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Method Development and Validation of Assay of Chlorpromazine Hydrochloride Tablet Formulation using UV-Visible Spectrophotometer

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Abstract: *The present study includes analytical method for determination of the drug Chlorpromazine Hydrochloride (CPH) in some Pharmaceuticals using Molecular Absorption, in addition to investigating complexes throughout. The analytical data obtained throughout this study could be summaries as follow. The method was found to be simple, safe, sensitive, and validated for the assay of chlorpromazine hydrochloride using phenol red, citrate buffer pH 3, and water as diluents. It was also found to be an accurate, reproducible, and cost-effective quality-control tool for the routine analysis of chlorpromazine hydrochloride in standard and pharmaceutical forms.*

Keywords: Chlorpromazinr, Phenol red, UV Spectroscopy, Linearity, Pricision.

I. INTRODUCTION

Adult's antipsychotics, also known as neuroleptics or major tranquilizers are a class of medication primarily used to manage psychosis including delusion, hallucinations, paranoia or disordered thoughts, principally in schizophrenia and bipolar disorder. They are increasingly being used in the management of non-psychotic disorders. Antipsychotics are usually effective in relieving symptoms of psychosis in the short term.[1]

The long-term use of antipsychotics is associated with side effects such as involuntary movement disorders, gynecomastia, and metabolic syndrome. They are also associated with increased mortality in elderly people with dementia. A psychotropic, Psychoactive or phenotropic drug is one that inhibit, sharpens or alters behahioural, mood and emotional responses Psychiatric illness in divided into the neuroses and the psychoses.[2]First-generation antipsychotics, known as typical antipsychotics, were discovered in the 1950s. Most second-generation[3] drugs, known as atypical antipsychotics, have been developed more recently, although the first atypical antipsychotic, clozapine, was discovered in the 1960s and introduced clinically in the 1970s. Both generations of medication tend to block receptors in the brain's dopamine pathways, but atypicals tend to act on serotonin receptors as well.[4] Antipsychotic drugs have a significant stronger effect on the central nervous system, but they are not CNS depressants, and as a rule they are more toxic[5]. However, even in long-term use they do not cause dependence and addiction, which is a very serious problem that originates from long-term use of anxiolytics.[6] Antipsychotics agents inhibit psychotic manifestation without curing the underlying disease. In a strict sense they are not really antipsychotics [7]. The term, however, continues to be used for the central nervous system depressant which calm severely disturbed psychiatric patients.[4] Chlorpromazine HCI is a potent anti-emetic, act by blocking D2 receptors in the Chemoreceptor trigger zone (CTZ). And antagonize apomorphine induced vomiting. In the present study an attempt has been made to prepare fast dissolving tablets of Chlorpromazine HCI in the oral cavity with enhanced dissolution rate.[8] The tablets were prepared with five superdisintegrants e.g: Sodium starch glycolate Crospovidone Croscammellose, L-HPC, Pregelatinised starch. The blend was examined for angle of repose, bulk density, tapped density, compressibility index and hausners ratio. The tablets were evaluated for hardness, friability, disintegration time, dissolution rate.[9]

II. EXPERIMENTAL METHODS

2.1 Methods Development

A. Selection of Wavelength

The selection of proper in this methods depends on the sample, diluvent and test solution. The standard solution and pharmaceutical test form where scanned by UV-Visible between 200-800nm on spectrum mode . Prepare the sample

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solution of Chlorpromazine Hydrochloride +Phenol Red (0.1M). And then sample Chlorpromazine Hydrochloride was diluted 10ug/ml in water. Where scanned using UV-Visible Spectrophotometer with in the wavelength region 400-570nm water as a blank. The resulting spectrum was presented .The absorption curve show Characteristic absorption maximum 0.297 at 500nm for Chlorpromazine Hydrochloride.

B. Preparation of Stock Solution

Standard stock solution of Chlorpromazine Hydrochloride and phenol red indicator was prepared by using dissolving 3mg drug and 0.3mg phenol red in 100ml water (1000ug/ml).

