**International Journal of Research in Pharmacy and Pharmaceutical Sciences**
**ISSN: 2455-698X**
**Impact Factor: RJIF 5.22**
**www.pharmacyjournal.in**
**Volume 3; Issue 1; January 2018; Page No. 28-31**

# A review on chromatographic method for estimation of Rosuvastatin calcium

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**Abstract**
Rosuvastatinis a drug which comes under class of statin. It works by three mechanism 1) Inhibiting cholesterol synthesis, 2) Increasing LDL uptake, 3) Decreasing of specific protein prenylation. The use of Rosuvastatin is for treatment of dyslipidemia. It is useful for the prevention of cardiovascular disease and to high cholesterol. Different Chromatographic methods are available for single and combination with other drugs. Most of Methods were of RP-HPLC, LC and HPTLC because these methods provided with best available reliability, repeatability, analysis time and sensitivity.

**Keywords:** valsartan, HPLC (high performance liquid chromatography), HPTLC (high performance thin layer chromatography), LC (liquid chromatography)

## 1. Introduction
Rosuvastatin calciumis a drug which belongs to class of statin with antilipidemic activity. The use of Rosuvastatin is for treatment of dyslipidemia. It works by three mechanism 1) Inhibiting cholesterol synthesis, 2) Increasing LDL uptake, 3) Decreasing of specific protein prenylation. It attach and inhibits hepatic hydroxymethyl-glutaryl coenzyme A (HMG CoA) reductase, the enzyme which catalyzes the conversion of HMG-CoA to mevalonate, a precursor of cholesterol. This help to a decrease in hepatic cholesterollevels and increase in uptake of LDL cholesterol.
Reported methods are categorized depending on the following considerations:
1. Single component analyzed by chromatographic method.
2. Analysis of Rosuvastatin calcium with other drugs by chromatographic method.

**Table 1:** Reported Analytical Method of Rosuvastatin calcium: [2-17]

| S. No. | Drug | Method | Description |
|---|---|---|---|
| 1. | Rosuvastatin Calcium in Tablets | **RP-HPLC** | **Detection wavelength:** 242 nm<br>**Mobile phase:** acetonitrile: water (40:60, v/v)<br>**Stationary phase:** YMC C8, 150×4.6 mm i.d., 5 µm particle size column<br>**Linearity range:**0.5-80 µg/ml<br>**Flow rate:** 1.5 ml/min<br>**Limit of detection:** 0.1 µg/ml<br>**Limit of Quantitation:** 0.5 µg/ml |
| 2. | Rosuvastatin calcium in bulk and pharmaceutical dosage form | **RP-HPLC** | **Detection wavelength:** 243 nm<br>**Mobile phase:** Acetonitrile : Potassium dihydrogen orthophosphate (50 : 50 v / v, pH 3)<br>**Stationary phase:** C- 18, 5 µm column having 100 x 4.6 mm i.d.<br>**Flow rate:** 0.5 ml/min<br>**Limit of detection:** 0.14 µg/ml<br>**Limit of Quantitation:** 0.46 µg/ml |
| 3. | Rosuvastatin calcium in bulk and pharmaceutical dosage form | **RP-HPLC** | **Detection wavelength:** 248 nm<br>**Mobile phase:** Buffer (pH 4.5): Acetonitrile: methanol (45:25:35)<br>**Stationary phase:** Luna C18, 5µm 4.6 mm×250 mm column<br>**Flow rate:** 1.0 ml/min<br>**Retention time:** 9.9 min<br>**Linearity range:** 25-75 µg mL<br>**Limit of detection:** 3.5 µg/ml<br>**Limit of Quantitation:** 10.5 µg/ml |
| 4. | Rosuvastatin calcium in bulk and pharmaceutical formulation | **RP-HPLC** | **Detection wavelength:** 252 nm<br>**Mobile phase:** acetonitrile: water(75:25 % v/v )<br>**Stationary phase:** C18G (250 x 4.6 mm i.d.,5µ) column<br>**Flow rate:** 0.6 ml/min<br>**Retention time:** 3.097 min<br>**Linearity range:** 5-40 µg /mL |

