ISSN: 2456-9909 (Online)

International Journal of Research in AYUSH and Pharmaceutical Sciences

Research Article

METHOD DEVELOPMENT AND VALIDATION OF LATANOPROST BY USING RP-HPLC IN PHARMACEUTICAL FORMULATIONS

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ARTICLE INFO

Article history:
Received: 15-03-2023
Revised: 22-03-2023
Accepted: 05-04-2023

Keywords:
Latanoprost, RP-HPLC, Precision, Validation.

ABSTRACT

Chromatography was performed with a mobile phase containing a methanol of assay (99.8%) with flow rate of 1ml/min. Quantitation was accomplished with an internal standard method. The procedure was validated for linearity (correlation coefficient = 0.990), accuracy and Limit of detection (LOD) intraday precision. To test validation of the Latanoprost three factors were considered as linearity, precision, LOD where mobile phase, flowrate and pressure are respectively selected as methanol, 1 ml/min, 1600 pascals.

INTRODUCTION

Drug Name: Latanoprost

Brand Name: XALATAN

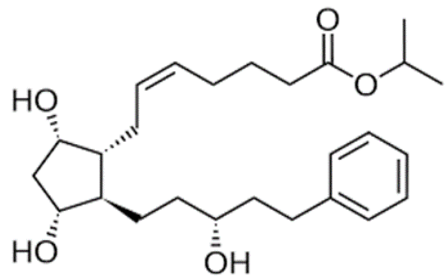

Figure: 1 Structure of Etoricoxib

MATERIALS AND METHODS

Preparation of solutions

Preparation of standard stock solution

Accurately weigh and transfer 1ml standard drug of Latanoprost into volumetric flask and add 9ml of methanol and dissolve by sonication process for 3 minutes and label it as standard stock solution of 1000µg/ml.

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	https://doi.org/10.47070/ijraps.v7i4.142

From the 1000µg/ml prepare 100µg/ml concentration by taking the volumes as 1ml of stock solution and 9ml of methanol into a test tube and label it as 100µg/ml.

From 100µg/ml prepare 10µg/ml concentration by taking the volumes as 1ml of stock solution and 9ml of methanol into an empty test tube and label it as 10µg/ml.

Preparation of stock solution

To detect the latanoprost tablet concentration take any branded tablet like XALATAN of latanoprost drug of powered dosage 10mg of equivalent weight and dissolve it in 10 ml of methanol of equivalent weight and sonicate it for 5 minutes, label it as sample solution.

Preparation of standard dilutions

Mobile phase(methanol) is used as a diluent. From the stock solution of concentration

100µg/ml pipette out the required volumes of concentration as 10µg/ml, 20µg/ml, 30µg/ml, 40µg/ml, 50µg/ml and 60µg/ml

HPLC Optimized Conditions

Mobile phase: Methanol and Acetonitrile (20:80)

Diluents: Hplc grade Methanol

Column: C18 (5 µm pore size)

Column Temp: Ambient

Wavelength: 205nm

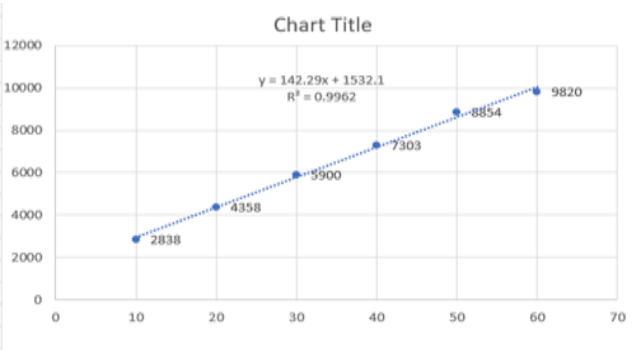
Injection Volume: 20 µl

RESULT AND DISCUSSION

Linearity

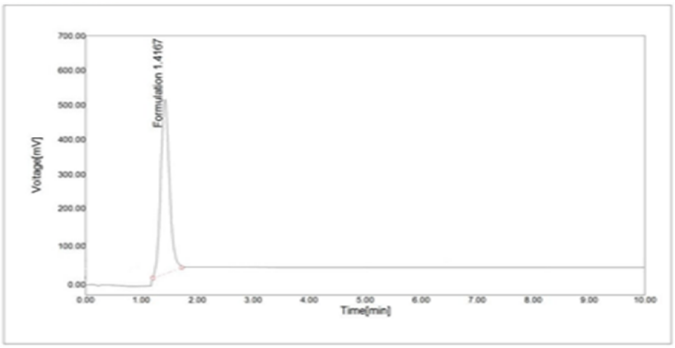
From the prepared stock solution, a series of calibration standards were prepared at concentrations of 10, 20, 30, 40, and 50µg/ml using mobile phase as solvent. The calibration curve for Latanoprost was constructed by plotting the mean peak area against the drug concentration. Regression equation was found to be y = 142.4x + 1529.4 (r2 = 0.9963). Linearity results were given in table 3 and linear graph is given in Figure 2.

Level	Concentration	peak area
Level – 1	10µg/ml	2838
Level – 2	20µg/ml	4358
Level – 3	30µg/ml	5900
Level – 4	40µg/ml	7303
Level – 5	50µg/ml	8854



Formulation

The sample solution prepared at a concentration of 100µg/ml was analyzed in the developed method conditions. The method can successfully separate and identify the Latanoprost. Hence the method was found to be suitable for routine analysis of Latanoprost and formulations.



Formulation	Dosage	% Assay
1.4167	50mcg	93.38%

CONCLUSION

The estimation of Latanoprost was done by RP-HPLC. The assay of Latanoprost was performed with tablets and the % assay was found to be 91.1% which shows that the method is useful for routine analysis. The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision Latanoprost which shows that the method is repeatable when performed in different days also.

The total recovery was found to be 91.1% for Latanoprost. The LOD and LOQ for Latanoprost was found to be 3.02 and 9.98.

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Cite this article as:
K.Srinivas, D.Narendra, P.V.V.Varaprasad, G.Jaya durga madhuri, K.Eswari, N.Shanti priya. Method Development and Validation of Latanoprost by Using RP-HPLC in Pharmaceutical Formulations. International Journal of Research in AYUSH and Pharmaceutical Sciences, 2023;6(4):14-16.
https://doi.org/10.47070/ijraps.v7i4.142
Source of support: Nil, Conflict of interest: None Declared

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