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Degradation Study of Different Brands of Rosuvastatin Calcium Tablet in Bangladesh Using UV Spectrophotometer

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Abstract:- Rosuvastatin calcium tablets are mainly five brands obtainable that is a synthetic compound which decreases the number of lipid portion which is placed as a hypercholesterolemia treatment. The major purpose of this study is to measure the stability of different brands of Rosuvastatin calcium on the stress condition. Degradation system is a procedure that includes the degradation of drug particles and drug ingredients at specific conditions. Those are generated into degradation products which can be studied to evaluate the quality and efficacy of the drug formulation. There are some guidelines of the International Conference on Harmonization (ICH) with some parameters which cause the degradation of a drug product includes heat test, UV light test, time test for 15 days, acidic pH test, basic pH test. In this study, using an ultraviolet UV spectroscopic system was exhibited for the exploration of the drug absorbance in the whole degradation products. The standard solution of the samples was prepared with water as a solvent to produce a solution containing Rosuvastatin calcium (10mg). Then similarly different brands of drugs were dissolved in water and various dilutions were made which measured the absorbance of Rosuvastatin calcium (10mg) based on an ultraviolet wavelength of 232 nm. The analysis of absorbance of sample preparation calculated at 232 nm against the ratio of blank sample and this study determined through comparing with the evaluation of absorbance data of different brands. The research content result as well as the limit of assays not less than 95% and not more than 105% of the labeled amount the limit of the assay which is specified by USP. It was the final decision that under-five procedures, the entire five brands were degraded in every stress conditions.

Keywords:- *Degradation study, Rosuvastatin calcium, UV Spectrophotometer, Storage Condition.*

I. INTRODUCTION

In Bangladesh, Rosuvastatin calcium is one of the most common drugs which is prescribed for the treatment of hypercholesterolemia. Rosuvastatin calcium (RSVCa) C44H54CaF2N6O12S2 or (C22H27FN3O6S)2 Ca, a member of the group of statins, is the calcium salt of (E)-7-[4- (4-fluorophenyl) -6-isopropyl-2- [methyl (methylsulfonyl) amino] pyrimidin-5-yl] (3R,5S)-3,5-di hydroxyhept-6-enoic acid[1,2], mol. mass 1001.14 g, while rosuvastatin (RSV) chemical formula is C22H28FN3O6S and it has mol. Mass that is 481.539 g. So, the statin group is an ingredient which reduces of production of the cholesterol level from the side of the liver. Rosuvastatin Calcium is an important stimulated product that diminishes the production of lipid levels so far this drug used as a preventive step of hypercholesterolemia and antilipidemic activity. Rosuvastatin Calcium inhibits selectively and competitively of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, then the rate-limiting enzyme that alters HMG-CoA to mevalonate, an first and rate-limiting last step in cholesterol biosynthesis[3].

The portion of the liver is the main part of the function of Rosuvastatin that is the selective body part for cholesterol-decreasing[4]. Rosuvastatin decreases cholesterol levels by a higher percentage of low-density lipoprotein (LDL) receptors on the cell membrane increase the uptake and catabolism of LDL. Additionally stops the synthesis of hepatic very-low-density lipoprotein (VLDL) which decreases the whole amount of VLDL and LDL ingredients in this procurement, it produces a large amount of high-density lipoprotein cholesterol and prevents triglycerides (HDL-C) [5-8]. The functional structure of RSV and RSV-Ca is as given in below Figure 1 & 2:

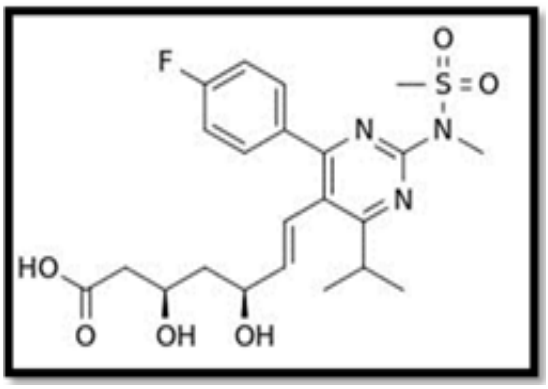

Fig 1:- Rosuvastatin (RSV)

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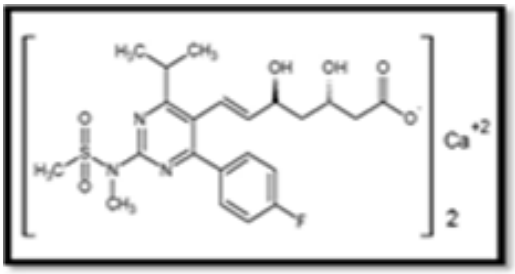

Fig 2:-Rosuvastatin Calcium (RSV-Ca).

