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Original Article

Post Marketing In-Vitro Relative Analysis of diverse brands of rosuvastatin calcium accessible in urban Karachi (Pakistan)

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ABSTRACT

Having a place with a class of medication known as "statins" Rosuvastatin calcium is an orally manufactured lipid lowering drug. It is another HMG-CoA reductase inhibitor that diminishes LDL and choestrol level. An amazing advantage hazard profile of Rosuvastatin makes it increasingly worthy to treat dyslipidemia. This statin is generally recommended in mix with different medications to treat hyperlipidemia. The point of this investigation was to set up pharmaceutical comparability among the brands accessible in Karachi Pakistan. Two distinct brands of Rosuvastatin Calcium proportional to Rosuvastatin tablets 5mg were incorporated. Six quality control parameters: weight variation, thickness test, hardness test, friability test, disintegration test, and dissolution test were performed through BP and USP monographs. All the test performed in this investigation were found under the limits. The examination recommends that both the brands of Rosuvastatin accessible in Karachi, Pakistan meet the determination for quality control investigation and were equivalent to each other.

Keyword: Rosuvastatin, comparative analysis, formulations, lipid lowering agent, HMG-CoA

INTRODUCTION

Rosuvastatin calcium, orally controlled, manufactured lipid lowering drug having a place down with a gathering of medications known as "statins." It works by bringing down the measure of cholesterol made by the liver. Raising "HDL" cholesterol, alongside the decrease in "LDL" cholesterol and triglycerides and diminishes the danger of coronary illness and anticipates strokes and heart attack.(1)Rosuvastatin has a place with another age of methane-sulphonamide pyrimidine and N-methane sulfonyl pyrrole-substituted 3, 5-dihydroxy-heptenoates.(2) Being another HMG-

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CoA reductase inhibitor, Rosuvastatin lessens low thickness lipoprotein and cholesterol level in plasma which is finished by restraining the generation of Mevalonate, which is a principle venture in the cholesterol combination. The site of activity is liver where Rosuvastatin represses 3-hydroxy-3methylglutaryl coenzyme A reductase. One of the fundamental driver of cardiovascular issues is elevated cholesterol level ; and these dangers can be deflected by the utilization of medications that brings down the cholesterol level in plasma.(3).It is a white or practically white hygroscopic powder which is uninhibitedly solvent in methylene chloride, marginally dissolvable in water and for all intents and purposes insoluble in anhydrous ethanol, it is accessible in the qualities of 5mg, 10mg, 20mg and 40mg.(1) Rosuvastatin is a totally manufactured compound having half life of 20 hours.(4)It is a hydrophilic compound because of the closeness of methane sulphonamide group(5). It isn't altogether used by cytochrome P450 chemicals. Rosuvastatin to a great extent in unaltered structure disposed of by both liver and kidney.(6) The pharmacokinetic properties of rosuvastatin are not changed in patients with gentle to direct hepatic impairment.(7), In at present available statins, rosuvastatin is the best at bringing down LDL-C, with decreases of up to 63% revealed with an every day portion of 40mg. (8) Food admission diminishes the rate of ingestion of rosuvastatin by 20% however not the degree of assimilation. Around 90% of rosuvastatin is protein bound for the most part to albumin. The oral bioavailability of rosuvastatin is 20%. (2)

MATERIAL AND METHOD

Various tests were performed to direct a similar investigation on two brands of Rosuvastatin Calcium 5mg tablets (RAST AND ROVISTA) accessible in market. Both of these brands were tried for the accompanying physical parameters.