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|---|---|---|---|
| 5. | Rosuvastatin calcium | **HPLC** | **Detection wavelength:** 242 nm<br>**Mobile phase:** n-heptane, 2-propanol and trifluoroaceticacid (85:15:01v/v)<br>**Stationary phase:** CHIRALPAK IB (250 x 4.6mm, 5µm) column<br>**Linearity range:** 5-40 µg /mL<br>**Limit of detection:** 0.07 µg/ml<br>**Limit of Quantitation:** 0.2 µg/ml |
| 6. | Rosuvastatin Calcium in Tablets | **RP-HPLC** | **Detection wavelength:** 242 nm<br>**Mobile phase:** acetonitrile: water (40:60, v/v) pH 3.5<br>**Stationary phase:** YMC C8, 150×4.6 mm i.d., 5 µm particle size columns<br>**Run time:** 10 min<br>**Flow rate:** 1.5 ml/min<br>**Linearity range:** 5-40 µg /mL<br>**Limit of detection:** 0.1 µg/ml<br>**Limit of Quantitation:** 0.5 µg/ml |
| 7. | Rosuvastatin API | **RP-HPLC** | **Detection wavelength:** 254 nm<br>**Mobile phase:** Ethanol: methanol: ethyl acetate (6:3:1 v/v)<br>**Stationary phase:** NUCLEODUR 150 mm×4.6 mm RP C8 column<br>**Flow rate:** 1.0 ml/min |
| 8. | Rosuvastatin in Nano-Formulation and Pharmaceutical Dosage form | **RP-HPLC** | **Detection wavelength:** 254 nm<br>**Mobile phase:** Buffer pH 4.8 (0.78%w/v of sodium dihydrogen orthophosphate in deionized water): acetonitrile (50:50v/v)<br>**Stationary phase:** Kromasil C-18, 4.6 x 250 mm (id), 5 µm HPLC column<br>**Run time:** 8 min<br>**Flow rate:** 1.0 ml/min<br>**Linearity range:** 1.56-50 µg /mL<br>**Limit of detection:** 0.17 µg/ml<br>**Limit of Quantitation:** 0.7 µg/ml |
| 9. | Rosuvastatin and Ezetimibe from their combination tablet dosage form | **RP-HPLC** | **Detection wavelength:** 230 nm<br>**Mobile phase:** Acetonitrile: water: 0.02 M phosphate buffer pH 8 (40:10:50 v/v)<br>**Stationary phase:** C18 250 × 4.6 mm, 5µ column<br>**Flow rate:** 1.0 ml/min<br>**Linearity range:** 30–90µg /mL<br>**Limit of detection:** Rosuvastatin: 0.05 µg/ml<br>Ezetimibe: 0.006 µg/ml<br>**Limit of Quantitation:** Rosuvastatin: 0.08 µg/ml<br>Ezetimibe: 0.05 µg/ml |
| 10. | Rosuvastatin and Ezetimibe in pharmaceutical formulations | **RP-HPLC** | **Detection wavelength:** 254 nm<br>**Mobile phase:** Tetra butyl ammonium hydrogen sulphate-acetonitrile (32:68, v/v)<br>**Stationary phase:** C 18 column<br>**Flow rate:** 1.0 ml/min<br>**Linearity range:** Rosuvastatin: 0.1-200µg /mL<br>Ezetimibe:0.1-200 µg /mL<br>**Limit of detection:** Rosuvastatin: 0.0282 µg/ml<br>Ezetimibe: 0.0297µg/ml<br>**Limit of Quantitation:** Rosuvastatin: 0.0853µg/ml<br>Ezetimibe: 0.0901 µg/ml |
| 11. | Rosuvastatin Calcium and Telmisartan in pharmaceutical dosage form | **RP-HPLC** | **Detection wavelength:** 298 nm<br>**Mobile phase:** Ammonium Dihydrogen Phosphate (pH 3) Buffer solution: Methanol (65:35v/v, pH 3.0)<br>**Stationary phase:** Inertsil ODS 3V C18 (250 x 4.6 mm, 5 µm) column<br>**Flow rate:** 1.5 ml/min<br>**Retention time:** Rosuvastatin: 6.1 min Telmisartan: 16.2 min<br>**Linearity range:** Rosuvastatin: 6-18 µg /mL<br>Telmisartan: 24-72 µg /mL<br>**Limit of detection:** Rosuvastatin: 0.6 µg /mL<br>Telmisartan:2.4 µg /mL<br>**Limit of Quantitation:** Rosuvastatin:1.8 µg /mL<br>Telmisartan:7.2 µg /mL |
| 12. | Rosuvastatin calcium and Ezetimibe in pharmaceutical dosage form | **RP-HPLC** | **Detection wavelength:** 252 nm<br>**Mobile phase:** Acetonitrile-Water (75:25, v/v)<br>**Stationary phase:** C18G (5 µm, 250 mm x 4.6 mm i. d. column)<br>**Flow rate:** 0.6 ml/min<br>**Linearity range:** 5-40 µg/ml |
| 13. | Rosuvastatin Calcium and Aspirin in marketed formulation | **RP-HPLC** | **Detection wavelength:** 243 nm<br>**Mobile phase:** Water: Acetonitrile (50/50 v/v)<br>**Stationary phase:** C18 Column (Grace smart (250mm× 4.6 mm. 5 µm) |

