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A REVIEW ON CHARACTERISTICS AND ANALYTICAL METHODS OF PITAVASTATIN: A POTENT STATIN DRUG

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ABSTRACT

The distinctive solutions are utilized within the treatment of hyperlipidemia join the fibric corrosive subordinates such as clofibrate, fenofibrate; bile corrosive sequestrants e.g. colestipol; cholesterol retention inhibitors e.g. ezetimibe; HMG CoA reductase inhibitors e.g. lovastatin, rosuvastatin, simvastatin and pitavastatin. Pitavastatin is novel medicate utilized within the treatment of hyperlipidemia. It must be given in single or in mixture with distinctive antihyperlipidemic specialists. Pitavastatin may be a exceptionally strong specialist called HMG CoA reductase inhibitors, or "statins." Pitavastatin lower the levels of low-density lipoprotein, or LDL and triglycerides within the blood, whereas expanding levels of high-density lipoprotein, or HDL. An colossal number of techniques counting Tall Execution Fluid chromatography (HPLC), UV–Visible spectroscopy are utilized for the assurance pitavastatin. There are different explanatory strategies utilized for sedate examination and these strategies have been approved agreeing to ICH rules (Q1A R2). Hence, this procedure can be securely utilized for standard pitavastatin quality control tests.

KEYWORDS: Hyperlipidemia, Antihyperlipidemic drugs, Pitavastatin, Analytical methods, HPLC.

INTRODUCTION

Hyperlipidemia is considered to be a major hazard calculate for cardiovascular infection (CVD). Cardiovascular infection accounts for one third of add up to passings around the world, and cardiovascular infection is anticipated to ended up the driving cause of passing and inability around the world by 2020.[1] Hyperlipidemia is an increment in one or more plasma lipids, counting triglycerides, cholesterol, cholesterol esters and plasma phospholipids and/or lipoproteins, counting exceptionally moo thickness lipoproteins and moo thickness lipoproteins, and diminished levels of high-density lipoprotein.[2] Hypercholesterolemia and hypertriglyceridemia are the driving cause of atherosclerosis unequivocally related to ischemic heart infection (IHD).[3] There's a solid relationship between IHD and the tall mortality rate. Higher level of plasma cholesterol cause more than four million passings in a year. Atherosclerosis could be a solidifying process of the courses due to the testimony of cholesterol within the blood vessel divider which causes the supply routes to narrow.[4] Atherosclerosis and disarranges related with atherosclerosis, such as coronary, cerebrovascular and fringe vascular infection, are quickened by the nearness of hyperlipidaemia.[5]

Hyperlipidemia is related to an increment in oxidative stretch that comes about in a noteworthy generation of oxygen free radicals, which can lead to oxidative changes in lowdensity lipoproteins, which play a critical part within the onset and movement of atherosclerosis and related cardiovascular infections.[6] Expository methods are utilized for subjective and quantitative investigation of bulk drugs and pharmaceutical details. The methods are exceptionally valuable in past and display settings. The foremost well known explanatory procedures are unmistakable UV spectroscopy, tall execution fluid chromatography (HPLC), etc. In this survey, we have examined a few expository strategies for bulk pitavastatin and details.[7]

Table 1: Various classes of antilipidemic drugs.

S.No.	Class	Example
1.	HMG CoA Reductase inhibitors	Lovastatin, Simvastatin, Metastatin, Pravastatin, Fluvastatin, Atorvastatin, Pitavastatin, Rosuvastatin
2.	Fibric acid derivatives	Clofibrate, Fenofibrate, Ciprofibrate
3.	Bile acid sequestrants	Cholestyramine, Colestipol
4.	LDL oxidation inhibitor	Probucol
5.	Pyridine derivatives	Nicotinic acid, Nicotinamide
6.	Cholesterol absorption inhibitors	Ezetimibe
7.	Miscellaneous agents	Dextrothyroxine

Table 2: Statins Approved By the US Food and Drug Administration.

