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SPECTROPHOTOMETRIC DETERMINATION OF ARIPIPRAZOLE AND TAPENTADOL USING CHLORANILIC ACID REAGENT

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Keywords:

Aripiprazole (ARP), Tapentadol (TAP), Chloranilic acid, Chloroform.

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ABSTRACT: The objective of the present work is to develop simple, precise and accurate colorimetric methods for the estimation of aripiprazole (ARP), tapentadol (TAP) using chloranilic acid reagent. ARP belongs to the class of antipsychotics. TAP is centrally acting analgesic drug. The methods are based mainly on charge transfer complexation of these drugs with p-chloranilic acid to give magenta purple colored products which were extracted into chloroform. The products were quantified at 543 nm for both ARP and TAP. The linearity of the methods was assessed in the range of 80-400 µg/ml for ARP and 200-1000µg/ml for TAP, respectively. The LOD and LOQ are 5.17 and 15.66; 82.5 and 250 for ARP and TAP, respectively. The colorimetric methods were extensively validated as per ICH guidelines and all the parameters were within the acceptance criteria with a correlation of 0.9999 and the % RSD less than 2. The results of the accuracy studies were nearer to 100%. The methods were proven to be more accurate, simple, precise and rapid by statistical validation.

INTRODUCTION: Aripiprazole, chemically is 7-{4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy}-3,4-dihydroquinolin-2(1H)-one, is a partial dopamine agonist of the second generation class of antipsychotics that is primarily used in treatment of schizophrenia or bipolar disorder a major depressive disorder. Moreover, like other anti-psychotics, it blocks several receptors on the nerves of the brain for several neurotransmitters. It is thought that its beneficial effect is due to its effects on dopamine and serotonin receptors. Its effects on these receptors are complex, involving stimulation of the receptors but to a lesser degree than the naturally-occurring neurotransmitters.

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Tapentadol chemically is 3-[(1*R*,2*R*)-3-(di methyl amino)-1-ethyl-2-methylpropyl]phenol hydrochloride which in India is available as TAPAL by MSN Labs, is a centrally acting analgesic with a dual mode of action as an agonist of the µ-opioid receptor and as a norepinephrin reuptake inhibitor. **Figure 1** and **2** represent the chemical structure of ARP and TAP respectively.

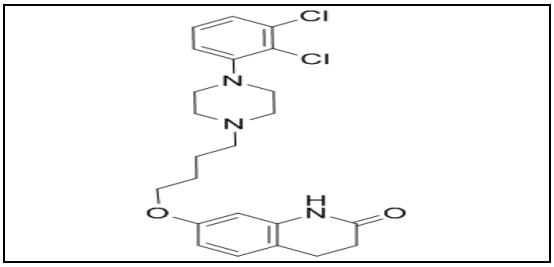

FIG 1: STRUCTURE OF ARP

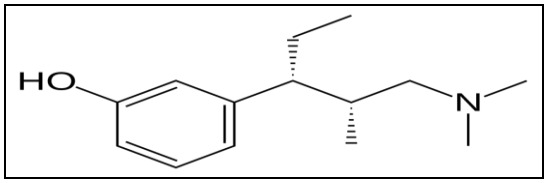

FIG 2: STRUCTURE OF TAP

A literature survey of these drugs revealed that there are very few HPLC [1-7] and spectrophotometric [8-15] methods for the determination of ARP and TAP. The purpose of this work was to develop a novel, simple, economical and efficient colorimetric method for quantitative analysis of the drugs and to validate the methods according to the ICH guidelines.

MATERIALS AND METHODS:

Instrumentation:

Double-beam Perkin Elmer (LAMBDA 25) UV-Vis spectrophotometer was used for spectral measurements.

Chemicals:

ARP and TAP are obtained as gift samples from Aurobindo Pharma Ltd, Hyd., chloroform and chloranilic acid of AR grade was used for the experimental work.

