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Original Research Article

Development and validation of UV spectrophotometric method for determination of chlorpropamide in bulk and formulation

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ABSTRACT

The current work focuses on the development and validation of a UV spectrophotometric technique for determining chlorpropamide in bulk and formulation. According to ICH criteria, UV spectrophotometric method was validated for a number of parameters, including linearity, precision, accuracy, sensitivity, limit of detection (LOD), and limit of quantification (LOQ). The maximum wavelength of chlorpropamide was discovered to be 580 nm, and a colorimetric method was created for the quantitative estimation of colour and to quantify the absorbance of a particular wavelength of light by a particular solution. The maximal wavelength of chlorpropamide in the complex mixture was discovered to be 710 nm. The UV spectrophotometric technique and colorimetry are simple, sensitive, accurate, repeatable, and exact. Chlorpropamide in bulk can be determined effectively using the suggested method.

1. Introduction

Chlorpropamide is an antidiabetic drug. It is a type 2 antidiabetic drug and used in treatment of diabetes mellitus. It entails triggering the release of insulin from pancreatic beta cells. By raising the number of receptors, it also improves the impact of insulin on the liver and promotes the use of peripheral glucose. BCS class of chlorpropamide is class 2 that is high permeability low solubility.[1–4]

Toxicity produced is hyperinsulinemia. The food interaction occurs due to alcohol consumption is facial flushing. The chlorpropamide is administered by oral route. The capacity of protein binding is 90%. It is soluble in organic solvent, practically insoluble in water at pH 7.3 the pka value of chlorpropamide is 5.0 at 20^{o}C. Chlorpropamide stored at 20 to 25^{o}C in well closed container. Chemical name is 4-chloro-N-(propylcarbonyl) benzene-sulfonamide. Trade name of chlorpropamide is Diabinese. Several researchers have focused on development and validation of chlorpropamide.

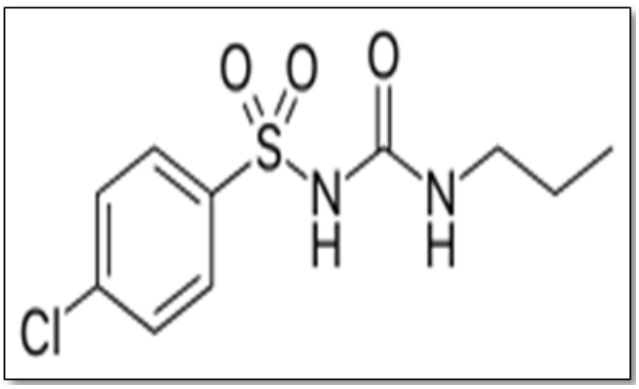

Fig. 1: Structure of chlorpropamide.

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The commonly used methods are UV spectrophotometric method and colorimetry. Using this method determine the maximum wavelength and absorbance of chlorpropamide. The purpose of this study is determining chlorpropamide in bulk and formulation, a UV spectrophotometric method was developed and validated.[5–8]

2. Materials and Methods

2.1. Equipment

Spectrophotometer UV-visible light (Shimadzu UV-1800, Shimadzu Corporation, Japan.)

2.2. Materials

The chemicals used for UV validation are drug Chlorpropamide purchased from YARROW CHEM. Lab. Pvt. Ltd. Methanol was purchased from LOBA chemicals.

2.3. Preparation of stock standard solution

The necessary quantity of chlorpropamide was dissolved in methanol to prepare a stock solution with a concentration of 100 mcg/ml. By serially diluting the stock solution, standard analyte solutions (10–60 mcg/ml) were prepared.

The Chlorpropamide stock solution 1.0 ml was transferred to a 10 ml volumetric flask and methanol was used to increase the volume to 10 ml. Similarly the concentrations of 2ml, 3ml, 4ml, 5ml, 6ml are prepared. By using UV/Visible spectrophotometer the baseline was corrected with blank.

The solution's absorbance was then compared to a blank sample at 580 nm.[9–12]

2.4. Colorimetric method development for determination of complex

2.4.1. Reagent blank

The aqueous solution of 0.5ml of 5%w/v sodium nitroprusside and sodium borate 3ml of 4%w/v were added to 2.5ml of distilled water in 10ml volumetric flask. Distilled water was used to make volume.

2.4.2. Standard solution

The aqueous solution of 0.5ml of 5%w/v sodium nitroprusside and sodium borate 3ml of 4%w/v were added to 2.5ml of distilled water and the drug chlorpropamide 0.05μg in 10ml volumetric flask. Distilled water was used to make volume.

2.5. Method validation

There are different parameters for method validation like Linearity, accuracy, precision, sensitivity, etc.

2.5.1. Linearity

Linearity gives straight line graph. The linearity can be obtained by preparing six solutions of chlorpropamide of concentration 10,20,30,40, 50, 60 μg/ml respectively and analyzing them.

2.5.2. Accuracy

Accuracy gives exactness of measured value and true value. For accuracy evaluation the solution were reanalyzed by using proposed method.

2.5.3. Precision

The level of accuracy was measured by percent relative standard deviation (% RSD). The % RSD was found to be less than 2. In precision repeatability of result occurs at same condition in different time intervals.

2.5.4. Sensitivity

The sensitivity comprises the Limit of Detection (LOD) and Limit of Quantification.