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|---|---|---|---|
| | | | **Flow rate:** 1.0 ml/min<br>**Retention time:** Rosuvastatin calcium: 4.30 min<br>Aspirin: 3.44 min<br>**Linearity range:** Rosuvastatin: 6-14µg /mL<br>Ezetimibe:45-105 µg /mL |
| 14. | Rosuvastatin calcium and Fenofibrate in Bulk and in Solid dosage | **RP-HPLC** | **Detection wavelength:** 240 nm<br>**Mobile phase:** Acetonitrile: 10 mM potassium dihydrogen phosphate buffer solutions of pH 5.5 (90:10 v/v)<br>**Stationary phase:** $C_{18}$, 250 x 4.6 mm, 5 µm particle column<br>**Flow rate:** 1.5 ml/min<br>**Retention time:** Rosuvastatin: 4.35 min Fenofibrate: 7.75 min<br>**Linearity range:** Rosuvastatin: 0.040-0.120µg /mL<br>Fenofibrate: 0.016-0.048 µg /mL<br>**Limit of detection:** Rosuvastatin: 0.02 µg /mL<br>Fenofibrate: 0.05 µg /mL<br>**Limit of Quantitation:** Rosuvastatin: 0.1 µg /mL<br>Fenofibrate: 0.09 µg /mL |
| 15. | Olmesartan and Rosuvastatin in pharmaceutical dosage form | **RP-HPLC** | **Detection wavelength:** 230 nm<br>**Mobile phase:** Buffer and Acetonitrile (45/55)<br>**Flow rate:** 1.0 ml/min<br>**Linearity range:** Olmesartan: 25-150µg /mL<br>Rosuvastatin: 12.5-75 µg /mL<br>**Limit of Detection:** Olmesartan: 0.06µg /mL<br>Rosuvastatin: 0.11 µg /mL<br>**Limit of Quantitation:** Olmesartan: 0.18µg /mL<br>Rosuvastatin: 0.35 µg /mL |
| 16. | Rosuvastatin and Amlodipine in pharmaceutical formulations | **RP-HPLC** | **Detection wavelength:** 240 nm<br>**Mobile phase:** acetonitrile and 0.1 M ammonium acetate buffer (pH 5)30:70 (v/v)<br>**Stationary phase:** C-18 column (250 mm × 4.6 mm, 5 µm)<br>**Flow rate:** 1.5 ml/min<br>**Retention time:** Rosuvastatin: 13.9 min Amlodipine: 29.3 min<br>**Linearity range:** Rosuvastatin: 1-200 µg /mL<br>Amlodipine: 0.5-100 µg/ml<br>**Limit of Detection:** Rosuvastatin: 0.30 µg /mL<br>Amlodipine: 0.15 µg/ml<br>**Limit of Quantitation:** Rosuvastatin: 0.5 µg /mL<br>Amlodipine: 1 µg/ml |
| 17. | Rosuvastatin and Aspirin in Bulk and Pharmaceutical Dosage Form | **RP-HPLC** | **Detection wavelength:** 290 nm<br>**Mobile phase:** Mobile phase A: 0.01N Phosphate buffer 32<br>Mobile phase B: Acetonitrile 68<br>**Stationary phase:** ODS (150 mm 4.6 mm, 5mm)<br>**Flow rate:** 1.0 ml/min<br>**Retention time:** Rosuvastatin calcium: 2.2 min<br>Aspirin: 4.0 min<br>**Linearity range:** 25-150 µg /mL<br>**Limit of Detection:** Rosuvastatin calcium: 3.02 µg /mL<br>Aspirin: 3.0 µg /mL<br>**Limit of Quantitation:** Rosuvastatin calcium: 10 µg /mL<br>Aspirin: 9.98 µg /mL |

## Conclusion

This review portray the reported Chromatographic methods developed and validated for estimation of Rosuvastatin calcium. According to this review it was concluded that for Rosuvastatin calcium different Chromatographic methods are available for single and in combination with other drugs. The mobile phase containing Phosphate buffer, Methanol and Acetonitrile were common for most of the chromatographic method to provide more resolution. For chromatographic method flow rate is observed in the range 0.5 – 1.5 ml/min to get good resolution time.For most of the chromatographic methods common solvent is Phosphate buffer and Methanol. Hence this all methods found to be simple, accurate, economic, precise and reproducible in nature. Most of Methods were of RP-HPLC, LC and HPTLC because these methods provided with best available reliability, repeatability, analysis time and sensitivity.

## Acknowledgement

The authors are thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy, Ahmedabad, India for providing all the facilities and encouragement to carry out the work.

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