Ultraviolet-visible (UV) spectrophotometer used for the degradation studies for observed the concentration of the absorbance of rosuvastatin calcium under different stress conditions such as acidic, basic, heating, UV light, time test by 232 nm by ICH guidelines. Spectroscopy theory is used for a small scale in the laboratory work and it is a cost-consuming way to determine the concentration of absorbance through passing the electromagnetic radiation (monochromatic light) of the beam and find a wavelength which called a spectrum. The visible range is 190nm - 380nm by ultraviolet-visible spectroscopy. The drug product is referred to as several degradation environment under the stress condition[9].

The degradation method is a procedure in which the natural degradation rate of the active pharmaceutical product is raised by the application of additional stress under environmental conditions[10]. It is required to demonstrate the specificity of stability indicating methods and also reveal the degradation pathways and degradation products of the active pharmaceutical ingredients and helps in the elucidation of structure and other characteristics of degradation products [11-12]. Chemical stability and efficacy of active pharmaceutical ingredients is a topic and play a vital rule for drug pharmacological activities. According to the FDA and ICH organization narrate that the criteria of substance stability measurement statistics to clarify the functional efficiency of a drug molecule and drug ingredient modify with time-related to several surrounding parameters. Most importantly, degradation study of the stability of active particle that utilizes for choosing appropriate preparation process and package labeling, at the same time that maintains a perfect environmental condition and drug life duration. Degradation study is a procedure which includes different segments of drug ingredients and the drug sample which can be an important part of the quality of the stability of the molecule [13]. In this study, the main concern is identifying and evaluating the absorbance of five several brands of rosuvastatin calcium. Previous research articles included high- performance liquid chromatography (HPLC) related and Spectrophotometric procedure for method development and validation of Rosuvastatin calcium[14-15] while still no UV-spectrophotometer system is used under degradation pathway in the research area in Bangladesh.

II. MATERIALS AND METHOD

A. *Experimental*

- *Rosuvastatin calcium*

The pharmaceutical preparation of Rosuvastatin Calcium (10mg) of the different brand such as Rosutin 10 mg, Rosuva 10mg, Rostab 10 mg, Rosu 10 mg, Rocuvas 10 mg was purchased from various medical drug stores of Bangladesh with manufacturing and expiry date of different brands from different pharmaceuticals like Beximco Pharmaceutical Ltd(privet), Square Pharmaceuticals Ltd.(privet), Acme Laboratories Limited(privet), Popular Pharmaceuticals Ltd.(privet), Incepta pharmaceutical Ltd(privet) respectively all the drugs were used of the same strength for determination of absorbance.

- *Reagents*

According to the analytical grade, all the reagents were used such as Rosuvastatin calcium, HCL, Sodium Hydroxide, and Deionized Water.

- *Glasswares*

Beaker, Test Tubes, Volumetric flask, Measuring Cylinder, Pipette, Glass rod, Spatula, Measuring flask, 1 cm rectangular quartz cell, Filter paper all the instruments were used and washed with pure water, after that cleaned with the de-ionized water that was formulated in the science laboratory that is used for determination of absorbance of the drugs.

- *Instruments*

UV-Spectrophotometer (Hach DR/4000), Electrical Analytical Balance (Mettler Toledo AB54), pH Meter (Hach Sension1), Water Bath (Hach HQ 14d).

- *Selection of wavelength*

About 100 ppm of Rosuvastatin calcium was accurately prepared and mixed with distilled water. In the meantime, the wavelength of maximum (λmax) was calculated at 232 as well as 252 nm but 232 nm wavelength was selected for absorbance measurement. At 252 nm it showed more degradation under UV-Spectrophotometer.

- *Preparation of 0.1 M HCL:*

9.1ml HCL took place and transferred into a liter volumetric flask which has an analytical grade that was 36%, 11 N, and de-ionized water was used for the final volume.

- *Preparation of 0.1 N NaOH:*

40 gm NaOH was dissolved in a minor amount of distilled water placed in a specialized liter volumetric flask and the total amount of volume was prepared until the double-distilled water.

➢ *Preparation of standard stock solution:*

Weighted and lastly fractured the tablets then weigh crushed tablets an appropriately for making standard solutions of rosuvastatin calcium, A Rosutin, Rosuva, Rostab, Rosu, Rocovas were weighted 50 mg appropriately and placed in 100 ml volumetric flask. 70ml water used for making up the volume and shake properly for 15 min then filtered properly and 20 ml of filtrate discard. Diluted 10 ml to 100 ml with water again diluted 10 ml of the resulting solution to 100 ml with distilled water was added and shaken vigorously for making the strength of the solution. Determined the whole absorbance at a max of 232 nm.

