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ESTIMATION OF RIZATRIPTAN IN TABLET DOSAGE FORM BY HPLC

A. Venkatesh*¹, C. Karuppasamy¹, G. Soma Sekhar¹, Y. Suresh¹, B. Jaffar Hussain¹, M. Jyothsna¹

¹*Department of Pharmaceutical Analysis, Safa College of Pharmacy, B. Thandrapadu, Kurnool, Andhra Pradesh, India.

ABSTRACT

A simple, accurate and precise reverse phase HPLC method validated for the determination of RIZATRIPTAN Tablet dosage form. Chromatography was carried on inertsilods 3v 5 μ m column using a mixture of PHOSPHATE BUFFER and acetonitrile, pH 7.8(in the ratio 70:30 v/v) as the mobile phase at a flow rate of 1.0ml /min with detection at 235 nm by ultra violet detector i.e. incorporated in HPLC. The retention time of the drug was found to be 3.360min. The method validation proofs were carried out as per the ICH guidelines. The developed method was validated for linearity over a range of 30 μ g/ml to 70 μ g/ml, with a correlation coefficient of 0.998, which shows the method is quite linear. Further precision, ruggedness, accuracy were validated. The % RSD for system precision was observed to be Less Than 2, the average recovery of 100.0% indicates the capability of the method, and finally no significant differences in % RSD values with respective Retention time prove the robustness of the method. As per ICH guidelines, method validation results are in good agreement. The proposed approach is effective and can be applied for the tablet dosage form estimation of Rizatriptan in tablet dosage form.

KEYWORDS

RIZATRIPTAN Tablet dosage form, Accurate, Rapid and Precise.

Author for Correspondence:

Venkatesh A,
Department of Pharmaceutical Analysis,
Safa College of Pharmacy,
B. Thandrapadu, Kurnool, Andhra Pradesh, India.

Email: karups.smily@gmail.com

INTRODUCTION

Rizatriptan is a triptan drug used for the treatment of migraine headaches. It is a selective 5-hydroxytryptamine₁ receptor sub type agonist. This compound belongs to the class of organic compounds known as tryptamines and derivatives. These are compounds containing the tryptamine backbone, which is structurally characterized by an indole ring substituted at the 3-position by an ethanamine. IUPAC Name dimethyl (2-[5-(1H-1,

2, 4-triazol-1-ylmethyl)-1H-indol-3-yl] ethyl}} amine Molecular weight: 269.3449 Molecular formula: C₁₅H₁₉N₅ Category: Analgesics, Serotonin Antagonists. An attempt was made in a stepwise manner to devise a simple, rapid, selective, validated and sophisticated method, like, High Performance Liquid Phase Chromatography (Reverse Phase) for Rizatriptan¹⁻⁵.

EXPERIMENTAL

Chemicals and solvents

Preparation of standard solution

Weigh accurately 50 mcg of RIZATRIPTAN in 50 ml of volumetric flask and dissolve in 10ml of mobile phase and make up the volume with mobile phase. From above stock solution 50 µg/ml of chromatogram. RIZATRIPTAN is prepared by diluting 1ml to 50ml with mobile phase. This solution is used for recording.

ASSAY

Preparation of samples for Assay

Standard sample

Weigh accurately 10 mg of RIZATRIPTAN in 100 ml of volumetric flask and dissolve in 10ml of mobile phase and make up the volume with mobile phase. From above stock solution 50 µg/ml recording chromatogram of RIZATRIPTAN is prepared by diluting 1ml to 50ml with mobile phase. This solution is used.

Sample

10 Tablets (each Tablet contains 50 mcg of RIZATRIPTAN) were weighed and taken into a mortar uniformly mixed. Test stock solutions of RIZATRIPTAN (50 µg/ml) and was prepared by dissolving weight equivalent to 50 mcg of RIZATRIPTAN and dissolved in sufficient mobile phase. After that filtered the solution using 0.45-micron syringe filter and Sonicated for 5 min and dilute to 100ml with mobile phase. Further dilutions are prepared in 5 replicates of 50 µg/ml of RIZATRIPTAN was made by adding 1 ml of stock solution to 10 ml of mobile phase¹⁻⁵ (Table No.1 and 2, Figure No.1 and 2).

Reagents used

Water	HPLC- Grade
Sodium Acetate	AR- Grade
Methanol	HPLC- Grade
Potassium Phosphate	AR- Grade
Acetonitrile	HPLC- Grade
Ammonium acetate	AR- Grade
Triethylamine	AR- Grade

Drugs used

Letrozole drug	Gift Samples obtained from Chandra labs, Hyd.
Letrozole-50 mcg (label claims)	Obtained from local pharmacy

RIZATRIPTAN			
S.No		Standard Area	Sample Area
1	Injection-1	5669.952	5671.137
2	Injection-2	5662.333	5662.791
3	Injection-3	5658.261	5673.739
4	Injection-4	5664.934	5673.399
5	Injection-5	5650.279	5669.467
6	Average Area	5663.515	5670.107
7	Tablet average weight	10mg	
8	Standard weight	10mg	
9	Sample weight	10mg	
10	Label amount	10mg	
11	std. purity	98.8	
12	Amount found in mg	49.46	
13	Assay (%purity)	98.91	

Observation

The amount of RIZATRIPTAN present in the taken dosage form was found to be 98.91%.

