EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 4
Issue: 8
224-227
Year: 2017

A REVIEW ON ANALYTICAL METHODS OF DIFFERENT STATINS

Prachet Pinnamaneni*, Sowjanya Koyi, Haritha Darapaneni and Rama Rao Nadendla

Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur-522034.

***Corresponding Author: Prachet Pinnamaneni**
Chalapathi Institute of Pharmaceutical Sciences, Lam, Guntur-522034.

Article Received on 08/06/2017 **Article Revised on 28/06/2017** **Article Accepted on 18/07/2017**

ABSTRACT
The main objective of this review article is to overview the various analytical methods and validation of different statins by using the RP-HPLC technique. Statin play a key role in reducing the cardiovascular diseases, that is why the use of statins in now a days is increasing rapidly. There are many analytical methods have been reported in the combination of statins by using the normal phase HPLC, reverse phase HPLC and also chiral HPLC.

KEYWORDS: HPLC, Statin, Analytical method.

INTRODUCTION

Statins, also known as HMG-CoA reductase inhibitors, are a class of lipid-lowering medications. They inhibit the enzyme HMG-CoA reductase which plays a central role in the production of cholesterol. Statins have been found to reduce cardiovascular disease (CVD) and mortality in those who are at high risk. The evidence is strong that statins are effective for treating CVD in the early stages of the disease (secondary prevention) and in those at elevated risk but without CVD (primary prevention).

Classification

Statins are classified in two ways

1. Based on manufacturing method.
2. Based on solubility.

1. Based on manufacturing method

One way to classify statins is by how they are manufactured. Some are derived from micro-organisms through biotechnology. These are called fermentation-derived or Type 1.

Others are made through chemical synthesis (no living organisms involved). These are synthetic, or Type 2 statins. It is common for pharmaceuticals to be made through fermentation or through chemical synthesis.

Manufacture method	Type	Drugs
Fermentation	Type 1	lovastatin, simvastatin, pravastatin, pitavastatin
Synthetic	Type 2	fluvastatin, atorvastatin, rosuvastatin

2. Based on solubility

Statins are soluble in both aqueous environments and oily environments. The solubility levels differ enough that it is possible to classify some as hydrophilic (better solubility in water) or lipophilic (better solubility in fats).

Solubility	Drugs
Water soluble (hydrophilic)	pravastatin, pitavastatin and rosuvastatin
Fat soluble (lipophilic)	atorvastatin, fluvastatin, lovastatin and simvastatin