LOD=3.3×SD/Slope

LOQ=10×SD/Slope

3. Results and Disussion

3.1. Linearity

It is a graph of concentration vs absorbance. Linearity is a mathematical relationship between two variable quantities that are directly proportional to each other. Data of regression analysis is shown in following table.

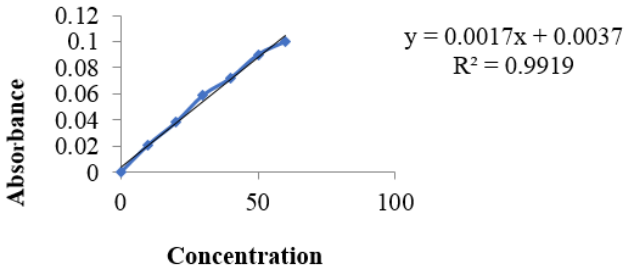

Fig. 2: Linearity graph of concentration Vs absorbance.

Table 1: Linearity study of chlorpropamide

S.No.	Concentration (μg)	Absorbance ()
1	00	00
2	10	0.021
3	20	0.038
4	30	0.059
5	40	0.072
6	50	0.09
7	60	0.1

Table 2: Precision study

S.No.	Conc.	Abs.	%RSD	Abs.	%RSD
		Intraday		Inter day	
1	10	0.002		0.039	
2	30	0.005	1.42	0.048	0.58
3	50	0.051		0.052	
		Standard deviation (SD)= 0.027			
S.No.	**Conc.**	**Abs.**	**%RSD**	**Abs.**	**%RSD**
		Intraday		Inter day	
1	10	0.001		0.038	
2	30	0.009	1.35	0.050	0.57
3	50	0.052		0.055	
		Standard deviation (SD)= 0.027			
S.No.	**Conc.**	**Abs.**	**%RSD**	**Abs.**	**%RSD**
		Intraday		Inter day	
1	10	0.002		0.039	
2	30	0.007	1.35	0.052	0.56
3	50	0.052		0.053	

3.2. Accuracy

Accuracy is closeness between test result value and true value. The % RSD value that were determined and found to be 2.

3.3. Precision

It is reproducibility of results when the procedure performed repeatedly (like intraday and Inter day). It is measured in terms of %RSD. The test result of % RSD were found to be less than 2 and hence the method is precise.

3.4. Sensitivity

Sensitivity is measured in terms of Limits of quantification and detection Chlorpropamide's LOD and LOQ were determined to be 2.99 g and 8.89 g, respectively.

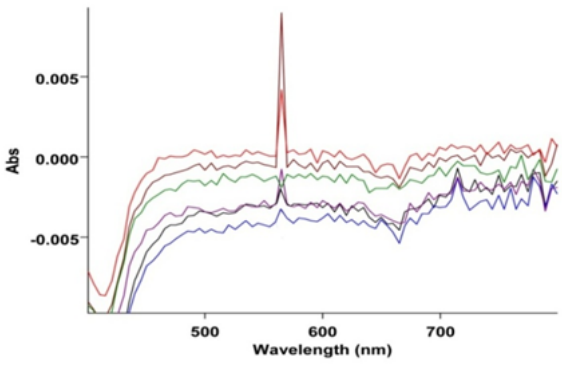

Fig. 3: Overlay of Absorbance Vs Wavelength**.**

The peaks of all concentrations observed at 580nm & their absorbance are given in table.

Table 3: Absorbance of all 10-60 μg samples

S.No.	Drug	Conc. (μg)	Abs
1		10	-0.006
2		20	-0.007
3		30	-0.009
4	Chlorpropamide	40	-0.008
5		50	0.004
6		60	0.009

Chlorpropamide shows UV absorbance 0.111 at 710nm. The method that was developed was based on the reaction of chlorpropamide, depending on its amino group, with SNP in an alkaline media to produce a coloured reaction product that could be seen at 710 nm. The reaction product's absorption spectrum is provided below.

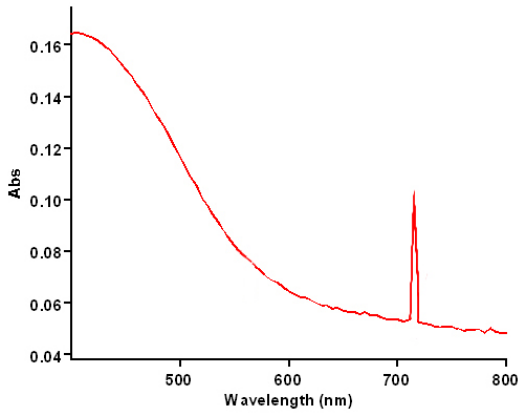

Fig. 4: Absorbance Vs Wavelength of colorimetric complex.

4. Conclusion

Analytical method was used to establish the method for the determination of chlorpropamide. The procedure was validated and was discovered to be accurate, simple, precise, reproducible and simple. Therefore, the technique can be successfully applied to routine analysis of the chlorpropamide medicinal dosage form. The outcome showed that the selective spectrophotometric method for determining chlorpropamide has been developed successfully using SNP. The reliability of the outcome and simplicity of the suggested procedure are its distinguishing features. [13–16]

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6. Source of Funding

None.

7. Conflicts of Interest

No conflicts of interest.

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