Preparation of stock solutions:

Stock solution for ARP:

About 25mg of ARP was weighed and transferred to a 25ml volumetric flask; 5 ml of chloroform was added to dissolve it and made to volume with the same. The resulting solution has a concentration of 1mg/ml.

Stock solution for TAP:

About 25 mg of TAP was weighed and transferred to a 25ml volumetric flask; 5 ml of chloroform was added to dissolve it and diluted to volume with chloroform. The resulting solution has a concentration of 1mg/ml.

Preparation of chloranilic acid (0.1%):

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

Procedures for calibration plot of ARP:

In a series of 10 ml volumetric flasks, 0.4-2.0 ml of a standard solution of ARP was pipetted out and 1ml of chloranilic acid reagent was added, final volume was made with 10 ml with chloroform. The absorbance of the purple colored chromogen was measured at 543 nm against reagent blank. The amount of ARP present in the sample solution was computed from its calibration curve.

Procedure for calibration plot of TAP:

In a series of 10 ml volumetric flasks, 1-5 ml of working standard solution of TAP was pipetted out and 1.5 ml of chloranilic acid reagent was added, final volume was made with 10 ml with chloroform. The absorbance of the purple colored chromogen was measured at 543 nm against reagent blank. The amount of TAP present in the sample solution was computed from its calibration curve.

Assay procedure for ARP:

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

Assay procedure for TAP:

Twenty tablets of commercial samples of tapentadol (Tapal 100 mg) were accurately weighed and powdered. Tablet powder equivalent to 25mg was dissolved in 25 ml chloroform, filtered and the procedure was carried out as mentioned above.

RESULTS AND DISCUSSION:

Method development:

The method was optimized for 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 **Table 1** and **2**. **Fig 3** and **Fig 4** represents the absorption spectrum of ARP and TAP, respectively.

TABLE 1: ORDER OF ADDITION AND CONCENTRATION OF REAGENTS

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

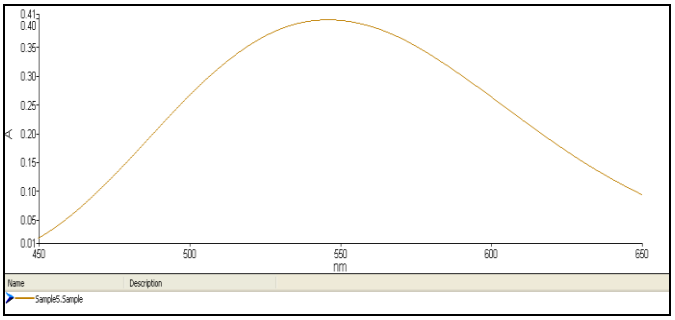

FIG 3: ABSORPTION SPECTRUM OF ARP WITH CHLORANILIC ACID

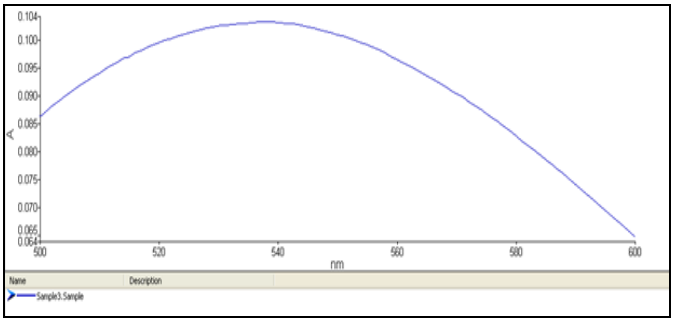

FIG 4: ABSORPTION SPECTRUM OF TAP WITH CHLORANILIC ACID

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 x10^{2}	180.33
Sandell's sensitivity (µg/cm^{2})/0.001 absorbance unit	240x10^{3}	600x10^{3}
LOD, µg/ml	5.18	82.5
LOQ, µg/ml	15.6	250
Slope(m)	0.00105	0.000174
Intercept(b)	0.90x10^{-3}	0.309x10^{-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 40-200 µg/mL, 200-1000 µg/mL respectively. The results were reported in **Table 3** and shown in **Fig. 5** and **6**.