S.No	Drug	Stationary Phase	Mobile Phase	Flow Rate	Detector & wave length
1	Atorvastatin & nicotinic acid	Agilent ZORBAX SB-C18 (150 × 4.6 mm, 3.5 µm)	acetonitrile: distilled water (85:15) at pH 4.5 (adjusted with phosphoric acid).	1.0 ml/min	UV, 261nm
2	Atorvastatin, Fenofibrate & Ezetimibe	Inertsil C18 column (ODS 3 V, 5 µ, 250 mm × 4.6 mm)	80 volumes of Methanol: 10 volumes of Acetonitrile and 10 volumes of Water	1.0 ml/min	PDA, 256nm
3	Atorvastatin Calcium and Fenofibrate	Luna C18 column (250×4.6 mm i.d. particle size 5 µ)	methanol: acetate buffer pH 3.7 (82:18 v/v)	1.5 ml/min.	UV, 248 nm
4	Atorvastatin, Ezetimibe & Fenofibrate	enable C-18 Column (25 mm x 4.6 mm i.d, 5 µm	acetonitrile and phosphate buffer (pH 3.3) in the ratio of 90:10% V/V	1.0 ml/min	UV, 254nm
5	Atorvastatin Calcium and Aspirin	Gemini C-18, 5 mm column having 250 x 4.6 mm	0.02 M potassiumdihydrogen phosphate: methanol (20:80) adjusted to pH 4 using ortho phosphoric acid	1.0 ml/min	UV, 240nm
6	Atorvastatin and Fenofibrate	Thermohypersil BDS C18column of dimension 100 × 4.6, 5µm	Methanol: Water (Adjusted with orthophosphoric acid to pH-2)4 0:60v/v	1.0 ml/min	PDA,274nm
7	Ezetimibe and Atorvastatin	hypersil BDS C18 coloumn (250 mm × 4.6 mm, 5 mm particle size).	phosphate buffer pH-4.5 and acetonitrile (35:65 v/v)	1.0 ml/min	UV, 228nm
8	Atorvastatin	P-Supelcosil C_{18}(5 µm, 150 × 4.6 mm)	acetonitrile:methanol:water (45:45:10 v/v/v)	1.0 ml/min	UV, 240nm
9	Atorvastatin Calcium, Losartan Potassium, Atenolol, And Aspirin	KYA TECH HiQSil C18HS (250 × 4.6 mm i.d., 5 µm particle size)	acetonitrile: 0.02 M potassium dihydrogen phosphate buffer (pH 3.4) (70:30% v/v)	1.0 ml/min	UV, 236nm
10	Atorvastatin & Aspirin	acquity UPLC™ BEH C18 column (1.7 µm, 2.1 × 50 mm)	acetonitrile and phosphate buffer (0.01 M, pH 2.0)	0.6 mL/min	UV, 247nm
11	Atorvastatin & Ubidecarenone	peerless C-8 column 250x4.6 mm, 5µ, L-7	Methanol : Acetonitrile (80:20)	1.5 ml/min	PDA,290nm
12	Atorvastatin & amlodipine	BEH C18 (100mm×2.1mm, 1.7µm) column	acetonitrile and 0.02 M Potassium dihydrogen phosphate (55:45)	0.3 mL/min	UV,242nm
13	atorvastatin	Eclipse XDB® column 5 µm (4.6 x 150 mm)	acetonitrile and 0.025 M potassium dihydrogenortho-phosphate buffer pH 5 (45:55 v/v)	1.5 mL/min	PDA,246nm
14	Atorvastatin& amlodipine	Zorbax® ODS column (5 µm, 4.6 x 250 mm),	acetonitrile/methanol/phosphate buffer pH = 3.0 (45:30:25, V/V/V); pH was adjusted to 2.5 ± 0.1 with orthophosphoric acid	1.0 ml/min	UV,254nm
15	amlodipine besylate and atorvastatin calcium	Intersil ODS C18(250x4.6 ID) 5µm.	0.1% Tri fluoro acetic acid buffer:Methanol(45:55v/v)	1.0 ml/min	UV,246nm
16	Atorvastatin and Ramipril	Phenomenex – Luna, C18 (250 x 4.6 mm i.d.,5µ) column	acetonitrile, water and methanol (55:40:5v/v/v)	1.0 ml/min	Uv,237nm
17	Atorvastatin	Chiral pak AD-H (250 mm × 4.6 mm ID) column	methanol: ethanol (1:1v/v)	1.0 mL/ min	Uv, 246nm
18	Atorvastatin, folic acid and fenofibrate	Inertsil ODS 3V (250x4.6mm) column	Phosphate buffer : acetonitrile (40:60v/v)	1.0ml/min	Uv, 235 nm
19	Atorvastatin and Telmisartan	Shishedo C18, 250×4.6mm, 5 micron size column	acetonitrile : phosphate buffer (45:55 v/v) pH 2.5	1.2ml/min	Uv, 254nm
20	Rousvastatin enantiomers	Chiralpak IB (250 x 4.6mm, 5µm) column	nheptane, 2-propanol and trifluoroaceticacid (85:15:01v/v).	1.0 mL/min	Uv, 242nm
21	Sitagliptin-Simvastatin	Agilent C8 Column (250 x 4.6 mm, 5µ)	Methanol : water (25:75)	1.0 ml/min.	Uv, 266nm
22	Sitagliptin Phosphate And Simvastatin	aHi-Q Sil C18(250 mm × 4.6 mm, 5 µm Particle size) column	acetonitrile, methanol and 10 mM phosphate buffer(65:25:10% v/v/v)	1.2 ml/min	Uv, 250nm
23	Metoprolol Succinate **(**METO) and Telmisartan	Prontosil C18 Column (5 µm, 250mm x 4.60mm)	acetonitrile: methanol: phosphate buffer pH-5 (35:35:30 % v/v/v)	1ml/min	Uv, 225nm
24	pitavastatin	Agilent eclipse XDB C_{18} column (150×4.6mm)	Phosphate buffer p^h3.4: acetonitrile (65:35v/v)	0.9ml/min	Uv, 244nm
25.	Simvastatin and ezetimibe	C18 ODS Hypersil column	acetonitrile:phosphate buffer (pH 4.5, 0.01M) in the ratio of 65:35 v/v	1.0 ml /min.	Uv, 232nm