C. Preparation of Working Standard Solution for Determining Precision

Weight accurately 3mg of standard Chlorpromazine Hydrochloride and transfer it in a 100ml volumetric flask, dissolve it in small amount of water and make up the volume up to 100ml with water. Weight accurately 0.3mg of phenol red indicator powder and transfer it in a 100ml volumetric flask, dissolve it in small amount of water and make up the volume up to 100mlwith water. From the above both solutions chlorpromazine hydrochloride take10ml and phenol red indicatortake 10ml and mix the both solution standard solution was prepared. From the above solution take 1ml,2ml,3ml,4ml,5ml and make up to 10ml with water which give rise to10ug/ml,20ug/ml,30ug/ml,40ug/ml,50ug/ml Solutions. Note the absorption of standard solution at 500nm wavelength using UV-Visible.

D. Preparation of Sample Solution for Determining Precision

Weight 10 Tablets and Calculate Average Weight

Crush 10 tablets with the help of Mortar-pestle equivalent to 3mg of Chlorpromazine Hydrochloride and transfer it in 100ml volumetric flask, dissolve it in small amount of water. From the above solution take 10ml add 10ml of phenol red indicator and mix well.Sample solution was prepared. From the sample take 1ml,2ml,3ml,4ml,5ml,and make up to 10ml with water

E. Determination of Validation: Accuracy

Preparation of Standard Solution

Take 30ml standard solution of Chlorpromazine Hydrochloride and 30ml phenol red and mix them. From the above solution take 2ml(6 volumetric flask), 4ml(3 volumetric flask), 6ml(3volumetric flask) solution and transfer it in a 10ml volumetric flask and make up the volume up to 10ml with water.the absorption of sample solution at 500nm wavelength using UV-Visible Spectrophotometer. The resulting spectrum was presented .

Preparation of Sample Solution

Take 30ml sample solution and 30ml of phenol red and mix it well. From the above solution take 2ml(6 volumetric flask), 4ml(3 volumetric flask), 6ml(3 volumetric flask) solution and transfer it in a 10 ml volumetric flask and make up the volume up to 10ml with water Where scanned using UV-Visible Spectrophotometer with in the at 500nm wavelength and water using as a blank. The resulting spectrum was presented .

III. RESULT AND DISCUSSION

Selection of wavelength for Maximum Absorption

S. N.	Wavelength	Absorption
1.	400	0.080
2.	410	0.068
3.	420	0.062
4.	430	0.059
5.	440	0.013
6.	450	0.018
7.	460	0.032
8.	470	0.066

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9.	480	0.135
10.	490	0.236
11.	500	0.297
12.	510	0.256
13.	520	0.162
14.	530	0.064
15.	540	0.025
16.	550	0.014
17	560	0.080
18	570	0.080