1. **Weight Variation Test** was performed on 20 tablets utilizing Electronic Balance Shimadzu ATX224 and saw that the 20 singular tablet's weight must exist in the BP/USP limit that NMT 02 tablets out of 20 tablets should cross ± 10% deviation. It is an important test parameter guaranteeing the weight consistency of tablets
2. **Thickness Test** was performed on 10 tablets of each brand on Pharma test PTB 311E (511 E). This test was performed to check the compaction along with punching of tablets.
3. **Hardness Test** were performed on 10 tablets of each brand on Pharma test PTB 311E (511 E). Hardness was performed to check the quality of the tablet and it must be sufficiently hard to hold up under the limit of NLT 4 Kg.
4. **Friability Test** was performed on 10 tablets of each brand utilizing Curio 2020 friabilator at 25 rpm/minute for 4 minutes to check the devastating quality, topping and cover of the tablets. It ought to be with in the point of confinement i.e NMT 1%.
5. **Disintegration Test** was performed on 06 tablets of each brand utilizing Curio 2020. The mechanical assembly has 6 cylinders and tablets were put in each container of bin rack which is additionally set in a 1000ml measuring glass containing water kept up at 37ºC, deterioration time was recorded and it is the time wherein no particles of any tablet left in the assembly.
6. **Dissolution Test** was perofrmed on 06 tablets of each brand utilizing Dawn DIS-09. It demonstrates that when tablet or container in the medium dissolute with perceived volume, the measure of dynamic fixing discharged from an oral strong dose structure ought to be inside as far as possible. USP Apparatus 2 (paddle) was utilized and as indicated by criteria that every tablet ought to be totally broken down following 30 minutes at 50 rpm and 37ºC. The disintegration tests of the tablets were resolved on Spectrophotometer at λmax 240nm and it ought to be NLT 75% after end of time.

RESULTS AND DISCUSSION

According to criteria 20 tablets of both the brands were weighed. We have applied BP limits for weight variation which are as: < 80mg, 10% difference is allowed, 80mg – 250mg, 7.5% difference is allowed and > 250mg, 5% difference is allowed. In this study the weights of both the brands were falling under 80mg – 250mg which allows 7.5% difference. The mean, standard deviation, upper control cutoff points and lower control breaking points of both the brands were determined and illustrated in the table 2. The standard deviation of both the brands were inside the authority limits. The thickness of two brands were additionally checked and their mean and standard deviation, upper control points of confinement and lower control cutoff points of both the brands were determined and illustrated in the table 4. The thickness may change because of contrast in granulation and weight connected to the tablets, the speed of the tablet pressure just as mileage on the length of punches. Thickness ought to be controlled inside ±5% variety of standard. Thus the thickness of both brands were found under the limit. In Pharmaceutical industries hardness testing is done to test the breaking point and structural integrity of tablets under transportation, handling before usage. It can affect the disintegration of the tablet. The crushing

strength of 4-8Kg for uncoated tablets were acceptable. In our study both the brands were film-coated and their hardness was illustrated in the tables 5. It is the tendency of the tablets to crumble, chip or break following compression. The tablets must be hard enough that they do not break in their packed from but must be friable enough to disintegration in the GI tract. From each brand 10 tablets were weighed before testing friability then placed in friabilator for 4 minutes (100 rpm) and then tablets were dedusted and weighed again to find the difference or % loss of the weight of tablets. Friability of both the brands were tested and found under the limit which was NMT 1.0% and shown in the table 6. Prior to dissolution, the solid dosage form which is tablet and capsule must disintegrate into small pieces first. It must be measured under standard conditions. The test is valuable as a quality confirmation of instrument. The orally regulated medication must show crumbling to accomplish great assimilation of dynamic fixing. For uncoated tablet the USP necessitates that tablet must break down inside 15 minutes. for film-coated tablets the USP necessitates those tablets must crumble inside 30 minutes. The tablets of both the brands were film-coated and their breaking down time falls under the farthest point and showed in the table 7. Dissolution testing is a necessity for all the solid oral dosage forms. For dissolution testing the industrial reference are the United States Pharmacopeia (USP) Apparatus I (bushel) and USP Apparatus 2 (paddle). Immediate, modified and extended release are usually tested in standard dissolution baths with USP 2 paddles. For oral dosage forms that are prone to floating, USP 1 (baskets) would generally be required. Here USP Apparatus 2 (paddle) is used and according to criteria each tablet should be completely dissolved in 30 minutes at 50 rpm and at 37ºC. The dissolution samples of the tablets were determined on Spectrophotometer at λ_{max} 240nmand it should be NLT 75% after completion of time. The results of the brands are illustrated in the table 8.

CONCLUSION

Rosuvastatin calcium is an extensively used antirhyperlipidimic drug. This research study concluded that all the results of both brands of rosovastatin calcium analyzed, i.e. Rovista and Rast were within the limits as mentioned in USP monograph all the results indicated that both brands are pharmaceutical equivalent.

Conflicts of interest: none
Acknowledgement: none

Table 1: Specification of drugs with batch no.