REFERENCES

1. Development and validation of RP-HPLC method for determination of Atorvastatin calcium and Nicotinic acid in combined tablet dosage form, Jaiprakash N. Sangshetti, Mohammed Aqeel. Zahid Zaheer, Rana Z. Ahmed, M.H.G. Dehghan. Indrajeet Gonjari, Journal of Saudi Chemical Society, September 2016; 20(Supplement 1): S328-S333.
2. RP-HPLC Method Development and Validation for the Simultaneous Estimation of Atorvastatin, Fenofibrate and Ezetimibe in a Pharmaceutical Dosage Form. Biochem Anal Biochem 4: 177. doi:10.4172/2161-1009-1000177.
3. Development and Validation of RP-HPLC Method for Simultaneous Estimation of Atorvastatin Calcium and Fenofibrate in Tablet Dosage Forms, IJPS, 2008 Mar-Apr; 70(2): 263–265.
4. Sahu PK, Murthy Pyla SR, Srinivas K and Swain S (2016) Simultaneous RP-HPLC Method Development and Validation of Atorvastatin, Ezetimibe and Fenofibrate. Pharmaceut Reg Affairs 5: 169. doi: 10.4172/2167-7689.1000169.
5. Development and validation of a RP-HPLC method for determination of atorvastatin calcium and aspirin in a capsule dosage form, D. A. Shah*, K. K. Bhatt[1], R S. Mehta1, M. B. Shankar[1], S. L. Baldania and T. R. Gandhi, Indian J Pharm Sci, 2007; 69(4): 546-549.
6. A Novel RP- HPLC Method Development And Validation Of Atorvastatin And Fenofibrate In Bulk And Pharmaceutical Dosage Forms, Vinjam Swathi* [2]Nanda Kishore Agarwal, Pharmatutor.org.
7. RP-HPLC Method For Simultaneous Estimation Of Atorvastatin Calcium, Losartan Potassium, Atenolol, And Aspirin From Tablet Dosage Form And Plasma, Neela M. Bhatia, Sachin B. Gurav, Swapnil D. Jadhav & Manish S. Bhatia, Journalof liquid chromatography & related technologies, 2012; 35(3): 428-443.
8. Validated Ultra HPLC Method for the Simultaneous Determination of Atorvastatin, Aspirin and their Degradation Products in Capsules, D. N. Vora & A. A. Kadav, Journalof liquid chromatography & related technologies, 2008; 31(18): 2821-2837.
9. Validated RP-HPLC Method for simultaneous determination of Atorvastatin and Ramipril and its application in drug formulation, Kuldeep Chouhan, Shubham Agrawal, Chanchal Raj, Samir Jain, A. Balasubramaniam and Navin R. Raj*, Technocrats Institue of Technology-Pharmacy, Bhopal, Madhyapradesh, India.
10. A Validated Lc Method For Determination Of The Enantiomeric Purity Of Atorvastatin In Bulk Drug And Dosage Forms M. Vishnu murthy1, 2, Katkam Srinivas1, N.Ramesh kumar1.
11. K.Mukkanti2 1Analytical Research and Development, Integrated product development operations, Dr. Reddy's Laboratories Ltd., Bachupally, Qutubullapur, R. R. Dist. 500 072 Andhra Pradesh, India.
12. Method Development And Validation For Simultaneous Estimation Of Atorvastatin, Fenofibrate And Folic Acid In Pharmaceutical Dosage Form K. Shivani, G.Tulja Rani* Department Of Pharmaceutical Analysis and Quality Assurance, Malla Reddy Institute of Pharmaceutical Sciences, Maisammaguda, Secunderabad, Telangana State, India.