S.No.	Generic name	Approval date
1.	Lovastain	08/31/1987
2.	Pravastatin sodium	10/31/1991
3.	Simvastatin	12/23/1991
4.	Fluvastatin sodium	12/31/1993
5.	Atorvastatin calcium	12/17/1996
6.	Cerivastatin sodium	06/26/1997 (withdrawn 2001)
7.	Rosuvastatin calcium	08/12/2003
8.	Pitavastatin calcium	08/09/2009

Pitavastatin may be a pharmaceutical called a statin. It is utilized to lower LDL (terrible) cholesterol and triglycerides and raise HDL (great) cholesterol within the blood.[8] This sedate is utilized nearby a solid eat less and other way of life changes to lower the risk of heart attack or stroke.[9] Pitavastatin calcium may be a unused specialist within the lesson of 3-hydroxy-3methylglutaryl coenzyme A reductase ("statins") inhibitors utilized for the treatment of essential hyperlipidaemia and blended dyslipidaemia.[10] It may be a manufactured lipidlowering medicate for verbal organization.[11]

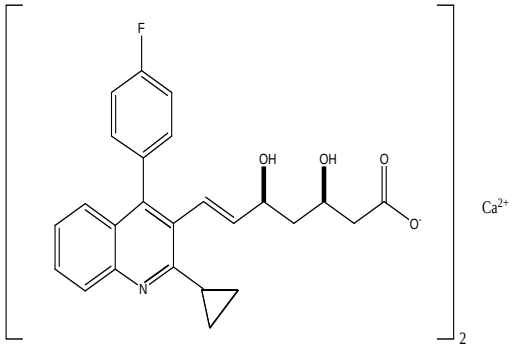

Figure 1: Chemical Structure of Pitavastatin calcium.

IUPAC NAME: calcium bis((3R,5S,6E)-7-[2-cyclopropyl-4-(4-fluorophenyl)quinolin-3yl]-3,5-dihydroxyhept-6-enoate)

Molecular formula: C50H46CaF2N2O8

Solubility: DMSO, DMF, Acetonitrile, methanol, diethyl ether, pyridine, chloroform

LogP: 4.82

Molecular weight: 880.984g/mol

Melting point: 138°C-139°C

Mechanism of action

- Pitavastatin could be a statin and competitive inhibitor of HMG-CoA (3-hydroxy3methylglutaryl coenzyme A) reductase, which catalyzes the change of HMG-CoA to mevalonate, an early arrange that limits the rate of biosynthesis cholesterol.[12,13]
- Pitavastatin acts primarily within the liver, where the diminish in hepatic cholesterol concentrations invigorates the positive direction of hepatic low-density lipoprotein (LDL) receptors which increment hepatic assimilation of LDL, subsequently lessening circulating levels of LDL- C.[14]
- In vitro and in vivo creature ponders moreover illustrate that statins apply vascular defensive impacts notwithstanding of their lipid-lowering properties, too known as the pleiotropic impacts of statins.[15,16]
- This incorporates made strides endothelial work, more noteworthy soundness of atherosclerotic plaques, decrease of oxidative stretch and irritation, and restraint of the thrombogenic reaction.[17,18]
- Statins have too been found to allosterically tie antigen 1 related with integrin β2 work (LFA1), which plays an critical part in leukocyte trafficking and enactment of T-lymphocytes.[19,20,21]

Uses

- To diminish the sum of greasy substances such as low-density lipoprotein (LDL) cholesterol ("awful cholesterol") within the blood.[22]
- And to extend the sum of high-density lipoprotein (HDL) cholesterol ("great cholesterol") in grown-ups.[23]
- Pitavastatin is additionally utilized in combination with diet to decrease the sum of cholesterol and other greasy substances within the blood in youths.[24]
- Bringing down the cholesterol and fat levels within the blood with pitavastatin has been appeared to avoid heart malady, angina (chest torment), strokes and heart assaults.[25,26]

PHARMACOKINETICS

Absorption

- It is retained through the small intestine
- 51% bioavailability orally

Volume of distribution

- 148L distribution

Protein binding

- More than 99% bound proteins in human plasma.

Metabolism

- The metabolism of pitavastatin is glucuronidation by means of hepatic uridine 5'-diphosphate glucuronosyltransferase (UGT) with ensuing arrangement of pitavastatin lactone.
- Metabolized marginally by CYP2C9 and to a lesser degree by CYP2C8.
- Negligible digestion system by the cytochrome P450 framework.[27,28,29]

Elimination

- Through urine (15%) and feces (79%)

Half life

- The half-life is approximately 12 hours.