No.	Name of product	Serial No.	Code No.	Batch No.
1.	ROVISTA	ROV-01	Brand 1	244F17
2.	RAST	RAS-02	Brand 2	100

Table 2: Statistical Weight Variation Table

No.	Serial No.	Batch No.	Average weight (mg)	S.D	Upper Limit (UCL)	Lower Limit (LCL)
1.	ROV-01	244F17	190	1.414	194	186
2.	RAS-02	100	145	3.281	156	134

Table 3: Weight Variation test

No.	Serial No.	Batch No.	Results (g)	BP/USP Limits	Deviation from BP/USP
1.	ROV-01	244F17	0.190	7.5%	All passed
2.	RAS-02	100	0.145	7.5%	All passed

Table 4: Statistical Thickness

No.	Serial No.	Batch No.	Average thickness (mm)	S.D	Upper Limit (X+3S)	Lower Limit (X-3S)
1.	ROV-01	244F17	4.25	0.023	4.319	4.181
2.	RAS-02	100	3.55	0.056	3.718	3.382

Table 5: Statistical Hardness test

No.	Serial No.	Batch No.	Average hardness (mm)	S.D	Upper Limit (X+3S)	Lower Limit (X-3S)
1.	ROV-01	244F17	10.55	1.26	14.33	6.77
2.	RAS-02	100	6.99	1.50	11.49	2.49

Table 6: Friability test

Serial No.	Batch No.	Friability (%)	Limits	Comments
ROV-01	244F17	0.08%	Less than 1.0%	Within limits
RAS-02	100	0.15%	Less than 1.0%	Within limits

Table 7: Disintegration test

Serial No.	Batch No.	Disintegration time (min)	Limits	Comments
ROV-01	244F17	01 minute 02 sec	NMT 30 minutes	Within limits
RAS-02	100	02 minutes 10 sec	NMT 30 minutes	Within limits

Table 8: Dissolution test

No.	Serial No.	Batch No.	MeanDissolution at 30 min	Acceptance criteria	Comments
1.	ROV-01	244F17	99.90%	NLT 75%	Within limits
2.	RAS-02	100	97.97%	NLT 75%	Within limits