13. Development And Validation Of Chiral Hplc Method For Quantitation Of Enantiomer In Rosuvastatin Calcium Prabhu Venkatesh Moodbidri*, Varadaraji Dhayanithi, Ganesh Belavadi Manjunathashastry, Hari Narayan Pati, Pardhasaradhi Vasireddy Advinus Therapeutics Ltd., 21 & 22, Phase II, Peenya IndustrialArea, Bengaluru-560058, Karnataka, India.
14. Validated RP-HPLC Method for the Estimation of Simvastatin and Sitagliptin Sujani PV1*, Y Padamanabha Reddy2, N Devanna3, SS Phanindra 41Department of Pharmaceutical Analysis, Procadence Institute of Pharmaceutical Sciences, Rimmanaguda, Medak (dt), Andra Pradesh, India 2Principal, RIPER, Anantapur, Andra Pradesh, India.
15. Development And Validation Of Rp-Hplc Method For Simultaneous Estimation Of Sitagliptin Phosphate And Simvastatin In Bulk And Tablet Dosage Form Vinit Chavhan, Minal Ghante & Sanjay Sawant Department of Pharmaceutical Chemistry, STE's Smt. Kashibai Navale College of Pharmacy, Sinhgad Technical Campus, Kondhwa-Saswad Road, Kondhwa (Bk), Pune-411048 India.
16. RP-HPLC Method Development and Validation for Quantitative Estimation of Metoprolol Succinate and Telmisartan in Bulk Drug and Their Dosage Forms Jain Nilesh *, Sharma Bhupendra Kumar, Jain Ruchi, Jain Deepak Kumar & Jain Surendra. *Sagar Institute of Research & Technology-Pharmacy, Ayodhya Bypass Road, Bhopal, M.P-462041, India.
17. Analytical method development and validation of simultaneous estimation of amlodipine besylate and atorvastatin calcium by RP-HPLC method K. S. Nataraj*, K. Alekhya, B. Surendra Babu, K. Gnananath and Ch. Bindu Shri Vishnu College of Pharmacy, Bhimavaram, West Godavari District, Andhra Pradesh, India.
18. Development And Validation Of Stability Indicating Rp-Hplc Method For Simultaneous Estimation Of Atorvastatin And Telmisartan In Bulk And Pharmaceutical Formulations Pasala Mounika, Bonthu Mohan Gandhi*, Vatchavai Bhaskara Raju, Kamatham Srinivas Sumanth, Venkata Koteswaramma Kagitapurapu, Kolli Srinivas, Meesala Santhi Neelima Sri Vasavi Institute of Pharmaceutical Sciences, Pedatadepalli, Tadepalligudem-534101, Andhra Pradesh.
19. Rp-Hplc Method Development And Validation For The Simultaneous Estimation Of Atorvastatin And Ezetimibe In Pharmaceutical Dosage Form Saroj Kumar Raul*, Atna Bhaskar Aravelli, Durgasi

Jhansi Maharajah's College of Pharmacy, Phool Baugh, Vizianagaram, Andhra Pradesh, India.

20. A new validated stability indicating RP-HPLC method for estimation of pitavastatin in tablet dosage forms k. sujatha* J.V.L.N. Seshagirirao, department of pharmacy, government polytechnique, vishakapatnam, A.P, india, Yalamarty college of pharmacy vishakapatnam, A.P, india.
21. Stability Indicating RP-HPLC Method for Simultaneous Determination of Simvastatin and Ezetimibe from Tablet Dosage Form, R. P. Dixit, C. R. Barhate[1], S. G. Padhye, C. L. Viswanathan[1] and M. S. Nagarsenker[*], Indian J Pharm Sci, 2010; 72(2): 204-210.