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Development And Validation Of Uv Spectrophotometeric Technique For Estimation Of Rosuvastain Drug In Bulk And Pharmaceutical Dosage Form

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Abstract:

Objectives: The goal of this study is to create and test a UV-Spectrophotometric method for estimating Rosuvastatin in bulk and pharmaceutical dosage forms utilizing a green solvent.
Method: Development of UV-Spectrophotometric method was carried out by using 2.5% Sodium citrate solution as green solvent. Rosuvastatin was detected at a wavelength of 229nm. According to ICH guidelines, the developed technique was verified in terms of linearity, precision, accuracy, and robustness. Rosuvastatin in pharmaceutical dose forms was successfully estimated using a newly developed and verified approach.
Results: Rosuvastatin has a maximum absorption wavelength of 229nm. In the concentration range of 5-20µg/ml, Beer's law was fallowed the recovery of Rosuvastatin Calcium in tablet form was found to be between 97 and 102 percent.
Conclusion: The method was found to be simple, environment friendly, reproducible and economical and can be used for routine analysis of Rosuvastatin in bulk and pharmaceutical dosage form. The 2.5% Sodium citrate solution can be used as green solvent.

INTRODUCTION:

Poor biopharmaceutical qualities, particularly water insolubility, have been identified as the cause of 41% of novel drug development failures. Many types of organic solvents, like the following solvents have been used: acetonitrile, methanol, chloroform, and dimethylformamide inadequately water-soluble medications to conduct inadequately water-soluble medication analysis. The negative aspect of these Organic solvents has several drawbacks, including toxicity (such as nephrotoxicity) and high cost and volatility. the teratogenicity of Therefore, these organic solvents are swapped out with safe, environmentally acceptable hydrotropic agents. Economical solvent for analysis using spectrophotometry. First (1) The first to report was Neuberg (1916). Hydrotropic After dissolving different organic materials such fats, carbohydrates, esters, and medications in aqueous solutions with hydrotropes present [2]

HYDROTROPY:

One of the greatest ways to avoid using organic solvents is to employ the hydrotropic solubilization principle. (3) Hydrotropy is a method of solubilization in which a large amount of a second solute is added to produce a rise in another solute's aqueous solubility. Concentrated hydrotropic aqueous solutions of urea, nicotinamide, sodium benzoate, sodium salicylate, sodium citrate, and sodium acetate have been found to improve the water solubility of numerous medications that are poorly soluble in water [4].

NEED OF SOLUBILITY

The solubility of medicinal molecules ultimately determines a medicine's bioavailability and therapeutic efficacy. Solubility is a crucial factor in achieving the intended medication concentration. for pharmacological reaction to be seen in systemic circulation. The literature review makes this clear. that higher the hydrotrope concentration, the more soluble in water poorly soluble medications. For this reason, extremely concentrated hydrotropic agent solutions were utilized in the current study. When creating hydrotropic solutions, distilled water was utilized. The aqueous solubility of weakly

medications that dissolve in water. Therefore, very concentrated hydrotropic agent solutions were employed in the current research project. Hydrotropic solutions were made using distilled water (5)
The Biopharmaceutical Classification System has four classes into which drugs can be categorized based on their solubility. In order to categorize drug substances according to their aqueous solubility and membrane permeability, the BCS Classification was introduced in the middle of the 1990s.

The BCS Classification System

- BCS-I Highly Soluble, Highly Permeable
- BCS-II Low Soluble, Highly Permeable
- BCS-III Highly Soluble, Low Permeable
- BCS-IV Low Soluble, low Permeable (6-7)

Information about drugs

The chemistry of rosuvastatin is [(E,3R,5S)4-(4-fluorophenyl)-2-[methyl(methylsulfonyl)amino]-7-[6-propan-2-ylpyrimidin-5-yl] Three, five-dihydroxyhept-6-enoic acid calcium salt using an empirical formula (C22H27FN3O6S). Class II of the BCS includes 2Ca. RSV. (8)