Toxicity

- Backache
- Constipation
- Diarrhea
- Muscle aches
- Pain in the arms or legs

RECENT UPDATES ON PITAVASTATIN

Pitavastatin astoundingly diminished LDL-C levels and was well endured when managed at the normal grown-up measurements in 14 male children matured 10 to 15 a long time with heterozygous HF. Pitavastatin is promising restorative operator for pediatric dyslipidemia with few security concerns. Pitavastatin was utilized to show the appropriateness of a bottom-up approach to foresee transport-mediated mien in sandwich-grown human hepatocytes (SCHH), permitting for the commitment of the transporter to be assessed. Anna Vildhede et al effectively mimic transporter-mediated forms in a complex framework such as SCHH at the level of single transport proteins employing a bottom-up approach.[30,31] Dyslipidemia as a

inclining figure for cardiovascular malady is common, particularly in HIV-infected patients utilizing protease inhibitors (PIs), counting atazanavir. Pitavastatin has barely any sedate intuitive and self evident adequacy in bringing down lipid levels in nonHIV contaminated individuals. HMG-CoA reductase inhibitor, pitavastatin, in macrophage miRNAs within the nearness and nonattendance of oxidized LDL, a trademark of a proaterogenic environment. Pitavastatin can differentially alter miRNAs within the nearness of bull LDL and the comes about give prove that the net impact on cholesterol homeostasis is interceded by a arrange of miRNAs. Soichi Kurioka1 et al recommend that the combination treatment of pitavastatin and sitagliptin may have a renal defensive impact in sort 2 diabetic patients with hypercholesterolemia. Hiroaki Satoh et al propose that pitavastatin has useful impacts on affront affectability in an insulin-resistant state. Subsequently, in spite of the fact that future thinks about are required to assess the affect of pitavastatin treatment on CV dreariness and mortality, considers recommend that pitavastatin will play an imperative part within the future treatment of dyslipidemia and by and large decrease of CV chance. A few analysts found that its dissolvability and bioavailability were expanded by the Pitavastatin Calcium SelfEmulsifying Medicate Conveyance Framework (SMEDDS) definition.[32]

UV and HPLC methods on Pitavastatin

1. UV spectrophotometric strategies for the assurance of pitavastatin calcium in pharmaceutical and unadulterated shapes have been created and approved concurring to ICH rules. Calcium standard arrangements of pitavastatin were filtered between the ranges of 200-400 nm. The greatest absorbance of pitavastatin calcium in DMF (strategy A), HCl (strategy B) and NaOH (strategy C) was recorded at 266 nm. They complied the concentration of Lagers law within the run of 1045 µg / ml (strategy A), 0.25-2.0 µg / ml (strategy B) and 0.25-2.0 µg / ml (strategy C) with relationship coefficients 0.9996, 0.9998 and 0.9998 separately.[33,34] The steadiness ponder appeared tall solidness of calcium pitavastatin in an acidic, soluble and tall temperature medium, but it experienced debasement beneath conditions of oxidative push. The created strategies were approved for linearity, accuracy, exactness, LOD, LOQ, strength, vigor and recuperation considers. This strategies can be effectively utilized for schedule quality control testing of pitavastatin calcium in commercial and bulk pharmaceutical definitions.[35]

2. The chromatographic strategy was created agreeing to the Quality by Plan (QbD) approach and ICH Q8 (R2) rules for the estimation of pitavastatin in pharmaceutical frame. For the

improvement of an explanatory strategy considering the current administrative necessity, a turned around stage tall execution fluid chromatography strategy has been optimized for schedule investigation of pitavastatin utilizing an expository quality by plan approach. Not at all like the schedule approach, this ponder started with an understanding of the quality target item profile, explanatory target profile, and chance appraisal for strategy factors that influence strategy reaction.[36] In this try a fluid chromatography framework combined with a C18 column (250 x 4.6 mm, 5 µ), a double pump and a photodiode cluster finder was utilized. The tests were performed based on a central composite plan arrange, which seem spare time, solvents and other assets. Sigma Tech program was utilized to arrange and analyze the test perceptions and get the quadratic prepare demonstrate. The method show was utilized as a prescient arrangement for maintenance time. The information from the form chart for the maintenance time were really set up and fulfilled the real test information. The optimized strategy was gotten at a stream rate of 1.2 ml / min utilizing the portable stage composition of methanol and OPA in water at 80: 20% v / v, pH balanced to 6.5 balanced with alkali at 10. %. The strategy was approved and built up at the adaptable input variable level for a tall degree of vigor and framework appropriateness amid strategy exchange.[37]

