the drug was taken in porcelain and solvent dichloro methane was added to completely solubilize the drug, slowly accurately weighed amount of β cyclodextrin was added by stirring, the stirring was continued until evaporation of solvent to get a solid mass. The obtained mass is subjected to drug release studies.

Solubility of Inclusion Complexes: Different ratios of inclusion complexes (1:1, 1:3, 1:5) were dissolved in 100 ml of water and shaken for 24 hrs. Obtained solution was analyzed by using UV Spectrophotometer at 252 nm.

Preparation of Mouth dissolving tablets[13,16,18,19,20,21,22]

Mouth dissolving tablets were prepared by direct compression method using the ingredients as shown in Table 1. The total tablet weight was 300 mg. All ingredients were weighed accurately according to the batch formula. Inclusion complexation of drug was mixed with Avicel 101. To this dehydrated banana powder (F1-F3), Plantago ovata powder (F4-F6), Orange peel powder (F7-F9) were added, mixed and passed through sieve No 60. After uniform mixing of ingredients, prior to compression Aspartame, Menthol, talc, magnesium stearate were added and mixed. The resulting uniform blends of composition per tablet as mentioned in Table 1 were directly compressed using 7 mm punch on 12 stations "B" Tooling Rotatory Tablet Compression Machine (Rimek) to produce convex faced tablets. The tablet press setting was kept constant for all formulations.

Table 1: Formulation of Mouth dissolving tablets of Rosuvastatin

S.No	Ingredients (mg)	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
1	Drug -β-Cyclodextrin inclusion complex	75	75	75	75	75	75	75	75	75
2	Avicel101	208.5	201	193.5	208.5	204	193.5	208.5	201	193.5
3	Dehydrated banana powder	7.5	15	22.5	-	-	-	-	-	-
4	Plantago ovata mucilage	-	-	-	7.5	15	22.5	-	-	-
5	Orange peel powder	-	-	-	-	-	-	7.5	15	22.5
6	Aspartame	3	3	3	3	3	3	3	3	3
7	Menthol	qs	qs	qs	qs	qs	qs	qs	qs	qs
8	Magnesium stearate	3	3	3	3	3	3	3	3	3
9	Talc	3	3	3	3	3	3	3	3	3
10	Total weight (mg)	300	300	300	300	300	300	300	300	300

Evaluation of Mouth dissolving tablets

Pre-compression Parameters[5,20,21,23, 24]

Bulk Density:A sample powder of API (25gm) was introduced in 50ml graduated cylinder. The volume of material was noted on graduated cylinder.

The bulk density was calculated by the formula given below:

$$Db = M / Vb$$

Where, M is the mass of powder, Vb is the bulk volume of the powder.

Tapped Density: It was measured by transferring a known quantity (25gm) of blend into a graduated cylinder and was placed on the tapped density apparatus. The initial volume was noted. The apparatus was set for 500, 750, and 1250 taps. The tapped density was determined as the ratio of mass of blend to the tapped volume.

$$Dt = M / Vt$$

Where, M is the mass of powder, Vt is the tapped volume of the powder.

Hausners Ratio: It is defined as the ratio of tapped density to the bulk density of the powder. It is calculated by the formula as follows:

$$HR = \text{Tapped density} / \text{Bulk density}$$

Carr's index(CI): Carr's index calculated as follows:

$$CI = DT\text{-}DB/DT \times 100$$

Where, DT is Tapped density of powder, DB is the Bulk density of the powder. It is expressed in percentage.

Angle of repose: A funnel was kept vertically in stand at a specified height above a paper placed on the horizontal surface. The bottom was closed and the weighed quantity of API was filled in funnel. The funnel was opened to release the powder on the paper to form a smooth conical heap. The height of the heap was measured using the scale. A border heap was marked circularly and its diameter was measured at four points. The average diameter was calculated and radius was found out from it. The angle of repose was calculated using the formula:

$$\tan \theta = h/r$$

Where, θ = Angle of repose, h = height of the cone, r = Radius of the cone base.

Post compression parameters[5,16,18,20,22,23,24]

Average weight: Twenty tablets from each batch were individually weighed and their average weight was calculated. From the average weight of the prepared tablets, the standard deviation was determined.

Hardness: The force required to break the tablet in a diametric compression was determined by using Pfizer hardness tester.