By increasing the number of LDL receptors on the cell surface and decreasing the amount of Low Density Lipoproteins (LDL), RSV absorb the circulating LDL2. It works by blocking the rate-limiting enzyme in the biosynthesis of cholesterol, 3-hydroxy-3-methylglutaryl-CoA reductase (HMGCoA reductase). RSV Calcium is usually taken at a dosage of 540 mg daily, which is highly reversibly bound to plasma protein and has an extended impact on the liver animal models of cholesterol synthesis (9)

Routine pharmaceutical research can benefit greatly from the use of a straightforward, validated UV-spectrophotometric method as an alternative to time-consuming and costly chromatographic techniques. Green solvents must be used in place of many hazardous solvents when analyzing drugs (10–12). Sodium citrate is a widely regarded as safe excipient according to the FDA Inactive Ingredients Database. Therefore, implementing the use of green solvent in this study's primary goal is calculation of the RSV. (13)

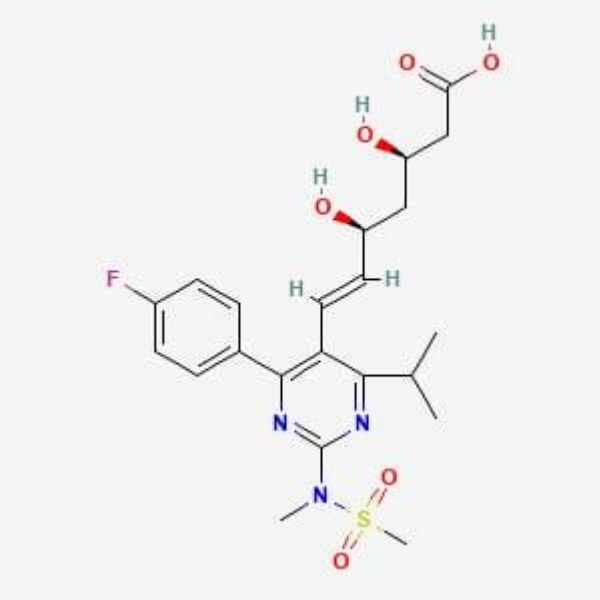


Figure 1. Structure of RSV Calcium

MATERIAL AND METHOD
Chemicals-

The hydrotropes sodium acetate and citrate were chosen for the study, and the medication rosuvastatin was used to improve solubility. The solvent used to create hydrotropes is distilled water. The source of Rosuvastatin was Aarti Pharmaceuticals

in Mumbai, NaoH ,Hcl , distilled water etc.for solubility study.Tablet formulation 10 mg of rosuvastain calcium was procured from the local pharmacy

Apparatus –

UV visible spectrophotometer, digital electronic balance was used for weighing of all samples.glasswares like beaker Measuring cylinder, glass rod, test tubes, volumetric flask, etc.

METHOD DEVELOPMENT –
1.Determination of wavelength maxima (λmax)-

Rosuvastatin calcium was scanned in sodium citrate.. Accurately Weighed 100 mg of drug was dissolved in 100 mL of respective Media (1000 µg/mL). From this solution 10 mL solution was Pipette out in 100 mL of volumetric flask and volume was made (100 µg/mL) and marked as stock solution. From the above stock Solution 2 mL was transferred in 100 mL of volumetric flask and Volume was made (2µg/mL). This solution was than scanned Over the range of 200 to 400 nm against a blank using Shimadzu, UV-visible spectrophotometer. The wavelength at which Maximum absorbance was achieved was considered as the Wavelength maxima ( ) for the pure drug

Using green or eco-friendly solvent was an additional strategy before the method was developed. The earth's environment is negatively impacted using organic solvents and their disposal. Sodium acetate and sodium citrate, two hydrotropic solvents, were used at concentrations ranging from 1% to 6%, and any increase in solubility was quantified by recording absorbance at each drug's λmax.

