INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN: 2320-2831

IJPAR |Vol.4 | Issue 1 | Jan-Mar-2015
Journal Home page: www.ijpar.com

Research article *Open Access*

A simple validated RP-HPLC method for quantification of sumatriptan succinate in bulk and pharmaceutical dosage form

Jampala Balaji[1*], K.Aruna[2], N.V.S.Naidu[1]

[1, 2]Department of Chemistry, Sri Venkateswara University, Tirupathi, India-517502

***Corresponding author: Jampala Balaji**

E-mail id: jbaluchem@gmail.com

ABSTRACT

A simple reverse phase high performance liquid chromatography method developed for quantification of sumatriptan succinate in bulk and pharmaceutical dosage form. This method achieved by using isocratic elution with mixed phosphate buffer (pH: 6.8) and acetonitrile mobile phase at 70:30 ratio, Hypersil BDS C18 (150 X 4.6mm, 5µm) column at temperature 30ºC, flow rate 1.0mL/min and 228nm UV with PDA detector. This method validated as per ICH guidelines. This method was simple, specific, precise, linear, accurate, robust and ruggedness for analysis of sumatriptan succinate.

Keywords: Sumatriptan succinate, Reverse phase HPLC, Hypersil BDS C18, Isocratic elution.

INTRODUCTION

Sumatriptan succinate is chemically 1-[3-(2-Dimethyl aminoethyl)-1H-indol-5-yl]-N-methyl-methane sulphonamide succinate (Figure: 1). Sumatriptan is a serotonin 5-HT1 receptor agonist. Sumatriptan succinate helps to relieve headache pain and associated symptoms of migraine (like nausea, vomiting, sensitivity to light and sound). It also helps to constrict dilated blood vessels that may contribute to development of migraines. It is official in BP[1], EP[2] and USP[3]. For the determination of Sumatriptan succinate, few methods are available by UV spectrophotometric method [4], by HPLC methods [5][6][7][8]. The developed RP-HPLC method has low run time and simultaneous estimation of sumatriptan succinate in bulk and pharmaceutical dosage form. It is very simple, specific, precise, linear, accurate and reproducible method.

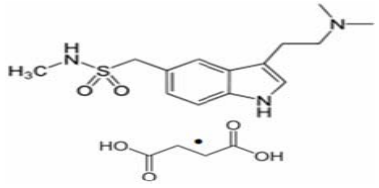

Figure1: Structure of Sumatriptan Succinate

MATERIALS AND METHODS

Apparatus

HPLC (Model: Alliance 2695 separation module, Make: Waters, Software: Empower-2), PDA detector (Model: 2996 photodiode array detector, Make: Waters), Digital pH meter (Model: LP-1393, Make: POLMAN), Sonicator (Model: Soltec, Make: Sonica), Electronic Weighing Balance (Model: ML204 Ia01, Make: Mettler Toledo).

Chemicals and Reagents

Acetonitrile (HPLC grade, Make: Qualigens fine chemicals), Potassium dihydrogen orthophosphate (AR grade, Make: S.D Fine Chem. Ltd), Dipotassium hydrogen phosphate (AR grade, Make: S.D Fine Chem. Ltd), Water (HPLC grade), Ortho phosphoric acid (AR grade, Make: Merck), Sumatriptan succinate (Richer Pharmaceuticals, India), Sumitrex 50mg tablets (Sun pharmaceuticals, India).

Chromatographic Conditions

This separation of analytes achieved by isocratically using Hypersil BDS C18 (150 X 4.6mm, 5µm) column, column oven temperature 30ºC, flow rate 1.0mL/min, UV at 228nm. Mobile phase was mixed phosphate buffer (pH: 6.8) and acetonitrile at 70:30 ratio. Diluent was mobile phase. Run time was 10min.

Preparation of mobile phase

2.72g of potassium dihydrogen orthophosphate and 2.72g of dipotassium hydrogen phosphate weighed and transferred to 1000mL volumetric flask and make up to the mark with water and adjusted pH: 6.8(±0.1)with diluted orthophosphoric acid solution. This mixed buffer and acetonitrile were taken in the ratio of 70:30 and mixed well then filtered through 0.45 µm Millipore filter paper and sonicated using sonicator up to 15min.