Thickness: Thickness was determined using Vernier calipers and the mean thickness value was calculated.

Friability: Friability test was done by Roche friabilator. Tablets were weighed and were subjected to combined effect of attrition and shock by utilizing a plastic chamber that resolve at 25 rpm dropping the tablets at distance of 6 inch with each revolution. Operated for 100 revolutions, the tablets were dusted and reweighed. The percentage friability was calculated as

$$\% \text{ Friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

Drug content[14]**:** DrugContent tablets was done in phosphate buffer pH 6.8 to find out the amount of drug present in one tablet. For this 5 tablets were crushed and wt. of powder equal to one tablet was taken. Then dissolved in phosphate buffer pH 6.8 in a 100 mL volumetric flask. Volume was made up to 100 mL. The resulting solution was filtered and absorbance was measured at 242 nm.

Disintegration time[5]**: S**ix tablets of each formulation were used to determine disintegration time. Phosphate buffer pH 6.8 was used as a disintegration medium and temperature was maintained at 37±2ºc.

Wetting time[14]**:** A tablet was carefully placed on the surface of the tissue paper in the petri dish at 25°C. The time required for water to reach the upper surface of the tablets and to completely wet them was noted as the wetting time.

Swelling Index and Water absorption ratio[14,18,19,24]:Swelling Index and Water absorption ratio was determined by the method described by Milind et al.

***In vitro* dispersion time**[14]:Tablet was added to 10 ml of phosphate buffer solution (pH 6.8) at 37±0.5°C. Time required for complete dispersion of a tablet was measured.

***Invitro* drug release studies**[9]**:** The dissolution was carried out using 900 ml of 6.8 P^H phosphate buffer as dissolution medium (USP, II paddle method) in Electrolab TDT L100 apparatus. The temperature of the dissolution medium was maintained at 37± 0.5^0C and the paddle was rotated at 75 rpm. 5 ml samples were withdrawn. The same volume was immediately replaced with the fresh media. The samples withdrawn were filtered, diluted and estimated spectrophotometrically at 242 nm. The cumulative amount of the drug released at each interval was calculated by using standard graph of Rosuvastatin.

Stability studies[25]**:** Stability studies at 40° C ±2°C /75% ± 5% RH was carried out for 3 months for optimized Rosuvastatin Mouth dissolving tablets (F6). The Rosuvastatin Mouth dissolving tablets were observed for colour, friability, hardness, disintegration time and *invitro* drug release for 3 months respectively.