1. Preparation of hydrotropic solvent-

Each Hydrotropes was weighed with amount 1gm, 2.5gm, 5gm and 6gm and dissolved in Separate glass container having distilled water to obtain 1% w/v 2.5%w/v, 5%w/v and 6%w/v Hydrotrope strength solution.

2. Preparation of drug solutions -

Prior solubility study was carried out by weighing 10 mg of drug and transfer into clean and Dry test tube and added slowly 1% hydrotrope solution; addition was continued till a notable Solubility was observed. Finally, volume was made to 50 ml with the hydrotrope solution.
Similarly, the procedure was repeated with same quantity of drug and in each conc. of Hydrotropes. This procedure has given a broad study upon solubility of drug in all these Aliquot of the prepared solution was further diluted to obtain 20µg/ml drug and absorbance Was measured against blank solution. In these way four different concentrations of drug was Available in each hydrotrope solvent. Similarly, the conc. effect on solubilization was studied by preparing the drugs solution in 2.5%, 5% and 6% hydrotropes.
Solubility study profile of drug Absorbance of each drug was measured in four different concentration strength of Hydrotrope; and graph was plotted in between absorbance against drug solutions in different Concentration strength of hydrotrope. In this way a solubility profile curve of each drug in Various strength of hydrotrpe was generated.

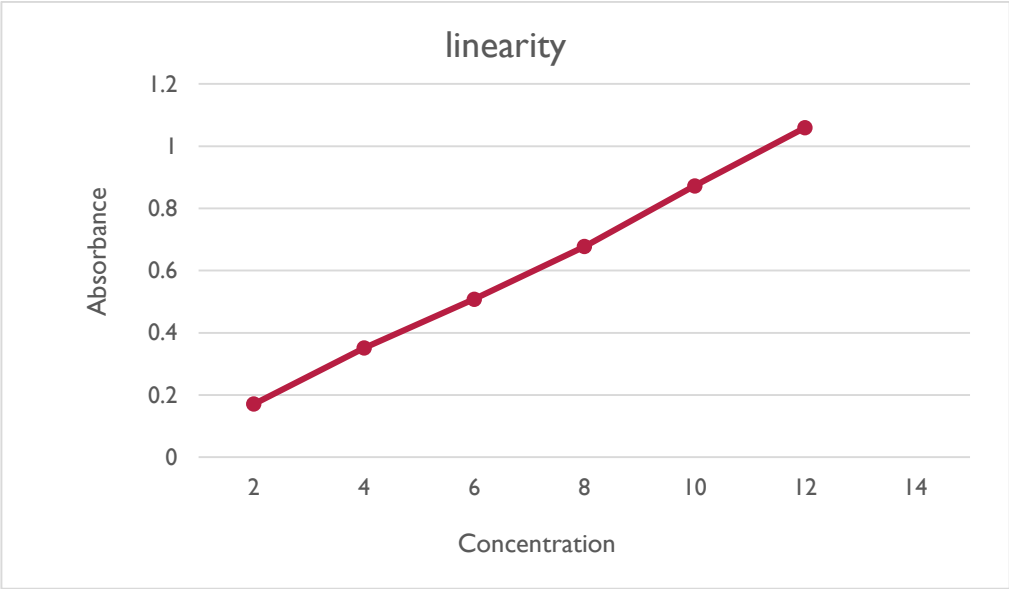
2. Preparation of Calibration Curve

For the preparation of standard calibration curve, concentration of 4-24µg/ml were prepared by pipetting out 0.4, 0.8, 1.2, 1.6, 2.0, 2.4 ml from the 100µg/ml solution in to a 10ml volumetric flask and made up the volume with sodium citrate. The absorbance of each solution was measured at 229 nm against sodium citrate as blank. Calibration curve of the Rosuvastatin Calcium was plotted by taking the absorbance obtained on y-axis and the Concentration of the solution on x-axis. The calibration curve is shown in fig

• Validation of rosuvastatin calcium by UV-Visible spectrophotometer
The developed method was validated for accuracy, precision, linearity, limit of detection, limit of quantitation and Robustness as per ICH guidelines(14)

- **Linearity**

For linearity study, from the stock solution II (100µg/ml) six solutions at different concentrations (4, 8, 12, 16, 20 and 24 Mg/mL) were prepared using six point calibration method. The samples were scanned in UV-Vis Spectrophotometer Against Sodium Citrate as blank. The selected drug shows linearity between the ranges of 4-24µg/ml.