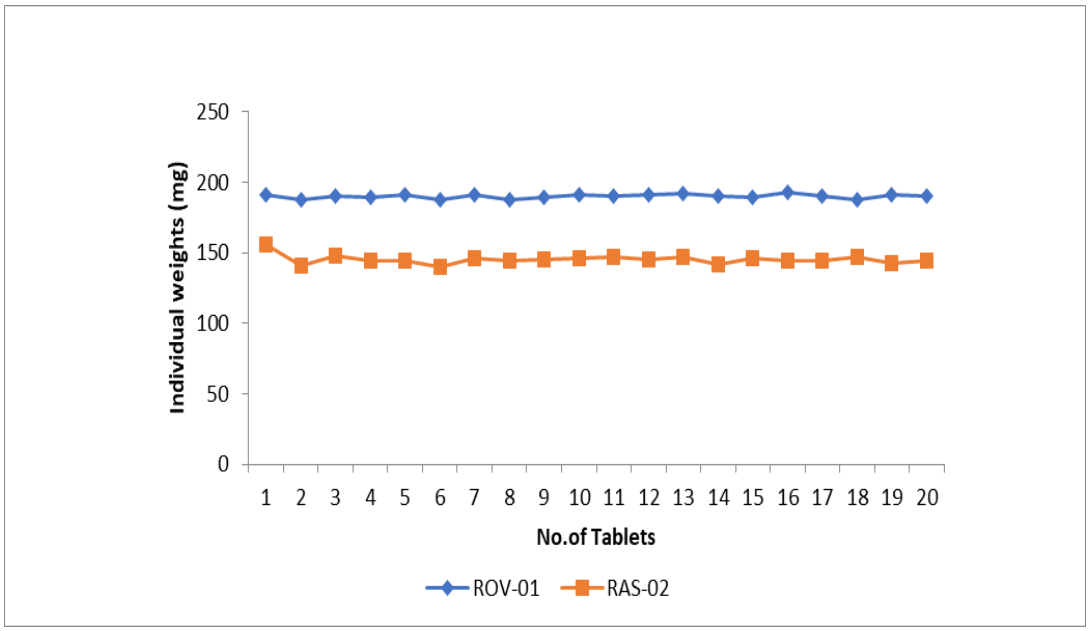

Figure 1 Graphical representation of weight variation of both brands

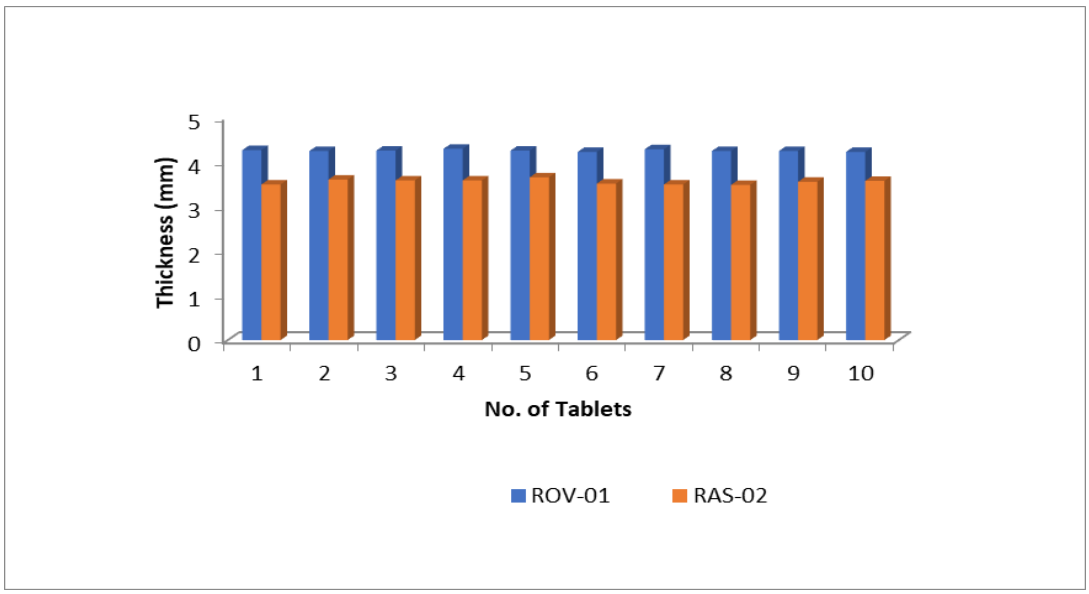

Figure 2 Graphical representation of thickness of both brands

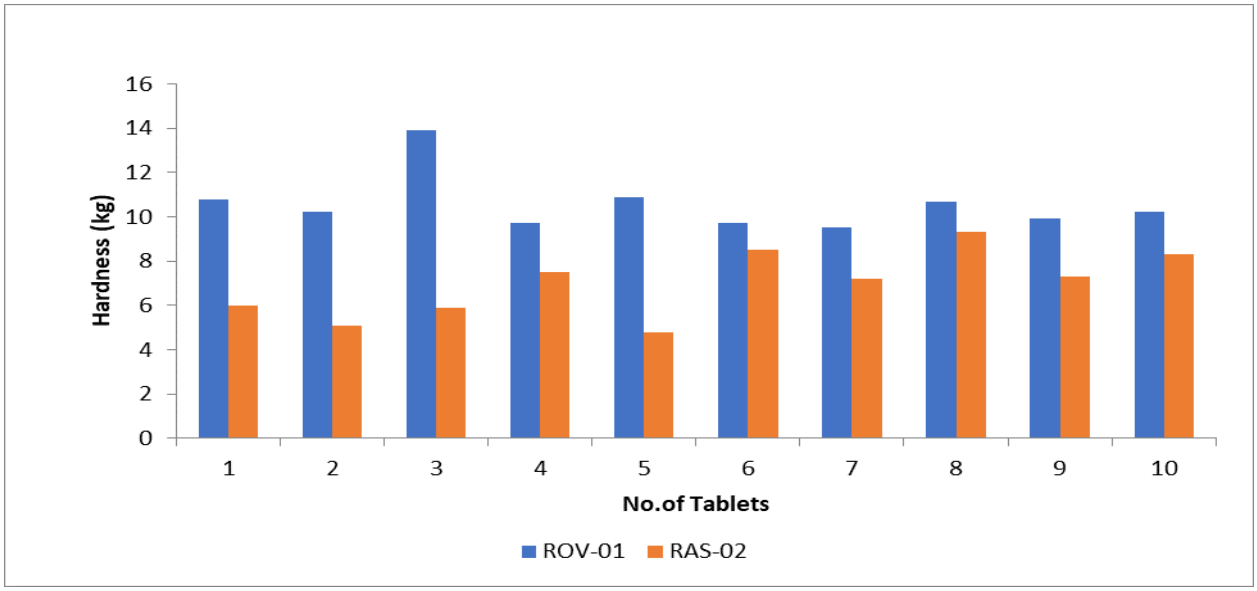

Figure 3 Graphical representation of hardness of both brands