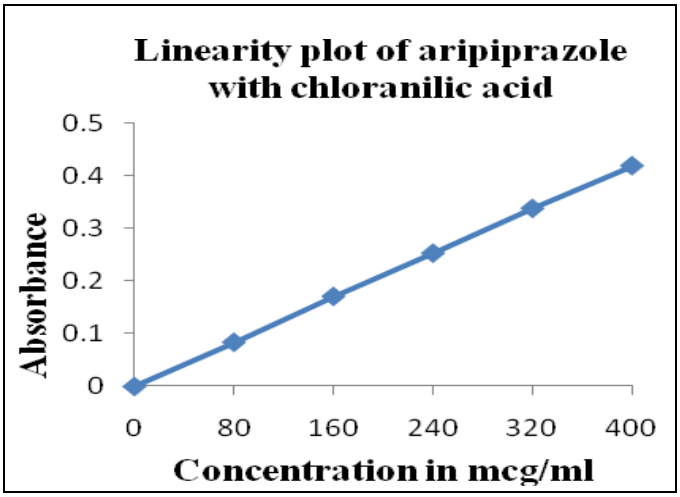

FIG 5: LINEARITY PLOT OF ARP

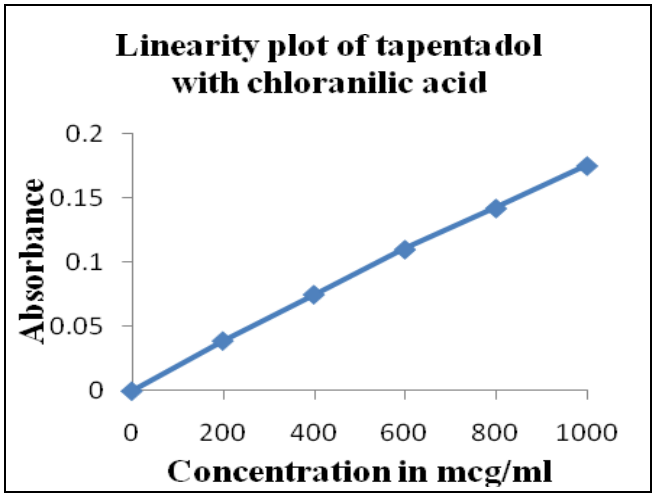

FIG 6: LINEARITY PLOT OF TAP

TABLE 3: LINEARITY OF ARP AND TAP

Method A		Method B	
Conc.(µg/ml)	Absorbance	Conc.(µg/ml)	Absorbance
80	0.084	200	0.039
160	0.171	400	0.075
240	0.253	600	0.11
320	0.343	800	0.142
400	0.419	1000	0.175

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 and reported in **Table 4**.

TABLE 4: RESULTS SHOWING PRECISION

Parameter	ARP		TAP	
	Inter day*	Intraday*	Inter day*	Intraday*
Conc, (µg/ml)	240		600	
Mean abs	0.247	0.25	0.123	0.115
SD	0.0081	0.0071	0.0121	0.008
% RSD	0.3089	0.862	0.813	0.275

*N=6

Robustness:

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

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 results were presented in **Table 5**. The percentage relative error indicates that the accuracy of the methods was found to be satisfactory.

TABLE 5: RESULTS OF ACCURACY STUDIES OF ARP AND TAP BY THE PROPOSED METHODS

S. NO.	ARP		TAP	
	% Recovery	% RSD	% Recovery	% RSD
50%	101.5	0.25	100.5	0.23
100%	99.5	0.18	100.1	0.184
150%	101.3	0.34	101.3	0.15

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 and tapentadol in bulk and pharmaceutical formulations.

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