ISSN: 2395-0536 Impact Factor- 2.90*

INTERNATIONAL JOURNAL OF PHARMACEUTICAL RESEARCH AND NOVEL SCIENCES

IJPRNS

DEVELOPMENT AND VALIDATION OF NEW HPLC METHOD FOR ATOMOXETINE IN PHARMACEUTICAL DOSAGE FORM

M.Suresh Babu*, R.Swathi, M.Durga Prasad, G.Purna Santhoshi, P.Satyasri

Department of Pharmaceutical Analysis, JITS College of Pharmacy, Kalgampudi, Andhra Pradesh, India.

ABSTRACT

A simple and selective HPLC method is described for the determination ofAtomoxetineChromatographic separation was achieved on a C18column using mobile phase consisting of a mixture of 40 volumes of Methanol, 40 volumes of Acetonitrile and 20 volumes of Water with detection of 253 nm. Linearity was observed in the range 50-150 µg /ml for Atomoxetine (r^2 =0.990) for the amount of drugs estimated by the proposed methods was in good agreement with the label claim. The proposed methods were validated. The accuracy of the methods was assessed by recovery studies at three different levels. Recovery experiments indicated the absence of interference from commonly encountered pharmaceutical additives. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

Key Words: Atomoxetine, HPLC method

Author for correspondence
M.Suresh Babu,
Department of Pharmaceutical Analysis,
JITS College of Pharmacy, Kalgampudi,
Andhra Pradesh, India.
Email id: sureshbabu3377@gmail.com

INTRODUCTION

Pharmaceutical analysis simply means analysis of pharmaceuticals. Webster' dictionary defines a pharmaceutical is a medical drug. A more appropriate term for a pharmaceutical is active pharmaceutical ingredient (API) or active ingredient to distinguish it from a formulated product or drug product is prepared by formulating a drug substance with inert ingredient (excipient) to prepare a drug product that is suitable for administration to patients. Research and development (R&D) play a very comprehensive role in new drug development and follow up activities to ensure that a new drug product meets the established standards is stable and continue to approved by regulatory authorities ,assuring that all batches of drug product are made to the specific standards utilization of approved ingredients and production method becomes the responsibility of pharmaceutical analysts in the quality control (QC) or quality assurance department . The methods are generally developed in an analytical R&D department and transferred to QC or other departments as needed. At times they are transferred to other divisions.By now it should be quite apparent that pharmaceutical analysts play a major role in assuring the identity, safety, efficacy, and quality of drug product, safety and efficacy studies required that drug substance and drug product meet two critical requirements.Established identity and purity and Established bio availability/dissolution. Atomoxetine is a nonstimulant medication marketed in the form of the R (-) isomer as this structure seems to have approximately nine-fold more potency than the S (+) isomer. It is a phenylpropanolamine

derivative that presents a similar structure to the tricyclic antidepressants. Atomoxetine was the first medication approved for attention deficit hyperactivity disorder (ADHD) that was not previously approved for other condition.Atomoxetine is recommended for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adults. It is recommended as a monotherapy in youths that do not respond correctly to stimulants.ADHD is a neurodevelopmental disorder that can be categorized as a mental health condition. The symptoms of this condition start at childhood, but they continue in adolescence and adulthood. The risk factors of ADHD are variable, and they include the consumption of cigarettes, alcohol or drugs during pregnancy, low brain weight, brain injuries, toxical exposure or genetic disorders. The main symptoms for this condition are difficult in paying attention, overactivity and impulsivity (1-5).Aim is to develop and validate new HPLC method for Atomoxetine in pharmaceutical dosage form.

MATERIALS AND METHODS

Determination of Working Wavelength (λmax)

Preparation of standard stock solution ofAtomoxetine

10 mg of Atomoxetinewas weighed and transferred in to 100ml volumetric flask and dissolved in Methanol and then make up to the mark with methanol and prepare 10 µg /ml of solution by diluting 1ml to 10ml with Methanol.

Preparation of samples for Assay (6-8)

Preparation of standard solution

weigh accurately 10 mg of Atomoxetine in 25 ml of volumetric flask and dissolve in 25ml of mobile phase and make up the volume with mobile phase.From above stock solution 20 µg/ml ofAtomoxetineis prepared by diluting 0.5ml to 10ml with mobile phase. This solution is used for recording chromatogram.

Sample preparation:weigh accurately 10 Tablets **(**Atomoxetine -60 mg)weigh accurately 10 mg of Atomoxetine in 25 ml of volumetric flask and dissolve in 25ml of mobile phase and make up the volume with mobile phase.From above stock solution 20 µg/ml ofAtomoxetineis prepared by diluting 0.5ml to 10ml with mobile phase. This solution is used for recording chromatogram.