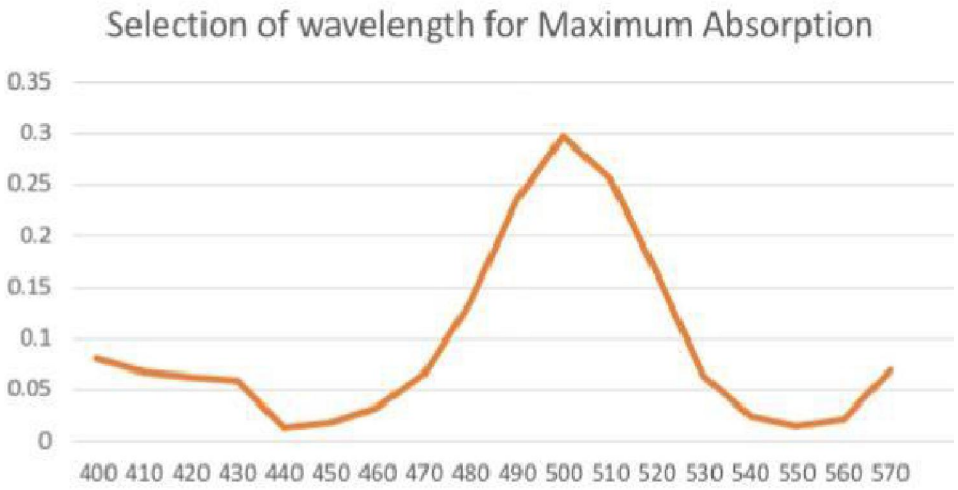

Fig 1: Selection of Maximum Absorption

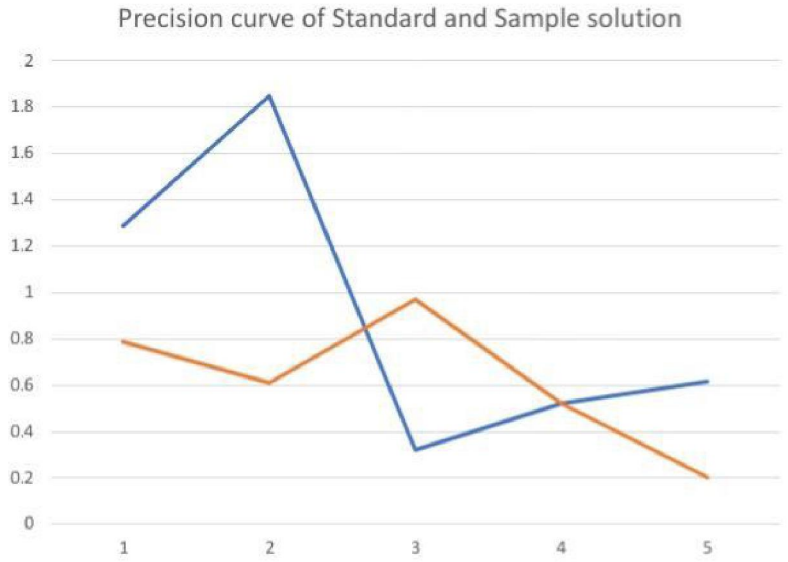

Fig 2: Precision Curve of Standard and Sample solution at wavelength 500nm.

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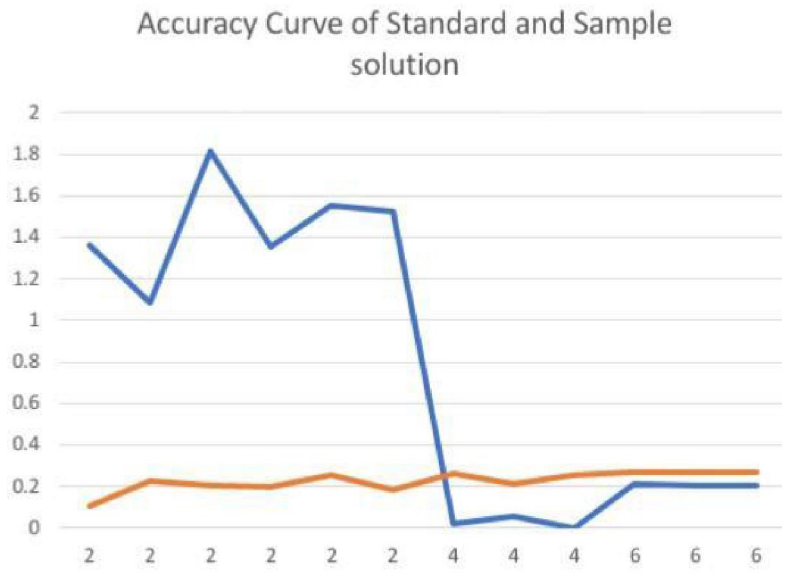