Calibration curve of Rosuvastatin Calcium at 229 nm

- **Precision**

The precision of proposed method was determined by Intra-day and Inter-day precision. Three different solutions of three Different concentrations (8, 12,16µg/ml) was analyzed, and it was expressed in terms of percent relative standard

Deviation (%RSD). For Inter-day and Intra-day %RSD were found in the range of 0.5992 and 0.477respectively.

- The analytical method's linearity is defined as its capacity to yield test results that are Exactly proportionate to the analyte concentration in the sample within the specified Range. The analytical method's range Does the range of the analyte that has been Shown to exist between the upper and lower levels within a reasonable range of Linearity and precision.

- **Ruggedness:**

The ruggedness of the developed method was analyzed By using a standard stock solution. A sample solution of Concentration 10 µg/ml was prepared and analyzed by Two distinct analysts at the same environmental Conditions,

- **Accuracy**

Accuracy of the present method was carried out by using the drug substance 10ppm as standard solution and spiked Solution at three different concentration levels of 80%, 100% and 120% in triplicates. Absorbance was measured at229 nm and results were expressed in terms of % recoveries. Standard deviation and % RSD was calculated.

- **Assay**

Twenty tablets of Rosuvastatin calcium were weighed accurately and powdered. Powder equivalent to 50 mg of was Weighed and transferred to a 50 ml volumetric flask and make up the volume up to 50ml with sodium citrate Which gives 1000µg/ml solution and sonicated for 15 minutes to get homogeneous solution. Then it was filtered through a Whatman filter paper. A final concentration of 100 mg/ml of Rosuvastatin calcium was prepared. From this 1ml was Taken and diluted to 10 ml with sodium citrate) which gives 10µg/ml solution and the absorption

- **Specificity**

The experimental conditions mentioned above were used to investigate the Interference of excipients in the determination of rosuvastatin. A dummy was ready. It was discovered that different pharmaceutical preparation ingredients did not affect The above-mentioned Rosuvastatin calcium estimation in sodium citrate. Reference Technique. (15)

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RESULTS:-

Table No 1: Absorbance of drug in various strength of hydrotropic solution. The plotted graph in between absorbance against different concentration of hydrotrope for Rosuvastatin is shown in Fig. The solubility profile curve of rosuvastatin in sodium Citrate is the sign of enhanced solubility as compare to other hydrotropes.

SR. NO.	NAME OF DRUG	NAME OF HYDROTROPE	ABSORBANCE OF DRUG IN CONC OF HYDROTROPES	
			1%	2.5%
1	ROSUVASTATIN	SODIUM CITRATE	1.8475	2.3475
		SODIUM ACETATE	0.8845	0.9300

In 2.5% sodium citrate solution, rosuvastatin demonstrated good solubility and slowly increased in solubility. Each drug's absorbance in a chosen hydrotropic solvent was provided in TabIe. in the sodium acetate solution, decreased.

