Research Article **CODEN: IJRPJK** **ISSN: 2319 – 9563**

International Journal of Research in Pharmaceutical and Nano Sciences

Journal homepage: www.ijrpns.com

https://doi.org/10.36673/IJRPNS.2021.v10.i03.A21

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF ETRAVIRINE TABLETS BY RP-HPLC

S. G. Raman*[1] and I. Sarath Chandiran[1]

[1*]Department of Pharmaceutical Chemistry, School of Pharmacy, Sri Balaji Vidyapeeth Deemed to be University, Puducherry-607402, India.

ABSTRACT

A new, simple, specific, rapid, accurate, and precise reverse phase HPLC method was developed for Etravirine tablets. They were chromatographic on a reverse phase column-(Symmetry c8, 150 x 4.6mm, 5µ), in a mobile phase consisting of mix buffer solution and methanol in the ratio (35.65).

KEYWORDS

Etravirine, RP- HPLC method, Validation and ICH guidelines.

Author for Correspondence:

Raman S G,

Department of Pharmaceutical Chemistry, School of Pharmacy, Sri Balaji Vidyapeeth Deemed to be University, Puducherry-607402, India.

Email: rtanush2015@gmail.com

INTRODUCTION

Etravirine is chemically is a 4-{[6-amino-5bromo-2-((4-cyanophenyl) amino)- 4 pyrimidinyl] oxy}-3, 5 dimethylbenzylnitrile, Prevents human immune deficiency virus (HIV) from multiplying in your body.

MATERIAL AND METHODS

Materials, Reagents, and Chemicals

Samples of Etravirine standards were obtained from madras Pharma Laboratories Pvt. Limited, (Chennai, India).

Mobile preparation: Dilute Glacial Acetic acid preparation

Dilute 1ml of glacial acetic acid to 10ml with water.

Buffer preparation

Dissolve 1.54g of ammonium acetate in 100ml of water. Adjust the pH to 6.0± 0.05 with dilute glacial acetic acid mix well and filter.

Validation parameters

Precision

The precision of an analytical method is the degree of agreement among induvial test results when the method is applied repeatedly to multiple samplings of homogeneous sample.

System Precision

The precision of the instrument was checked by repeated injections of a concentration and measurement of peak areas

Sample preparation procedure

Determine the average weight using not less than 20 tablets. Weigh and finely powder not less than 20 tablets. Weight accurately and transfer tablet powder equivalent to about 200mg into a 200ml volumetric flask. Add 140ml of diluent and shake for 15mins. Shake mechanically at 180 rpm for 10mins.

Linearity

The linearity of an analytical method is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of analyze in samples within a given range.

Linearity stock preparation

Linearity solution 5%

0.5ml of stock solution to 100ml with diluent. 101ml/100ml*0.5ml/100ml*1000=5.100mcg/ml.

Linearity solution 25%

2.5ml of stock solution to 100ml with diluent 101ml/100ml*2.5ml/100ml*1000=25.25mcg/ml.

Linearity solution 50%

5ml of stock solution to 100ml with diluent 101ml/100ml*10ml/100ml*1000= 101.0mcg/ml.

Accuracy

The accuracy of an analytical method is the closeness of results obtained by that method to the true value. The accuracy of an analytical method should be established across its range.

Preparation of standard

Weigh 101mg (100mg) of Etravirine standard in 70ml of buffer solution for 15minutes, dilute 100ml with diluent filter. Dilute 5ml of the filtrate to 50ml with diluent.

Preparation of sample 25%

Required weight= 0.025g or 25mg

Average weight= 101mg

Label claim= 100mg

Average weight/ label claim x required weight

$$\frac{101\text{mg}}{100\text{mg}} \times 0.025\text{g} = 0.0253\text{g}$$

RESULTS AND DISCUSSION

The working conditions for HPLC method was established for Etravirine and then applied on pharmaceutical dosage form. From the optical characteristics of the proposed method, it was found that Etravirine obeys repeatability (method precision)

Method validation report

Summary

The developed method was validated for various parameters like accuracy, precision, linearity.