3. A clear, delicate, dependable exact and quick turned around stage tall execution fluid chromatography (RP-HPLC) strategy has been created and approved for the assurance of calcium pitavastatin utilizing paracetamol as an inside standard. The chromatographic framework comprised of the Shimadzu LC-10ATVP, SPD-M10 AVP pump with PDA finder. The division was gotten on phenomenex C18 (250 x 4.60), column with molecule measure of 5 µ in isocratic mode at room temperature. The test was infused through an infusion valve with a 20 µl inspecting circle. 0.5% Acidic Corrosive: 35:65 acetonitrile (%, v/v) was utilized as the portable stage with a stream rate of 1ml / min. UV discovery was performed at 245 nm.[38] A calibration chart was drawn appearing a linearity extend of 1-5 µg / mL with the relationship coefficient of 0.9986. The LOD was found to be5 ng/mL, whereas the LOQ was found to be 20 ng/mL. Approval ponders unveil that the strategy is particular, quick, solid and reproducible. To think about the legitimacy of the strategy, recuperation considers and repeatability considers were performed beneath the same ideal conditions. Framework reasonableness thinks about were moreover calculated, counting column proficiency, determination, capacity figure, and top deviated figure. Subsequently, the proposed strategy is dependable, quick, exact and particular, so it can be utilized for the quantitative examination of pitavastatin calcium.[39]

4. Optimization of the HPLC strategy includes a few factors whose impact has been broadly examined. Be that as it may, in most cases, as it were handle factors are considered. In this work, the impact of the composition of the blend on the most elevated quality parameters of pitavastatin calcium within the shape of bulk and tablet doses was explored employing a simplex blend plan. A simplex middle of gravity plan with hub focuses was created in a pseudo-component representation from the unadulterated mix components. Twelve versatile stages of the ternary blend comparing to expanded design points were tried to partitioned the sedate within the test. A factual investigation was performed to create the polynomial condition for each reply. The allure approach was utilized to decide the ideal versatile stage composition. In expansion, the strategy was approved concurring to ICH rules utilizing specificity, linearity, exactness, accuracy, affectability, framework appropriateness and vigor. The comes about of the exploratory plan were factually tried in full and in portion to get the foremost reasonable show that accurately describes the changes within the extent of these solvents within the portable stage close the locale of most elevated ideal quality.[40] The strategy illustrated ideal chromatographic division with isocratic elution of the versatile stage containing a blend of acetonitrile-water (pH 3.0) -tetrahydrofuran (43:55:02, v/v/v) with a stream rate of 1.0 ml/minute. Test optimization methodology plan could be a capable apparatus for capturing the most noteworthy quality information whereas running a least number of tests. The composition of the mobile stage has been effectively optimized employing a simplex centroid mix plan with a attractive quality approach. Besides, the created strategy can be connected for schedule quantitative analysis of Pitavastatin Calcium in bulk and tablet measurement frame, because it demonstrated to be basic, touchy and vigorous.[41]

5. An rudimentary, quick, exact, exact, solid and reproducible UV spectroscopic strategy has been created for the synchronous estimation of pitavastatin calcium and fenofibrate in bulk and pharmaceutical frame. The strategy is based on the strategy of concurrent conditions. Pitavastatin calcium and fenofibrate have a greatest assimilation (λmax) at 245 nm and 286 nm, individually. Beer's law was complied within the concentration extend of 2-12 µg / mL and 32-192 µg / mL for pitavastatin calcium and fenofibrate, individually. Recuperation thinks about are demonstrative of the exactness of the strategy and run from 97.66-107.22% and 103.33110.55% for pitavastatin calcium and fenofibrate, individually, at three diverse levels of standard increments. Exactness ponders have delivered palatable comes about.[42]

CONCLUSION

In outline, the pitavastatin could be a novel statin with awesome clinical applications is broadly utilized in numerous antihyperlipedimic definitions. The over depicted explanatory strategies were frequently utilized for the evaluation and distinguishing proof pitavastatin.