Preparation of standard solution

Prepared 20mg of sumatriptan succinate working standard in 100mL diluent for standard stock solution. Transferred 10mL of the standard stock solution in to 100mL volumetric flask and made up to the mark with diluent. This standard solution used to sample analysis.

Preparation of sample solution

Bulk sumatriptan succinate analysis

20mg of bulk sample weighed and transferred in to 100mL volumetric flask then made up to the mark with diluent then used as a sample stock solution. Transferred 10mL of the sample stock solution in to 100mL volumetric flask and made up to the mark with diluent. This sample solution used to sample analysis.

Pharmaceutical formulations analysis

5 tablets of Sumitrex 50mg powdered using mortar. 142mg of this powder sample weighed and transferred in to 100ml volumetric flask and dissolved in 50mL diluent then made up to the mark with diluent . This sample solution filtered then used for sample analysis.

Sample analysis

Injected 20µL of blank (diluent), standard solution and sample solution in HPLC for sample analysis.

Method Validation

Specificity and Selectivity

The specificity of the method was checked by injecting blank solution and sample solution. There was no interference from blank and excipients at the retention time of analyte peak.

Linearity

Linearity was checked by preparing six concentrations of the substance ranging from 25% to 150%. A concentration of 20ppm solution was proposed in the procedure as a 100%. Hence, the test substance was prepared at concentrations of 5ppm, 10ppm, 15ppm, 20ppm, 25 ppm and 30ppm for determination of linearity. Estimations were carried out as per the procedure mentioned. Observations were recorded and a linearity curve was prepared using regression analysis. The correlation coefficient was 1.000. Linearity graph was shown in Fig.8.

Accuracy

The accuracy of the method was determined by % of recovery method for the spiked concentration levels of 10ppm (50%), 20ppm (100%) and 30ppm (150%). The accuracy results were shown in table1.

Precision

The method precision and system precision were calculated. The results were within limits**.** The results were shown in table2.

Robustness of the Method

Changing with the flow rate (±0.1mL/minute) and column oven temperature (±2ºC) and calculated RSD. The results were within limits.

Ruggedness of the Method

The ruggedness of the method was performed with different analyst and different day analysis and calculated RSD. The results were within limits.

Degradation Studies

Degradation studies were performed in the presence of acid, base, heat and UV. In all conditions sumatriptan was degraded and gave impurities. In acidic condition it degraded more compare with other conditions.

RESULTS AND DISCUSSIONS

The developed method was validated as per ICH guidelines for specificity, linearity, accuracy, precision, robustness and ruggedness. The results were within limits. As per degradation studies sumatriptan succinate was unstable in presence of acidic condition, basic condition, heating condition and UV condition. In acidic condition it was degraded more compare with remaining conditions.

