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METHOD DEVELOPMENT FOR QUANTIFICATION OF ARIPIPRAZOLE AND TAPENTADOL BY VISIBLE SPECTROPHOTOMETRY

R.Vijayalakshmi[1], Dr.N.Aruna Kumari[2]

Dr. Jayarao Kommu[3]

[1]Department of pharmaceutical analysis, GIET School of Pharmacy
NH-16, Chaitanya Knowledge city, Rajamahendravaram -533296
[2]Assoc.Prof of Engineering Chemistry, GIET(A),
NH-16, Chaitanya Knowledge city, Rajamahendravaram -533296
[2]Asst.Prof, Welfare Institute of Science Technology and Management
Visakhapatnam

ABSTRACT

The objective of the present work is to develop two simple, precise and accurate colorimetric methods for the estimation of aripiprazole and tapentadol using chloranilic acid reagent. The method was developed on Perkin Elmer LAMBDA 25 UV –VIS spectrophotometer with 1cm quartz cells. The methods are based mainly on charge transfer complexation reaction of these drugs with p-chloranilic acid to give magenta purple color with maximum absorbance measured at 545 nm for aripiprazole and 540 nm for tapentadol respectively. These methods obeys Beer's law in the concentration range of 40-240 µg/ml for aripiprazole and 100-600 µg/ml for tapentadol, respectively. The colorimetric methods were extensively validated as per ICH guidelines and all the parameters were within the acceptance criteria with correlation of 0.999 and % RSD less than 2 for all the two methods. The recovery studies confirmed accuracy of proposed method and low values of standard deviation confirmed precision of the method. The methods were proved to be more accurate, simple, precise and rapid by statistical validation.

Key words: Aripiprazole (ARP), Tapentadol (TAP),chloranilic acid, chloroform.

I. INTRODUCTION

Aripiprazoleis 7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}-3,4-dihydroquinolin-2(1H)-one, is a second generation class of antipsychotics used intreatment of schizophrenia or bipolar disorder. Tapentadol chemically, is 3-[(1*R*,2*R*)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride is a centrally acting analgesic with a dual mode of action as an agonist of the µ-opioid receptor and as a norepinephrine reuptake inhibitor.Literature survey of these drugs revealed that there are very few HPLC and spectrophotometric methods for the determination of ARP and TAP. The purpose of this work was to develop a novel, simple,

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economical and efficient colorimetric method for quantitative analysis of the drugs and to validate the methods according to the ICH guidelines.

II. EXPERIMENTAL

2.1 Instrumentation and Chemicals

Double-beam Perkin Elmer (LAMBDA 25) UV-Vis spectrophotometer was used for spectral measurements.ARP and TAP are obtained as gift samples from AurobindoPharma Ltd, Hyd., chloroform andchloranilic acid of AR grade was used for the experimental work.

2.2 Preparation of chloranilic acid (0.1%):

50 mg of chloranilic acid was dissolved in 5ml isopropyl alcohol and made up to 50ml with chloroform.

2.3 Preparation of stock solutions for ARP and TAP:

About 25mg of ARP and TAP were weighed and transferred to a 25ml volumetric flasks;5 ml of chloroform was added to dissolve both of it and made to volume with the same. The resulting solutionshas a concentration of 1mg/ml.

2.4. Assay procedure for ARP and TAP:

Twenty tablets of commercial samples of aripiprazole (Aria 30mg) and tapentadol (Tapal 100 mg) were accurately weighed and powdered. Tablet powder equivalent to 25mg was weighed and dissolved in 25ml chloroform for both and filtered and the procedure was carried out.

III. RESULTS AND DISCUSSION

Method development

The method was optimizedfor the order of addition, proper concentration of the reagent, selection of the wavelength and the stability of the product. The parameters were mentioned as shown in table1 and fig 1 represents the absorption spectrums of ARP and TAP, respectively.