RESULTS AND DISCUSSION

Figure 1: FTIR spectrum of Rosuvastatin

Figure 2: FTIR Spectrum of Optimised formulation

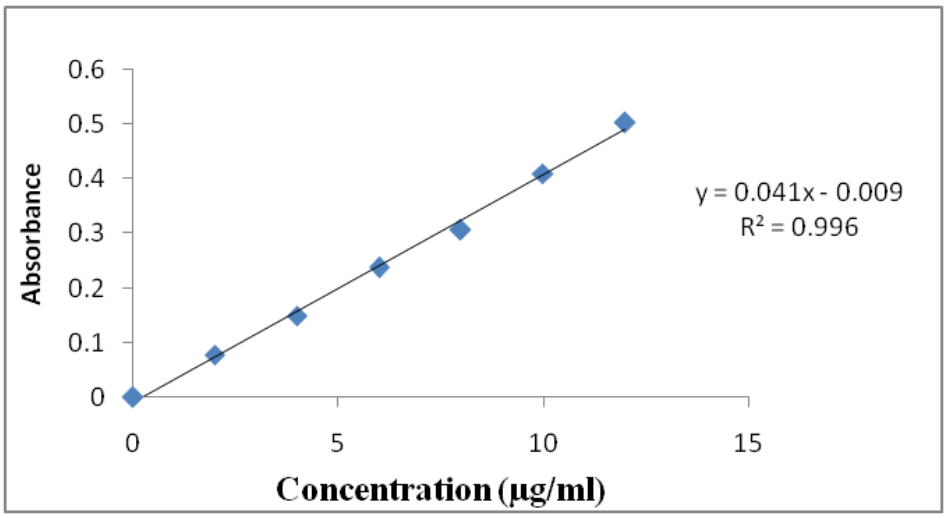

Figure 3: Calibration curve of Rosuvastatin

Table 2: Evaluation of Pre-compression parameters

Formulation code	Bulk density (g/ml)	Tapped density(g/ml)	Hausners ratio	Carr's index (%)	Angle of repose(°)
F1	0.437±0.15	0.482±0.25	1.102±0.52	9.33	22.51±0.11
F2	0.463±0.23	0.512±0.13	1.105±0.23	9.57	26.23±0.23
F3	0.445±0.14	0.499±0.45	1.121±0.45	10.85	24.16±0.51
F4	0.445±0.45	0.502±0.12	1.128±0.52	11.35	27.40±0.18
F5	0.463±0.23	0.514±0.23	1.110±0.14	9.92	25.21±0.45
F6	0.442±0.23	0.479±0.25	1.083±0.35	7.72	25.41±0.22
F7	0.431±0.25	0.464±0.21	1.076±0.47	7.11	23.26±0.19
F8	0.412±0.13	0.462±0.39	1.121±0.21	10.82	24.00±0.12
F9	0.422±0.14	0.461±0.19	1.092±0.15	8.45	25.21±0.64

All values are expressed as mean ±standard deviation (n=3)

Table 3: Evaluation of Post-compression parameters

Formulation code	Average Weight (mg)*	Hardness (kg/cm²)***	Friability (%)***	Thickness (mm)**	Drug content (%) ***	Disintegration time (sec) **	Wetting time (sec)***
F1	297±0.15	4.42±0.15	0.25±0.05	3.65±0.05	97.12±0.25	30±0.21	41±0.15
F2	300±0.23	4.50±0.21	0.31±0.12	3.69±0.02	98.04±0.96	23±0.33	40±0.25
F3	299±0.31	4.67±0.15	0.29±0.02	3.72±0.03	99.61±1.58	19±0.27	43±0.22
F4	299±0.16	4.43±0.15	0.28±0.23	3.69±0.02	98.02±1.19	22±0.19	44±0.69
F5	299±0.41	4.33±0.25	0.27±0.21	3.72±0.02	99.28±0.11	20±0.12	35±0.12
F6	**299±0.31**	**4.32±0.12**	**0.26±0.22**	**3.66±0.01**	**99.28±0.12**	**15±0.44**	**32±0.11**
F7	298±0.16	4.12±0.31	0.27±0.61	3.65±0.02	98.24±0.31	32±0.14	42±0.25
F8	298±0.22	4.50±0.34	0.28±0.12	3.71±0.03	97.23±0.56	29±0.11	46±0.33
F9	299±0.21	4.61±0.15	0.29±0.22	3.71±0.05	98.31±0.12	25±0.22	44±0.27

All values are expressed as mean ±standard deviation (n=20*, n=6**, n=10***)

Table 4: Evaluation of Post-compression parameters

Formulation code	*In-vitro* dispersion time* time (sec)	Water absorption Ratio (%)*	Swelling Index(%v/v)*
F1	29.7±0.21	74.2±0.12	72.9±0.14
F2	25.1±0.23	78.3. ±0.15	76.1±0.19
F3	22.2±0.24	81.1±0.16	79.8±0.14
F4	23.1±0.31	86.5±0.14	78.1±0.13
F5	20.9±0.35	89.7±0.13	80.3±0.04
F6	**17.8±0.34**	**92.8±0.14**	**85.1±0.15**
F7	35.8±0.26	68.9±0.15	65.4±0.16
F8	32.9±0.24	72.4±0.12	68.1±0.16
F9	28.4±0.21	75.6±0.12	72.6±0.15

All values are expressed as mean ±standard deviation (n=3*)