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REFERENCES

1. Ginghina C, Bejan I, Ceck CD. Modern risk stratification in coronary heart disease. Journal of medicine and life, 2011; 4(4): 377.
2. Jørgensen T, Capewell S, Prescott E, Allender S, Sans S, Zdrojewski T, De Bacquer D, De Sutter J, Franco OH, Løgstrup S, Volpe M. Population-level changes to promote cardiovascular health. European journal of preventive cardiology, 2013; 20(3): 40921.
3. Mishra PR, Panda PK, Apanna KC, Panigrahi S. Evaluation of acute hypolipidemic activity of different plant extracts in Triton WR-1339 induced hyperlipidemia in albino rats. Pharmacologyonline, 2011; 3: 925-34.
4. Jeyabalan S, Palayan M. Antihyperlipidemic activity of Sapindus emarginatus in Triton WR-1339 induced albino rats. Research Journal of Pharmacy and Technology, 2009; 2: 319-23.
5. Shattat GF. A review article on hyperlipidemia: types, treatments and new drug targets. Biomedical and pharmacology journal, 2015; 7(1): 399-409.
6. Kumar D, Parcha V, Maithani A, Dhulia I. Effect and evaluation of antihyperlipidemic activity guided isolated fraction from total methanol extract of Bauhinia variegata (linn.) in Triton WR–1339 induced hyperlipidemic rats. Asian Pacific Journal of Tropical Disease, 2012; 2: S909-13.
7. Wells, G. B., Dipiro, J., Schwinghammer, T., Hamilton, C. Phamacotherapy Handbook, 7thedn, USA, TheMcgraw Hill Companies, 2007; 98-108.
8. Cleeman JI, Grundy SM, Becker D, Clark L. Expert panel on detection, evaluation and treatment of high blood cholesterol in adults. Executive summary of the third report of the

National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP III). Jama, 2001; 285(19): 2486-97.

9. Baker WL, Datta R. Pitavastatin: a new 3-hydroxy-3-methylglutaryl coenzyme a reductase inhibitor for the treatment of hyperlipidemia. Advances in therapy, 2011; 1: 13-27.
10. Shitara Y, Sugiyama Y. Pharmacokinetic and pharmacodynamic alterations of 3hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors: drug–drug interactions and interindividual differences in transporter and metabolic enzyme functions. Pharmacology & therapeutics, 2006; 112(1): 71-105.
11. Aoki T, Nishimura H, Nakagawa S, Kojima J, Suzuki H, Tamaki T, Wada Y, Yokoo N, Sato F, Kimata H, Kitahara M. Pharmacological profile of a novel synthetic inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A reductase. Arzneimittel-Forschung, 1997; 47(8): 904-9.
12. Kumar NS, Nisha N, Nirmal J, Sonali N, Bagyalakshmi J. HPLC determination of pitavastatin calcium in pharmaceutical dosage forms. Pharm Anal Acta, 2011; 2(119): 2.
13. Harada-Shiba M, Arisaka O, Ohtake A, Okada T, Suganami H. Efficacy and safety of pitavastatin in Japanese male children with familial hypercholesterolemia. Journal of atherosclerosis and thrombosis, 2015; 28753.
14. Vildhede A, Mateus A, Khan EK, Lai Y, Karlgren M, Artursson P, Kjellsson MC. Mechanistic modeling of pitavastatin disposition in sandwich-cultured human hepatocytes: a proteomics-informed bottom-up approach. Drug Metabolism and Disposition, 2016; 44(4): 505-16.
15. Kumar P, Mangla B, Singh S. Pitavastatin: A Potent Drug. Int J Pharma Res Health Sci., 2018; 6(1): 2070-74.
16. Kurioka S, Ohyama Y, Ichibangase A, Murata H, Kataoka N, Shimomura H, Sawaki H, Imai T, Ohashi S. Combination Therapy of Pitavastatin and Sitagliptin Improves the Estimated Glomerular Filtration Rate in Patients with Type 2 Diabetes. J Diabetes Metab, 2016; 7(667): 2.
17. https://www.drugbank.ca/drugs/DB08860
18. https://reference.medscape.com/drug/livalo-zypitamagPitavastatin-999209
19. http://www.drugsdb.com/rx/livalo/
20. https://ultra.news/t-t/32597/lupin-gets-fda-nod-genericcholesterol-drug/
21. https://www.drugs.com/dosage/Pitavastatin.html

