

## Novel titrimetric method for the determination of rosuvastatin in pure form

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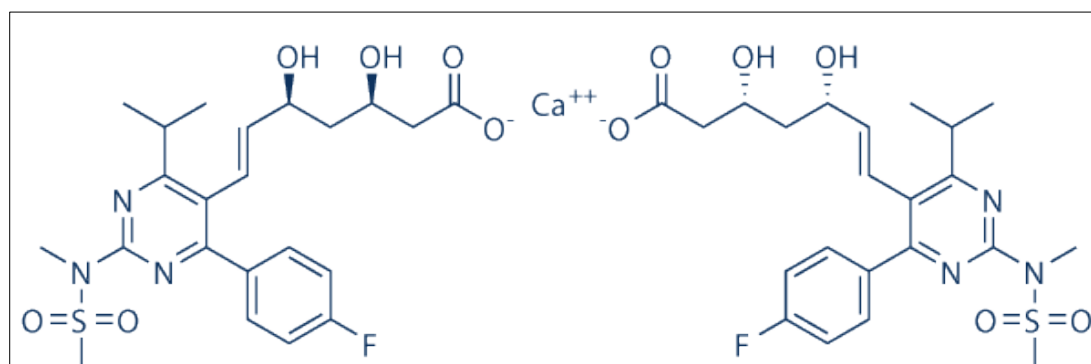
### Abstract

In this experiment assay of Rosuvastatin was performed by titrimetric method. The titration performed is a complexometric titration. The complexometric titration used is an easy, inexpensive volumetric titration method. This method is based on reaction of calcium with a solution of disodium ethylenediaminetetraacetate (EDTA). Complex of calcium and EDTA is formed. Erichrome black T is used as an indicator in this complexometric titration. At pH 12-13, Erichrome black T changes the color from pink to blue. The appearance blue color is determined to be the endpoint of this experiment. The titrations were carried out in triplicates and the average reading was taken to calculate the percentage assay. The percentage purity was found to be 103.05%

**Keywords:** Complexometric Titration; Percentage Assay; Rosuvastatin; EDTA; Erichrome Black-T

### 1. Introduction

Rosuvastatin calcium is bis[(E)-7[4-(4-fluorophenyl)-6-isopropyl-2-[methyl (methyl sulfonyl) amino] pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid] calcium salt with empirical formula  $(C_{22}H_{27}FN_3O_6S)_2 Ca$  and molecular weight 1001.14. Rosuvastatin calcium is a white to off white powder that is soluble in acetonitrile and acetone; slightly soluble in water and methanol. Rosuvastatin is a hydrophilic compound with a partition coefficient (octanol/water) of 0.13 at pH 7.0 [1]. Rosuvastatin belongs to a group of drugs called statins. It is used to treat high cholesterol. It is an HMG-CoA reductase inhibitor which acts by reducing the production of cholesterol in the body thereby decreasing the amount of cholesterol that may build up onto the walls of the arteries, leading to blockage of blood transport to brain, heart and various parts of the body [2,3].



**Figure 1** Structure of Rosuvastatin calcium

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Complexometric titration is a method wherein reacting substances and the standard solution react to form a soluble but very slightly dissociate complex substances. The formation of complexes is the basis of this titrimetric assay. The complexes formed are by the reaction of a metal ion (an acceptor, a central atom or a cation) with an anion, a neutral molecule or rarely a positive ion [4]. The indicator used in this experiment is Erichrome black T (pH 12-13) which gives a color change of blue from pink and the color change of pink to blue is determined as the end point in this procedure. [5,6].

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## 2. Method and materials

### 2.1. Chemical required

MgCl<sub>2</sub> · 6 H<sub>2</sub>O pure was from SDFCL, disodium EDTA, ammonia was taken from SDFCL, ammonium chloride from SDFCL, Calcium carbonate which was used was from SDFCL, Rosuvastatin was gifted from a company.

### 2.2. Preparation of reagents

4.0g of MgCl<sub>2</sub> was dissolved in 30ml of distilled water which in 50ml volumetric flask and the volume was made up to the mark with distilled water. 51ml of ammonia was taken in 100ml volumetric flask, to it distilled water was added and made up the volume with distilled water. Accurately weighed 2.0g of disodium EDTA was taken and dissolved in 250ml of distilled water in 1000ml volumetric flask. 5ml of previously prepared MgCl<sub>2</sub> was added along with 1ml of 6M ammonia and make up the volume with water. Accurately weighed 6.0g of ammonium chloride was dissolved in 100ml of 6M ammonia, stirred until it was dissolved.

### 2.3. Sample solution preparation

Accurately weighed 125mg of Rosuvastatin calcium was taken in a 500ml conical flask. Dissolved it in 100ml of water, to it 12.5 ml of prepared ammonia-ammonium chloride buffer was added and stirred for 10 min. 12.5mg of indicator was added and shaken for about a minute. It was then titrated against disodium EDTA-magnesium solution until color changes to pink from blue and the readings were noted down. This was repeated for two more trails. Their average value was taken to calculate the assay percentage.



**Figure 2** Colour change from pink to blue indicating the end point

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## 3. Results and discussion

The Rosuvastatin calcium was titrated against EDTA- magnesium until the color change from pink to blue is observed since the color change of blue from pink determined as the endpoint.

Equivalent factor: Each ml of 0.01M disodium EDTA-MgCl<sub>2</sub> = 0.0114 mg of Rosuvastatin.

**Table 1** Titration of Rosuvastatin using 1M EDTA

Trail number	Initial burette reading(ml)	Final burette reading(ml)	Total Volume of EDTA consumed(ml)
1	0	12.8	12.8
2	12.8	25.8	13
3	25.8	38.6	12.8

% Purity= volume of EDTA consumed × equivalent factor × Actual normality ÷ weight of Rosuvastatin(mg) × expected normality

$$=12.8 \times 10.0114 \times 0.01 \div 125 \times 0.01 \times 100$$

$$\% \text{ Purity} = 103.05\%$$

#### 4. Conclusion

Assay was performed for the Rosuvastatin which was obtained as gift from a company by using titrimetric method. The end point of this titration was observed to be the color change of the solution in the conical flask turning blue from pink. The percentage purity was found to be 103.05%.

#### Compliance with ethical standards

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##### *Declaration of conflict of interest*

No conflict of interest.

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