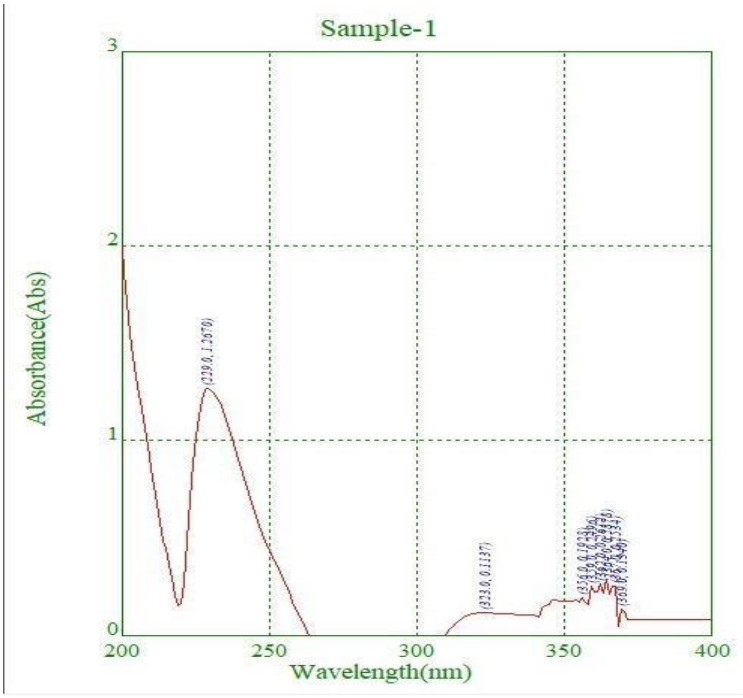

Fig:- UV Spectra of Rosuvastatin in Sodium Citrate.

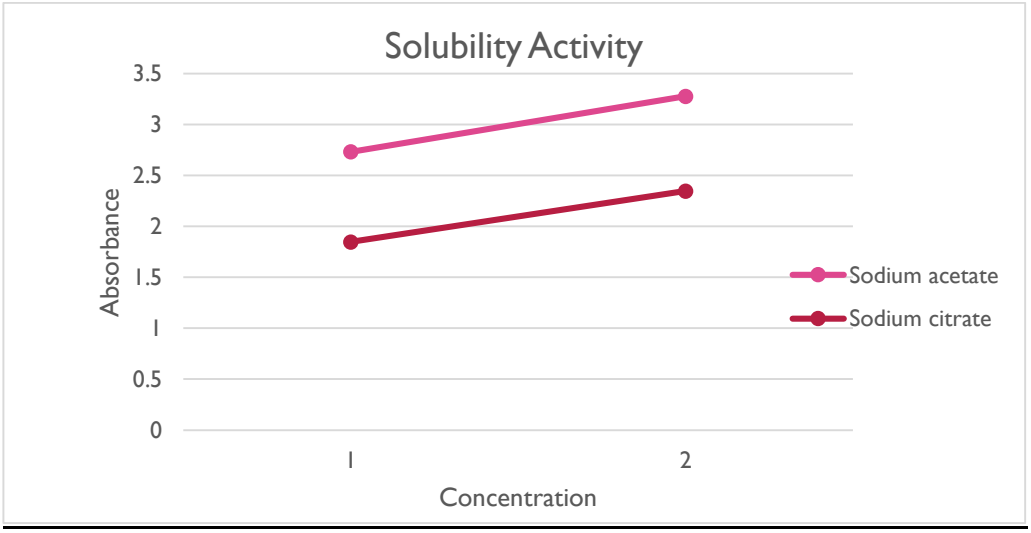

Fig:- Solubility profile of Rosuvastatin in selected hydrotopes.

• Drug solubility in a suitable hydrotrope was calculated.

SR. NO	Name of drug	Conc. Of Hydrotropes in %	Amount of Durg (mg)	Volume of solvent (ml)	Solubility (%w/v)
1	Rosuvastatin	2.5% Sodium citrate	10		

Table No.:- Calculated solubility of drug in suitably found hydrotrope.

CONCLUSIONS:

It was determined that sodium citrate is a useful solvent for increasing rosuvastatin solubility. Occasionally Hydrotrope solvents work better at lower concentrations than at higher ones.We one could argue that these two hydrotropes are environmentally friendly solvents for these two medications, and by using These It is possible to create solvent formulations
with increased bioavailability. While Using Method advancement or method It could make sense to use environmentally friendly solvents rather than organic ones.

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