Fig 3: Accuracy Curve of Standard and Sample solution at wavelength 500nm

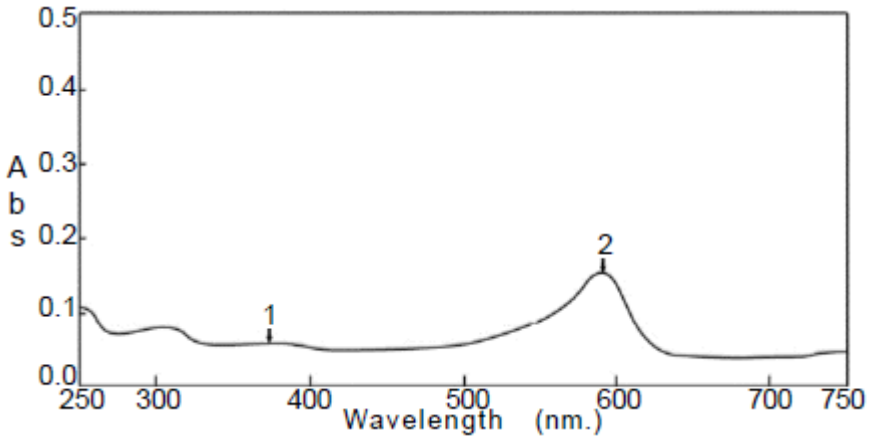

Fig 4: Standard and Sample solution at wavelength 500nm

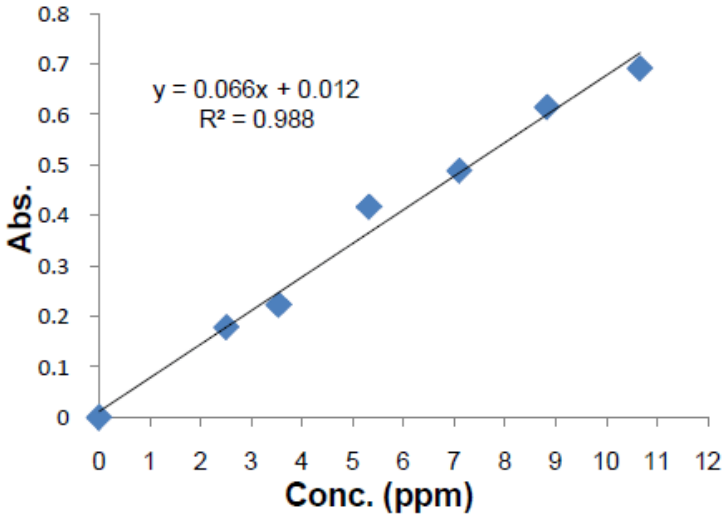

Fig 5: Linearity curve for chlorpromazine standard test.

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Table 2: Precision table for Solution and Sample Solutions at wavelength 500nm.

S. N.	Concentration Of Solution in ml	Absorption Of Standard Solution	Absorption Of Sample solution
1	1ml	1.286	0.786
2	2ml	1.851	0.610
3	3ml	0.321	0.970
4	4ml	0.519	0.523
5	5ml	0.613	0.200

Table 3: Accuracy table of Standard solution and Sample solution

S.N.	Concentration Of Solution (In 10 ml)	Absorption of Standard solution at 500 wavelength	Absorption of Sample solution at 500 wavelength
1	2ml	0.105	1.358
2	2ml	0.225	1.082
3	2ml	0.206	1.818
4	2ml	0.197	1.352
5	2ml	0.256	1.552
6	2ml	0.186	1.522
7	4ml	0.261	0.023
8	4ml	0.211	0.053
9	4ml	0.257	0.001
10	6ml	0.266	0.211
11	6ml	0.268	0.205
12	6ml	0.268	0.201

IV. CONCLUSION AND DISCUSSION

The proposed method is validation elements -specificity, simple, accurate, precision, rapid, robustness, linearity, accuracy, system stability, sensitive spectrophotometric method has been suggested for the determination of Chlorpromazine Hydrochloride in aqueous solution. The suggested method does not require temperature control or the solvent extraction step, method was applied, successfully valid for the determined Chlorpromazine Hydrochloride Drug in pure and pharmaceutical preparations. The simplicity of the method allows for application in laboratory for routine quality check also it may be utilized for the determination of content uniformity and dissolution profiling of this product. Overall, the method provides solution for determination of Chlorpromazine in the tablet with excellent selectivity, precision and accuracy in a cost effective manner

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