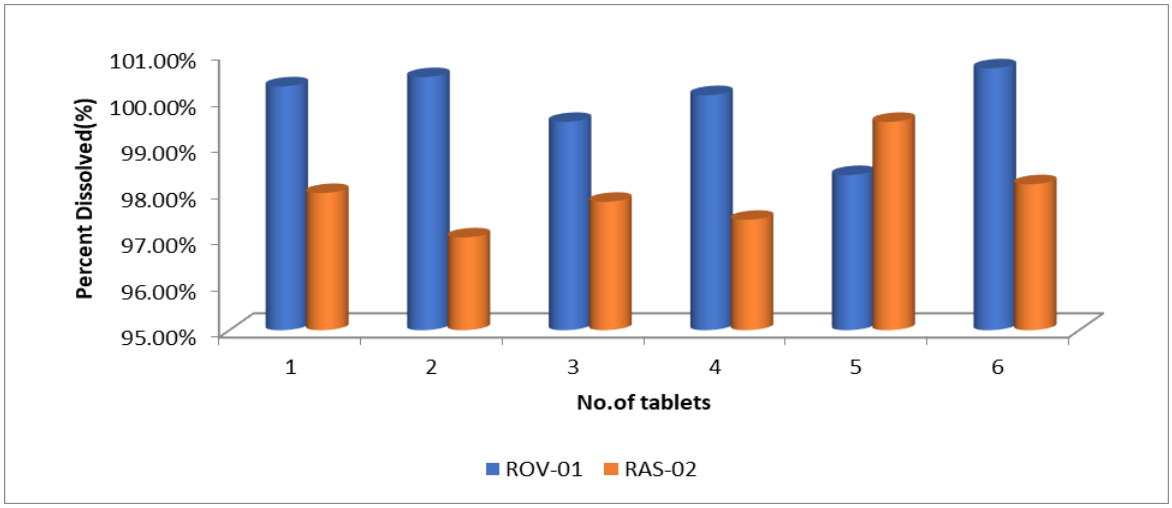

Figure 4 Graphical representation of dissolution test of both brands

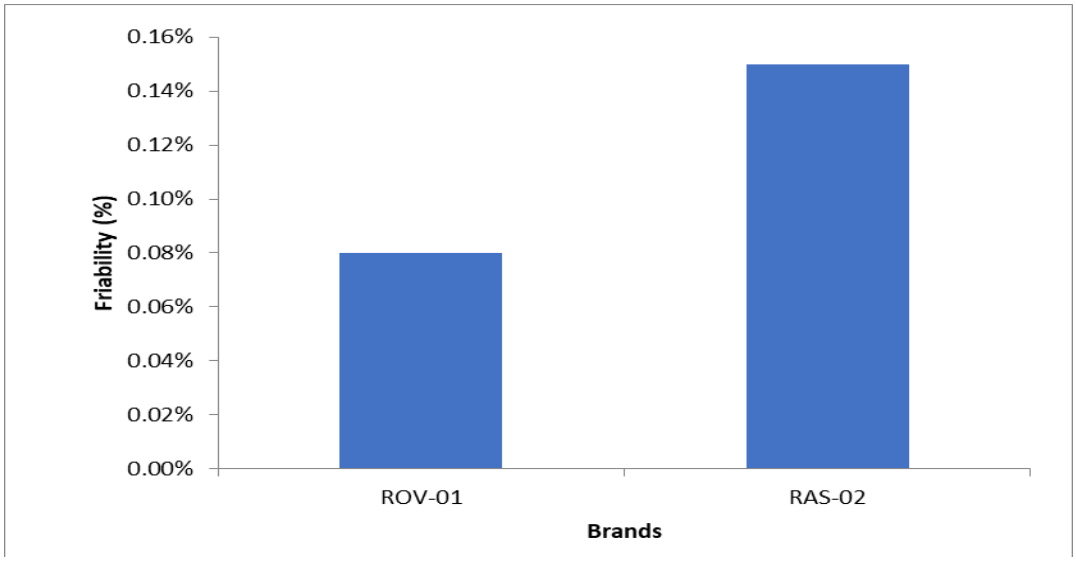

Figure 5 Graphical representation of friabilty test of both brands

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