***Invitro* drug release studies**

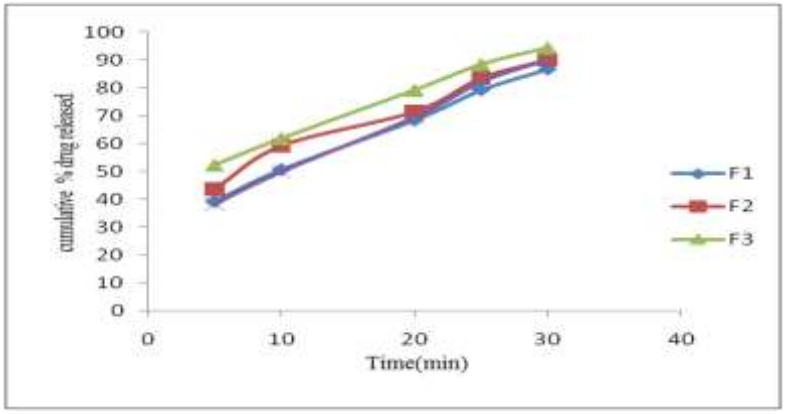

Figure 4: % drug release of rosuvastatin from formulations F1-F3

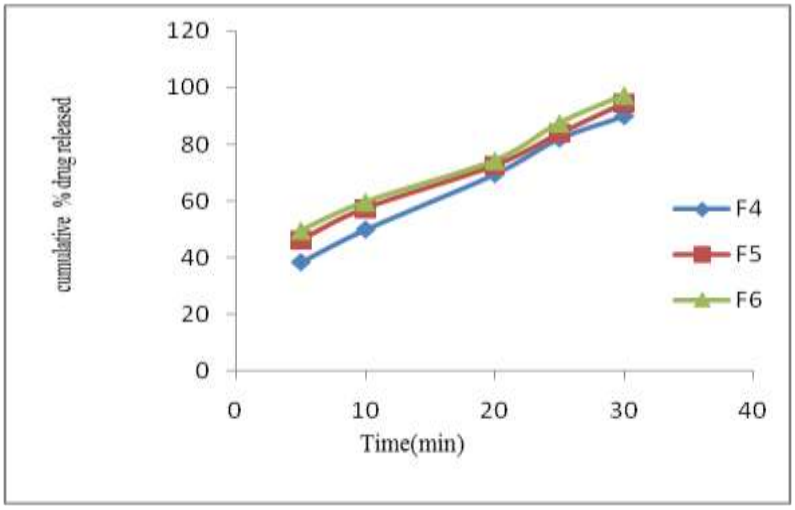

Figure 5: % drug release of rosuvastatin from formulations F4-F6

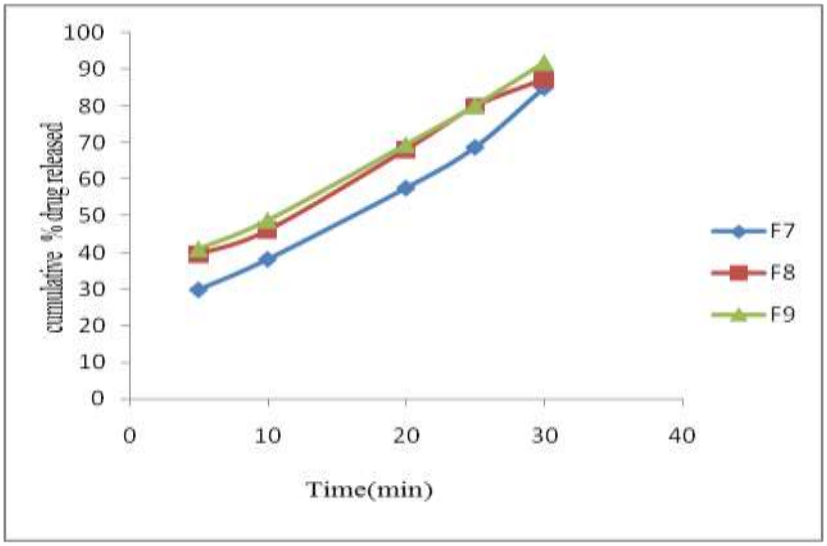

Figure 6: % drug release of Rosuvastatin from formulations F7-F9

Table 5: Stability studies of Optimised Formulation (F6)

Optimised formulation (F6)					
Months	**Colour**	**Friability**	**Hardness**	**Disintegration time**	**%Cumulative drug release**
1	White	0.26±0.04	4.42±0.2	15±0.2	97.13±0.3
2	white	0.27±0.04	5.20±0.5	15±0.3	96.95±0.1
3	white	0.27±0.20	5.13±0.1	16±0.1	96.15±0.1