RESULTS AND DISCUSSION

The wavelength of maximum absorption (λ_{max}) of the drug, 10 µg/ml solution of the drug in Methanol were scanned using UV-Visible spectrophotometer within the wavelength region of 200–400 nm against Methanol as blank. The absorption curve shows characteristic absorption maxima at 253 nm for Atomoxetine, selected as detector wavelength for the HPLC chromatographic method.

The amount of Atomoxetine present in the taken dosage form was found to be 101.49% respectively (Fig-1 and Table-1).

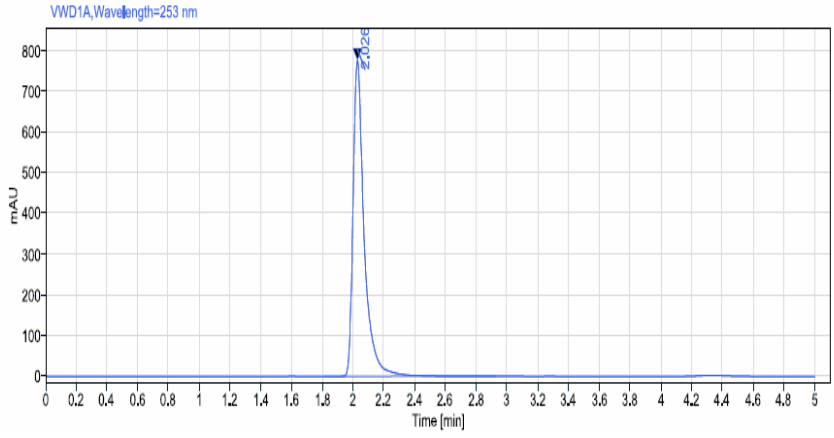

Fig-1 Chromatogram of Assay sample preparation

Table -1 Assay Results

Atomoxetine		
	Standard Area	**Sample Area**
Injection-1	3844.82	3906.83
Injection-2	3846.71	3905.34
Injection-3	3850.83	3907.13
Injection-4	3851.11	3908.74
Injection-5	3854.26	3907.29
Average Area	3849.546	3907.066
Standard deviation	3.76	
%RSD	0.1	
Assay(%purity)	101.49	

The %RSD ofdeterminations of ATOMOXETINE found to be within the acceptance criteria (less than 2.0%). %Assay Also within the limits (95.0 to 105.0) hence method is precise (Table-2)

Table -2 Method precision results for atomoxetine

S. No.	RT	AREA
1	2.027	3855.52
2	2.026	3855.32
3	2.026	3855.67
4	2.026	3854.45
5	2.026	3856.67
AVG	2.0262	3855.526
SD	0.00045	0.795
%RSD	0.022	0.021

From the above results % Assay and %RSD obtained acceptance criteria, so method is rugged (Table-3).

Table-3 Ruggedness Results of atomoxetine

Atomoxetine	**%Assay**
Analyst 01	101.05
Analyst 02	101.00
%RSD	0.72

CONCLUSION

From the above experimental results and parameters it was concluded that, this newly developed method for the simultaneous estimation of Atomoxetine was found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.

REFERENCES

1. Chatwal**,** R**.** G**.;** Anand**,** K**.** S**.** High performance liquid chromatography**.** *Instrumental methods of chemical analysis***,** 5thed**.;** Himalaya publishers**:** Mumbai, 2010**;** 2.570-2.629**.**
2. Sharma**,** B**.** K**.** High performance liquid chromatography**.** *Instrumental methods of chemical analysis***,** 24th ed**.;** Goelpublishers**:** Meerut**,** 2005**;** 295 - 300**.**
3. Dong,W. M. HPLC instrumentation and trends. *Modern HPLC for practicing scientists*, USA, 2006; 5-10, 78-110.
4. Swartz, M. E.; Ira Krull, S, Analytical method development. *Analytical method development and validation*, 1st ed.; Marcel Dekker, Inc: New York, 2009; 17-80.
5. Satinder, A.; Dong, M. W. Method development and validation. *Pharmaceutical analysis by HPLC*, 15th ed.; New York, 2005; 16-70.
6. ICH, *Text on Validation of Analytical Procedures*, ICH – Q2A, International Conference on Harmonisation, IFPMA, Geneva, 1995, 2-3, A–1 to A–3.
7. ICH, *Validation of Analytical Procedures: Methodology*, ICH – Q2B, International Conference on Harmonisation, 1996, 1-3.
8. ICH Guidelines, Q2 (R1) - Validation of Analytical Procedures: Text and Methodology,2005, 1-6.