The proposed method is applied for determination for Etravirine Tablet

Hence the proposed method is found to be satisfactory and could be used for the routine analysis if Etravirine Tablet.

The proposed assay method shows interesting features such as rapidity, simplicity, high sensitivity and low cost per analysis, involving neither sophisticated nor sophisticated nor expensive instrumentation.

Analysis of Etravirine in pharmaceutical dosage forms.

Injection No	Concentration	Peak Area
1	101mcg/ml	3569188
2	101mcg/ml	3572308
3	101mcg/ml	3572579
4	101mcg/ml	3572486
5	101mcg/ml	3576656
Mean		3572244
% RSD		0.08

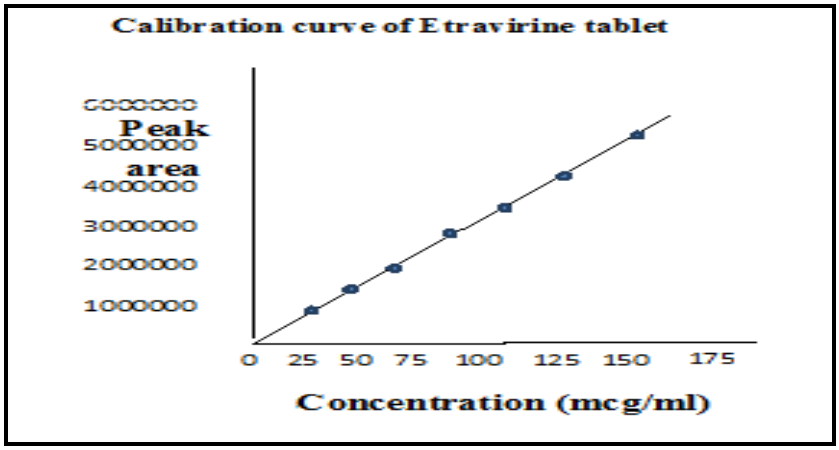
Sample No	Peak Area	% Release
1	3672213	102.44
2	3647377	101.71
3	3648151	101.83
4	3675495	102.53
5	3631581	101.22
6	3635931	101.40
Mean		101.85
%RSD		0.52

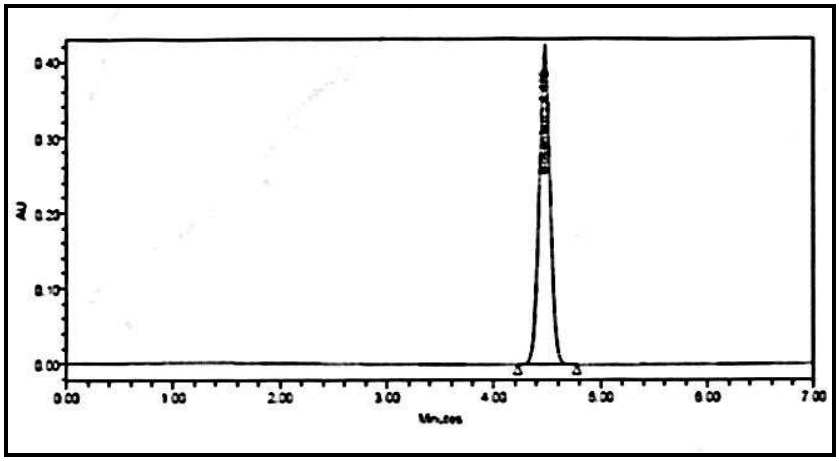
S.No	% Level	Concentration	Mean Area (Peak area)
1	5%	2.503	203686
2	25%	25.032	916428
3	50%	50.5	1828921
4	80%	80.8	2938700
5	100%	101.0	3639823
6	120%	121.1	4573995
7	150%	151.5	5482943