22. Parashar P, Mangla B, Joshi SK. Design & development of novel lipid based carrier system for delivery of pitavastatin calcium. International Journal of Pharmaceutical Sciences and Research, 2016; 7(12): 5030.
23. Kajinami K, Takekoshi N, Saito Y. Pitavastatin: efficacy and safety profiles of a novel synthetic HMG-CoA reductase inhibitor. Cardiovascular drug reviews, 2003; 3: 199-215.
24. Mukhtar RY, Reid J, Reckless JP. Pitavastatin. International journal of clinical practice, 2005; 2: 239-52.
25. Streel B, Hubert P, Ceccato A. Determination of fenofibric acid in human plasma using automated solid-phase extraction coupled to liquid chromatography. Journal of Chromatography B: Biomedical Sciences and Applications, 2000; 742(2): 391-400.
26. Márk L, Császár A. Antilipemic agents in combined therapy. Orvosi hetilap, 2002; 143(34): 1973-8.
27. Fazio S. The role of statin therapy in primary hyperlipidemia and mixed dyslipidemia. US Endocrinology, 2011; 1: 23-9.
28. Nanjappan SK, Narayanan N, Jayabalan N, Narayanan S, Bagyalakshmi J. HPLC Determination of Pitavastatin Calcium in Pharmaceutical Dosage Form. Pharma. Ana. Acta, 2011; 2: 119-22.
29. Panchal HJ, Suhagia BN, Patel MM, Patel BH. Estimation of pitavastatin calcium in tablet dosage forms by column liquid chromatography and ultraviolet spectrophotometry. Journal of AOAC International, 2009; 92(1): 158-64.
30. Gomas AR, Ram PR, Srinivas N, Sriramulu J. Degradation pathway for pitavastatin calcium by validated stability indicating UPLC method. American Journal of Analytical Chemistry, 2010; 1(2): 83.
31. Neelima B, Kumar PR, Bindu VH, Prasad YR. A validated stability indicating RPHPLC method for estimation of pitavastatin in bulk and pharmaceutical dosage form. Int J Pharma Sci., 2013; 3: 309-15.
32. Jain N, Raghuwanshi R, Jain D. Development and validation of RP-HPLC method for simultaneous estimation of atorvastatin calcium and fenofibrate in tablet dosage forms. Indian journal of pharmaceutical sciences, 2008; 2: 263.
33. Choudhari VP, Nikalje AP. Simultaneous Estimation of Atorvastatin, Ezetimibe and Fenofibrate in Pharmaceutical Formulation by RP-LC-PDA. Pharm Anal Acta, 1: 111. doi: 10.4172/2153-2435.10001 11.
34. Kutty SV, Eapen SC, Shameer M, Faizal PP. Validated UV-Visible spectrophotometric method for the estimation of fenofibrate in pure and pharmaceutical formulation using

MBTH reagent. International Journal of Pharmaceutical Sciences and Drug Research, 2012; 4(1): 74-6.

35. Akabari AH, Shah DR, Shah SA, Suhagia BN. Kinetic determinations of pitavastatin calcium by stability indicating HPTLC method. Journal of Liquid Chromatography & Related Technologies, 2015; 38(4): 521-31.
36. Alves de Almeida A, Spacino Scarminio I. Statistical mixture design optimization of extraction media and mobile phase compositions for the characterization of green tea. Journal of separation science, 2007; 3: 414-20.
37. Kojima J, Fujino H, Yosimura M, Morikawa H, Kimata H. Simultaneous determination of NK-104 and its lactone in biological samples by column-switching high-performance liquid chromatography with ultraviolet detection. Journal of Chromatography B: Biomedical Sciences and Applications, 1999; 724(1): 173-80.
38. Satheesh Kumar N, Baghyalakshmi J. Determination and quantification of pitavastatin calcium in tablet dosage formulation by HPTLC method. Analytical letters, 2007; 40(1315): 2625-32.
39. Nakamura T, Sugaya T, Kawagoe Y, Suzuki T, Inoue T, Node K. Effect of pitavastatin on urinary liver-type fatty-acid-binding protein in patients with nondiabetic mild chronic kidney disease. American journal of nephrology, 2006; 26(1): 82-6.
40. Tian L, Huang Y, Jia Y, Hua L, Li Y. Development and validation of a liquid chromatography–tandem mass spectrometric assay for pitavastatin and its lactone in human plasma and urine. Journal of Chromatography B., 2008; 865(1-2): 127-32.
41. Fujino H, Yamada I, Shimada S, Yoneda M. Simultaneous determination of taxol and its metabolites in microsomal samples by a simple thin-layer chromatography radioactivity assay—inhibitory effect of NK-104, a new inhibitor of HMG-CoA reductase. Journal of Chromatography B: Biomedical Sciences and Applications, 2001; 757(1): 143-50.
42. Sharma S, Singh N, Ankalgi AD, Rana A, Ashawat MS. Modern Trends in Analytical Techniques for Method Development and Validation of Pharmaceuticals: A Review. Journal of Drug Delivery and Therapeutics, Feb 15, 2021; 11(1-s): 121-30.