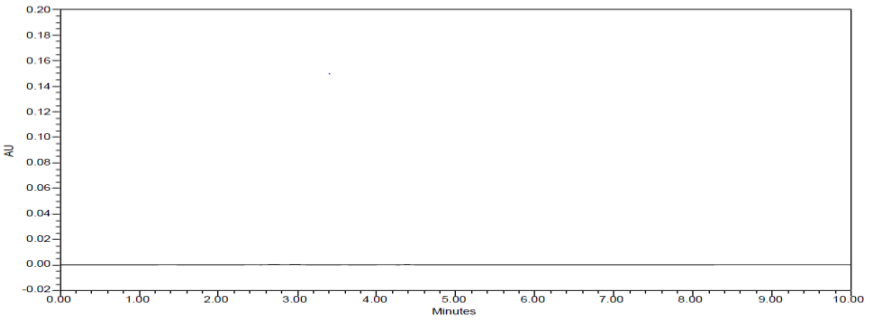

Figure 2: Chromatogram of Blank

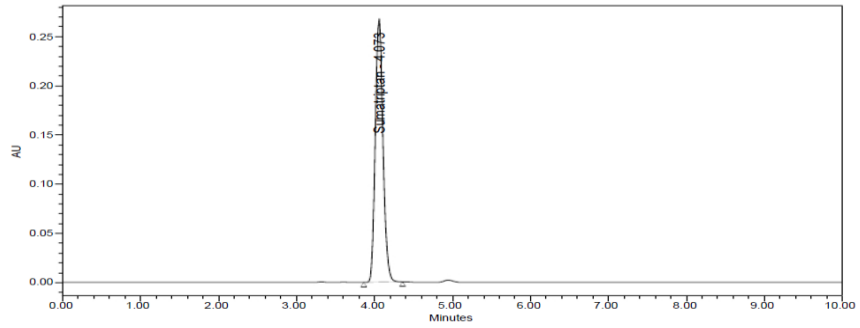

Figure 3: Chromatogram of Sample solution

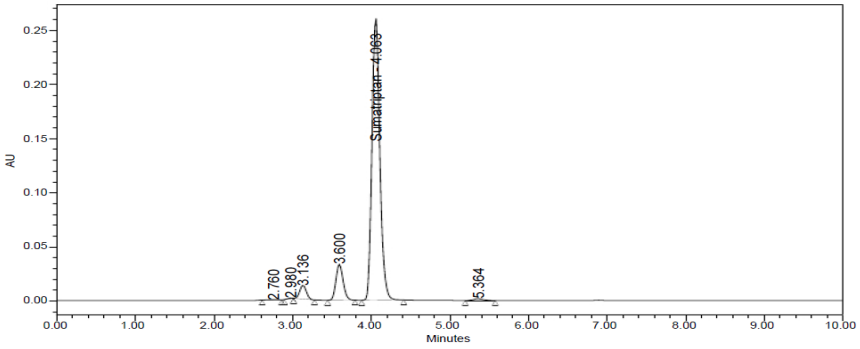

Figure 4: Chromatogram of Sample solution degradation in acidic condition

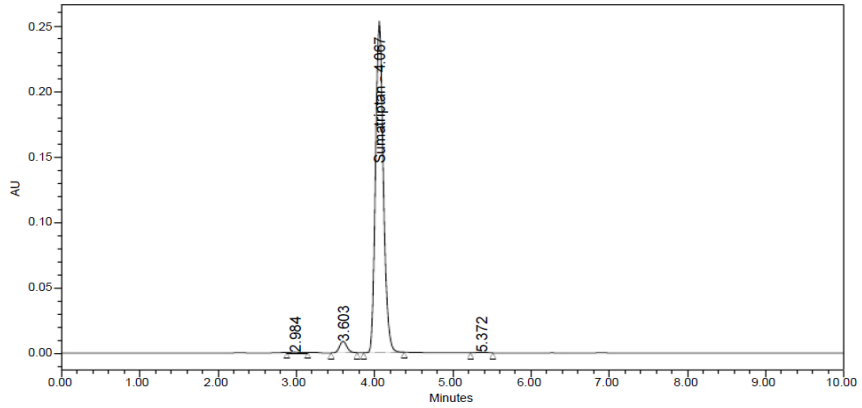

Figure 5: Chromatogram of Sample solution degradation in basic condition

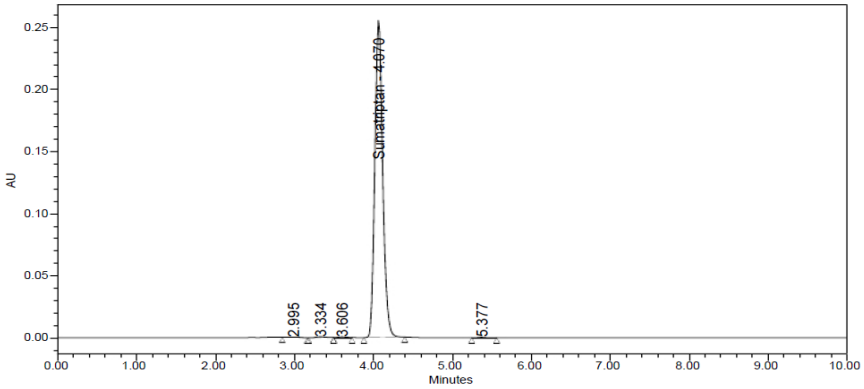

Figure 6: Chromatogram of Sample solution degradation in heat condition

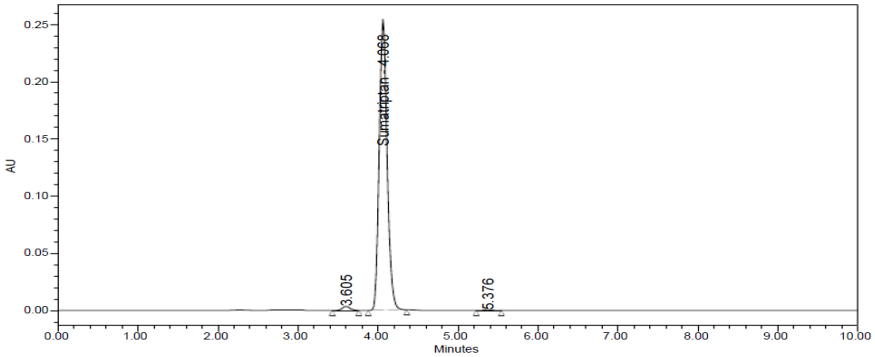

Figure 7: Chromatogram of Sample solution degradation in UV condition

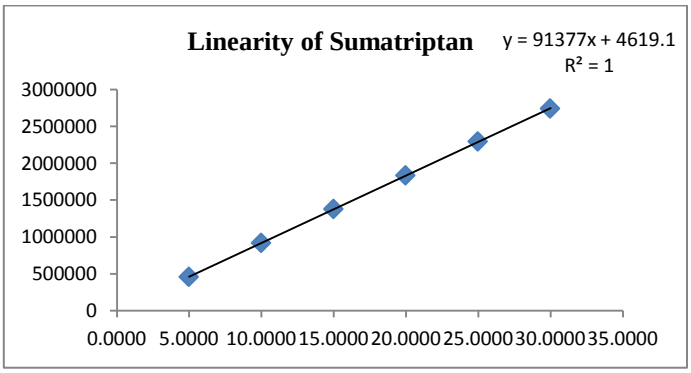

Figure 8: Linearity graph for sumatriptan succinate analysis

Table 1: Accuracy

Concentration Level(spike)	Recovery
50%	100.15%
100%	99.67%
150%	99.69%

Table 2: Precision

Precision	%RSD
System Precision	0.28%
Method Precision	0.29%

CONCLUSION

The developed RP- HPLC method was very simple, selective and reproducible method for analysis of sumatriptan succinate in bulk and pharmaceutical It was accurate, precise, linear, robust and ruggedness method. As per best of my knowledge this method was very simple method for determination of sumatriptan succinate in both bulk and pharmaceutical dosage forms.

REFERENCES

[1] British Pharmacopoeia, Vol.2, 1964**,** 2009.
[2] European Pharmacopoeia, 6th Edition, Vol.2, 3005, 2008.