S. No	Theoretical Recovery	(%)peak area	% Recovery	Mean (%)	% RSD
1	25-1	189754	98.63	99.83	1.08
2	25-2	189523	100.73		
3	25-3	188913	100.13		
4	50-1	1798399	100.57	100.65	0.22
5	50-2	1798986	100.48		
6	50-3	1799675	100.91		
7	100-1	3582037	100.90	100.84	0.09
8	100-2	3583001	100.73		
9	100-3	3582032	100.90		

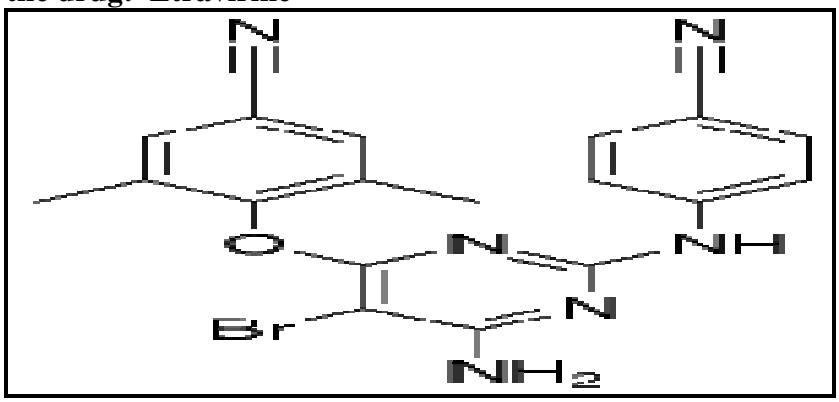
S.No	Test Parameters	Observed Results		Specification Limit
1	Accuracy	25	99.8	95-105%
		50	100.7	
		100	100.8	
2	Repeatability	101.9%		90-110%
3	Linearity	0.9999		r^2 not less than 0.99

Calibration curve of Etravirine tablet





Chemical structure of the drug: Etravirine



CONCLUSION

The developed RP - HPLC method is simple and selective for estimation of Etravirine in Tablet dosage form was found to be accurate, rapid and sensitive.

ACKNOWLEDGEMENT

The authors wish to express their sincere gratitude to Department of Pharmaceutical Chemistry, School of Pharmacy, Sri Balaji Vidyapeeth Deemed to be University, Puducherry-607402, India for providing necessary facilities to carry out this research work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

REFERENCES

1. Braith W and Smith F J. Chromatographic methods, *Kluwer Academic Publisher,* 5th Edition, 1996, 1-2.
2. Code Q2B, Validation of analytical procedures; Methodology, *ICH Harmonized Tripartite Guidelines, Geneva, Switzerland,* 1996, 1-8.
3. Skoog D A, West D M, Holler F J. Introduction analytical chemistry, sounder college of publishing, *Harcourt Brace College Publishers,* 1994, 1-5.
4. Willard H, Merritt L L, Dean J A and Settle F A. Instrumental methods of analysis, *CBS Publishers and Distributors, New Delhi,* 7th Edition, 1991, 436-439.
5. ICH Q2A. Validation of Analytical methods, Definition and Terminology, *ICH Harmonized Tripartite Guidelines,* 1999.
6. Abhilash P R, Rao J V. HPTLC Method Development and validation for Determination of Etravirine in bulk and tablet dosage form, *Int J Pharm Biol Sci,* 3(3), 2013, 515-522.
7. Kumar P R, Chinnalalaiah R. Development and Validation of anew RP-HPLC method for estimation of Etravirine in bulk and pharmaceutical dosage form, *Int J Pharm Biol Sci,* 3(4), 2013, 291-294.
8. Thangabhalan B, Gollapudi C, Sunitha N, Babu M S. Stability Indicating RP-HPLC method for the estimation of Etravirine in pure and tablet dosage form, *Int J Pharm Biol Sci,* 1(4), 2013, 581-591.

Please cite this article in press as: Raman S G. Analytical method development and validation of Etravirine tablets by RP-HPLC, *International Journal of Research in Pharmaceutical and Nano Sciences,* 10(3), 2021, 174-178.