TABLE 1: Order of addition and concentration of reagents

ARP + 0.5 ml chloranilic acid (0.1%) + chloroform
TAP + 1.5mlchloranilic acid (0.1%) + chloroform

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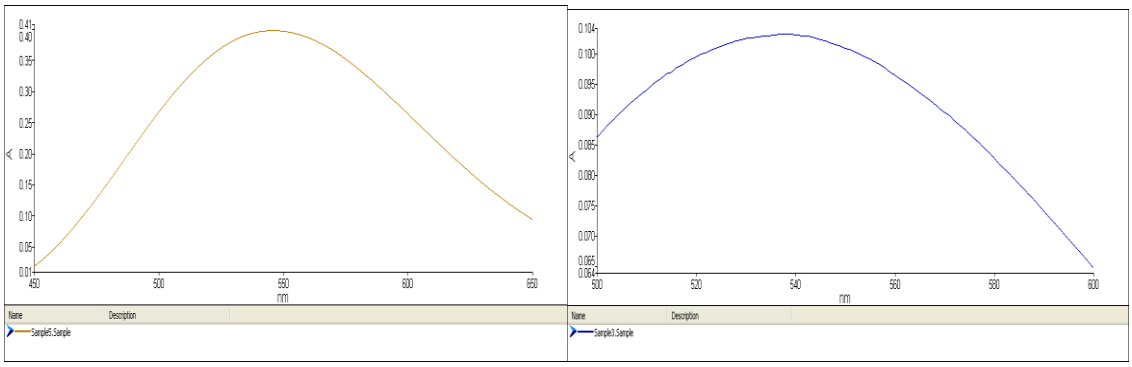

FIG 1: Absorption spectrums of ARP and TAP with chloranilic acid

Method validation

ARP and TAP are validated for accuracy, precision, linearity, LOD, LOQ, ruggedness and robustness and the results were found to be satisfactory. Regression parameters were presented in table 2.

TABLE 2: Optical and regression parameters

Parameters	ARP	TAP
Beer's law range (µg/ml)	80-400	200-1000
Molar extinction coefficient ($L.mole^{-1}.cm^{-1}$)	10.53×10^2	180.33
Sandell'ssensitivity ($\mu g/cm^2$)/0.001 absorbance unit	240×10^3	600×10^3
LOD, µg/ml	5.18	82.5
LOQ, µg/ml	15.6	250
Slope(m)	0.00105	0.000174
Intercept(b)	0.90×10^{-3}	0.309×10^{-2}
Correlation coefficient(r)	0.9999	0.9998

Linearity and range

Linearity was assessed by performing single measurement at several analyte concentrations of ARP, TAP showed good correlation between the concentration range of 40-200µg/ml, 200-1000µg/mlrespectively.

Precision

Precison of the method was determined by repeatability. Six replicate solutions of same concentration were prepared and absorbances of the solution were measured for three batches on the same day and on three successive days and % RSD was calculated.

Robustness

Robustness was checked by altering the optimized parameters and the % RSD was found to be within the acceptable limit.

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Ruggedness

System to system/ analyst to analyst/ variability study was conducted on different colorimeters and the results were satisfactory.

Limit of detection (LOD) and limit of quantification (LOQ)

LOD and LOQ were determined by analyzing progressively lower concentrations of standard solution using optimized conditions and the results were found to be satisfactory and presented in table 2.

Accuracy

In order to determine the accuracy of the proposed methods, pure drug solution at three different concentration levels (within the working range) were prepared and analyzed. The percentage relative error indicates that the accuracy of the methods was found to be satisfactory.

IV. CONCLUSION

The proposed colorimetric method is simple and sensitive with reasonable precision, accuracy and constitute better alternative to the existing ones for the routine determination of aripiprazole andtapentadolin bulk and pharmaceutical formulations.

REFERENCES

1. Kalaichelvi R, Thangabalan B andSrinivasaRao D:Validated RP-HPLC Method for Analysis of Aripiprazole in a Formulation. E-Journal of Chemistry. 2010,7:827-832.
2. Kalaichelvi R, Thangabalan B, Srinivasarao D andJayachandran E: UV spectrophotometric determination of aripiprazole in bulk and pharmaceutical formulation. E-Journal of Chemistry. 2009,6:S87-S90.
3. Ahmed Helmy G, Fatma Abdel-Gawad M andEman Mohamed F: Spectrophotometric study on determination of aripiprazole in tablets by charge-transfer and Ion-Pair complexation reactions with some acceptors. Asian Journal of Pharmaceutical Analysis.2012, 2:12-19.
4. OmkarSherikarD andPriti Mehta J: Development and validation of RP- HPLC, UV-spectrometric and spectrophotometric method for estimation of tapentadol Hydrochloride in bulk and in laboratory sample of ablet dosage form. Journal of Chemical and Pharmaceutical Research.2012, 4:4134-4140.