Table No.1: Result for RIZATRIPTAN by using mobile phase

S.No	Name	Rt (min)	Peak Area	Asymmetry	Efficiency
1	RIZATRIPTAN	3.360	5671.137	1.759	6908

Table No.2: Linearity of RIZATRIPTAN

S.No	Conc.(µg/ml)	Area
1	30	3701.699
2	40	4597.349
3	50	5665.736
4	60	6461.637
5	70	7438.255

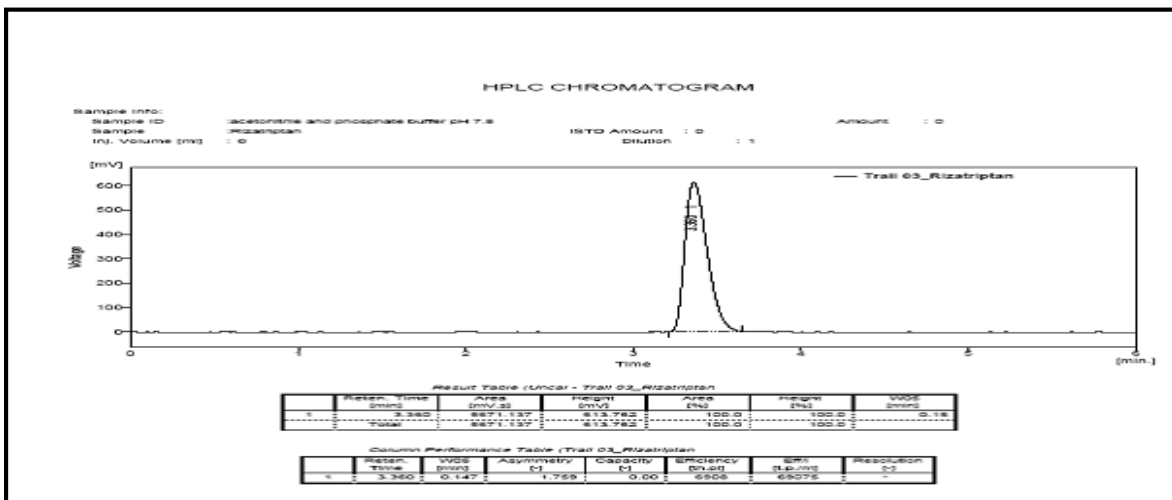


Figure No.1: Chromatogram of RIZATRIPTAN by using mobile phase

Observation:

The efficiency was more than 2000. Hence it was taken for optimization.

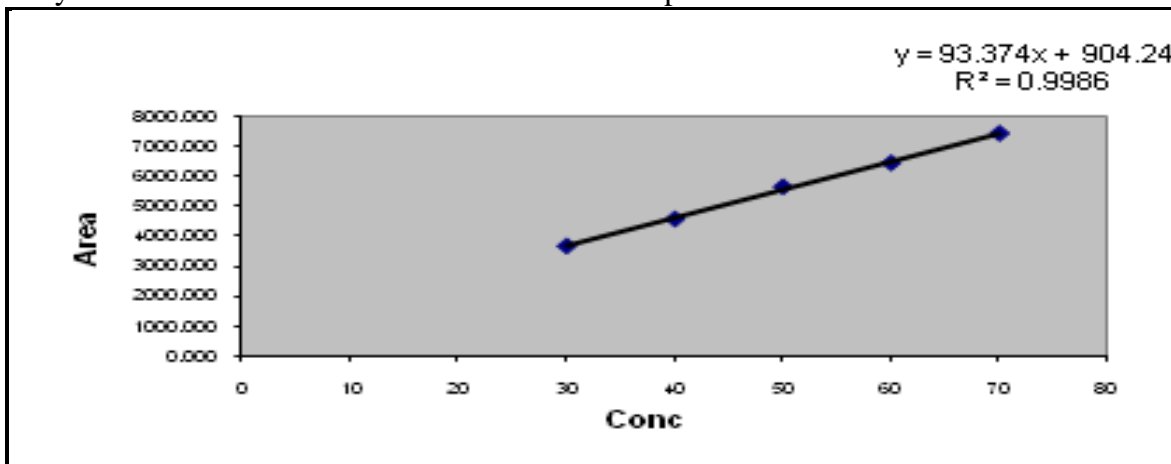


Figure No.2: Linearity graph for RAZITRIPTAN

CONCLUSION

Thus it can be concluded that the methods developed in the present investigation are simple, sensitive, accurate, rapid and precise. Hence, the above said method can be successfully applied for the RAZITRIPTAN in tablet dosage form.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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