[3] USP, The United States Pharmacopoeia, 31st Revision, US Pharmacopoeia Convention Inc. Rockville, MD, vol.3, 3310,2008.
[4] Rajesh Kumar Nayak, Sunil Kumar Swain, Susanta Kumar Panda, Kanhu Charana Sahu, Debananda Mishra, Sanjay Kumar, "Method Development and Validation of Sumatriptan in Bulk and Pharmaceutical Dosage Forms By UV Spectrophotometric Method", International Journal of Pharmaceutical & Biological Archives, 2(4),1100-1105, 2011.
[5] Solanki Sagar D, Dr. Patel Paresh U, Dr. Suhagiya Bhanubhai N, "Development and Validation of Reversed-Phase High Performance Liquid Chromatographic Method for Estimation of Sumatriptan Succinate in Pharmaceutical Dosage Form", Int. J. Drug Dev. & Res., **3**(3), 266-269, 2011.
[6] Ravi Sheshala, Nurzalina Khan1 and Yusrida Darwis, "Validated high performance liquid chromatography (HPLC) method for the determination of sumatriptan in rabbit plasma: Application to pharmacokinetic study", Afr. J. Pharm. Pharmacol, 6(2), 98-107, 2012.
[7] Sagar D. Solanki, Dr. Paresh U. Patel, "Development and Validation of Reversed-Phase High Performance Liquid Chromatographic Method for Simultaneous Estimation of Sumatriptan Succinate and Naproxen Sodium in Pharmaceutical Dosage Form", Int J Pharm Pharm Sci, Vol 4, Suppl 1, 276-278, 2012.
[8] Aaditya Singh, Shiv Bhadra Singh, "Simultaneous Estimation of Sumatriptan Succinate, Metoclopramide Hydrochloride and Paracetamol by RP-HPLC method", J. Pharm. Sci. & Res, 4(6), 1848 – 1851, 2012.