B. Procedure for degradation Studies

➢ *For heat:*

In this study, for the effect of heat, 10 ml stock solution in 90ml distilled water in 100ml volumetric flask of each brand was taken in three separate flasks and Placed the initial solution in the warm water bath at 80°C for 30 min and recorded the total absorbance at the specific wavelength of 232nm.

➢ *For Time:*

For the procedure of time testing, we preserved the 100ml primary solution for 15 days at room temperature (25°C) and definite the absorbance before and after 15 days at the same wavelength.

➢ *For UV light:*

Under direct UV sunlight, primary solutions remained for a period of 30 minutes. Upon completion of the time period, then absorbance determined by UV spectrophotometer.

➢ *For acidic pH:*

Under study of the effect of acidic condition, 10 ml stock preparation in 90ml distilled water in a beaker of each brand was taken in three separated flask and added 0.1 N HCL dropwise to the last solution and initiating 0.1 N HCL until the pH take place in 3 and the total complete solution was converted to an individual, after that the whole absorbance of the solutions was noted at the specific wavelength of 232 nm.

➢ *For basic pH:*

The Same strength of volume the rosuvastatin calcium solution placed in a beaker and 0.1 N NaOH until the pH reaches 9.5. Then basic solutions were put into a cuvette severally and then total absorbance of the samples observed at the wavelength of 232 nm.

III. RESULTS AND DISCUSSION

This research was performed with the purpose to compare the degree of degradation in five different brands of Rosuvastatin calcium including Rosutin 10 mg, Rosuva 10mg, Rostab 10 mg, Rosu 10 mg, and Rocuvas 10 mg. Table 1 and Figure 1 show the % of assay of different brands after and before degradation. The research content result as well as a limit of assays not less than 95% and not more than 105% of the labeled amount the limit of the assay which is specified by USP.

Most of the types of Rosuvastatin calcium find out the final limit of assay before any degradation study. To this research, Brand Rosutin, Rostab, and Rocovas are degraded after heating while the brand of Rosutin and Rocovas are degraded by UV light exposure. Also, this analysis data shows that in all of the five brands of the Rosuvastatin calcium group, the % of assay after the base was higher in all among the group. Most of the brands of Rosuvastatin calcium reveal degradation result within 15 days which was a great impact on time of rosuvastatin calcium HCL solution.

IV. CONCLUSION

In this research study follow the proper guidelines of ICH as well as stress-degradation rules. According to this research finding Rosuvastatin Calcium were degraded almost every stress conditions. The data analysis and method system is fully accurate and successfully degrade several types of dosage form. So, finally all targeted brands of rosuvatatin calcium degraded from stages for all applicable force degradation research field.

Brands	% of assay before performing stress	% of assay after heating	% of assay after UV light	% of assay after acid	% of assay after base	% of assay after time
Rosutin	139.73 %	121.89 %	115.03 %	81.80 %	145.22 %	94.37 %
Rosuva	74.67 %	92.24 %	86.70 %	67.79 %	98.54 %	48.03 %
Rostab	148.67 %	108.10 %	89.95 %	73.79 %	78.92 %	76.32 %
Rosu	97.71 %	87.55 %	78.95 %	59.52 %	87.54 %	58.55 %
Rocovas	124.20 %	131.20 %	123.10 %	110.08 %	167.28 %	108.69 %

Table 1:- % availability of different brands of Rosuvastatin Calcium before and after degradation.

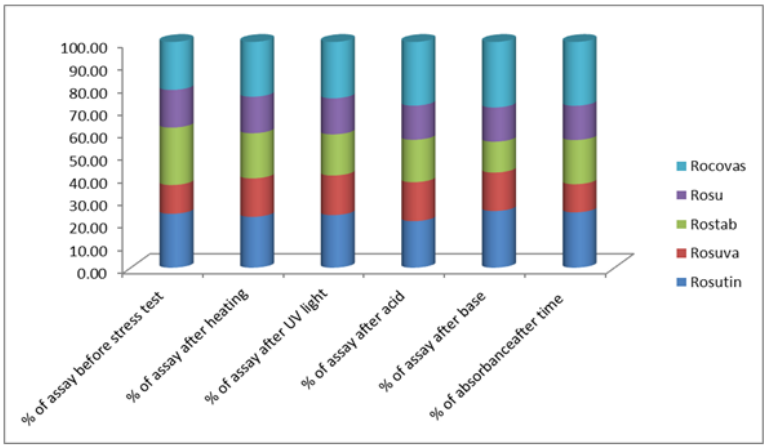

Fig 3:- % Availability before and after degradation.

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