DISCUSSION

On comparison of FT-IR spectrums it was observed that there is no appearance of new peaks and shifting of already existed peaks (Figure 1 & 2). Drug and the excipients were found to be compatible. By studying organoleptic properties it was found that Rosuvastatin was white in colour with metallic taste, amorphous powder. The melting point of Rosuvastatin was determined by capillary tube method and it was found to be 153°C. Solubility studies showed that the Rosuvastatin was soluble in methanol & dichloro methane and insoluble in water. The prepared solution of Rosuvastatin was scanned for maximum absorbance in UV double beam spectrophotometer (shimadzu) in the range of 200-400 nm, by using 6.8 pH phosphate buffer as blank. The lambda max of the drug was found to be 242nm. Calibration curve of Rosuvstatin in 6.8 pH phosphate buffer was estimated (shown in figure 3) and its R^2 value was found to be 0.9967. 1:1 inclusion complex has shown 65%, 1:3 has shown 89% and 1:5 has shown 73% of solubility. Dissolution study with β-cyclodextrin- Rosuvastatin complex (1:5), has shown faster drug release. Hence 1:3 ratio was selected for formulating the Rosuvastatin mouth dissolving tablets. Precompression parameters were evaluated and tabulated in table 2. The bulk density and tapped density for the formulations were calculated. The values ranges from 0.412 to 0.463 and 0.461 to 0.514 respectively. The angle of repose was in the range of 22.51º to 27.40º shows that blend have good flow property. The compressibility index of pre compressed blends was in the range of 8.45% to 11.35%. Hausners ratio in the range of 1.076 to 1.128. Density differences between the formulations were negligible and the density values of formulations were well within limits, indicated that the prepared dry blend were non-aggregated and indicated good free flowing property. The post compression parameter studies were performed and results were tabulated in table 3 & 4. Tablets obtained were of uniform weight (due to uniform die fill), with acceptable variation as per IP specifications i.e. below 7.5%. The thickness of tablets was found to be 3.65 to 3.72 mm which shows uniform thickness due to uniform die fill. In all the formulations, the friability values were less than 1% and meet the Indian pharmacopoeia (I.P) limits. The hardness results were in the range of 4.12 to 4.67 kg/cm². The drug content for all formulation was found to be in the range of 97.12-99.28% which was within the acceptable limits. All the formulations dispersed within 32.9 sec and disintegrated with in 32sec. Formulations with Plantago ovata as Superdisintegrant showed faster disintegration than Banana powder, orange peel powder formulations. *Invitro* drug release studies were performed and shown in Figure 4, 5 and 6. The formulations which contain dehydrated banana powder (F3) as super disintegrating agent has shown 94% of drug release, formulations with Plantago ovata mucilage (F6) as super disintegrating agent has shown 97% of drug release and the formulation with orange peel powder (F9) as super disintegrating agent has shown 91% drug release at the end of 30min. order of release (Plantago ovata> banana powder> orange peel powder). Plantago ovata due to its mucilaginous swelling activity (85.1%v/v) and water absorption ratio (92.8%) created enough hydrodynamic pressure for quick and complete disintegration of the tablet. All formulations have shown highest R^2 for zero order. Hence drug release follows Zero order. Stability studies for the optimised formulation F6 were carried out by storing the selected formulation at 40° C ±2°C /75% ± 5% RH for three months tabulated in table 5. For every one month interval the tablets were analyzed for the colour, friability, hardness, and disintegration time and *invitro* drug release. The increase in the disintegration time was observed in the tablets after 3 months of study. This may be due to increase in hardness of tablets after storage of 3 months. However there is no significance change in all the parameters.

CONCLUSION

The oral disintegrating tablets of Rosuvastatin were prepared successfully by direct compression method using Plantago ovata

mucilage powder, Banana powder and Orange peel powder Super disintegrants. The *In-vitro* drug release studies showed that the formulation F6 containing 7.5% Plantago ovata mucilage powder showed 97% of drug release at the end of 30min and disintegrated within 15sec may be due to mucilaginous swelling activity that creates enough hydrodynamic pressure for quick and complete disintegration of the tabletand after 3 months of accelerated stability studies showed 96% drug release at the end of 30 min and disintegrated within 16 sec. The isolated Plantago ovata mucilage powder exhibits faster drug dissolution and improved bioavailability, thereby helping in effective therapy and improved patient compliance.

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