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Spectroscopic determination of metformin hydrochloride by using ninhydrin

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ABSTRACT

A simple and sensitive spectrophotometric method has been developed and validated for the estimation of metformin hydrochloride in bulk and in tablet formulation. The primary amino group of metformin hydrochloride reacts with ninhydrin in alkaline medium to form a violet colour chromogen, which is determined spectrophotometrically at 572 nm. It obeyed Beer's law in the range of 9-19 µg/ml. Percentage recovery of the drug for the proposed method ranged from 97-100% indicating no interference of the tablet excipients. The proposed method was found to be accurate and precise for routine estimation of metformin hydrochloride in bulk and from tablet dosage forms.

KEYWORDS

Metformin hydrochloride;
Ninhydrin.

Metformin hydrochloride, chemically 1, 1-dimethylbiguanide hydrochloride[1] ($C_4H_{11}N_5$.HCl) is white crystalline powder, hygroscopic and freely soluble in water, used as a hypoglycemic drug[2]. Literature survey reveals that only few methods like HPLC and GC have been reported for estimation of the metformin hydrochloride in pharmaceutical formulations and biological fluids[3-9]. Official method includes UV spectrophotometric method for estimation of the drug from the tablets[1]. However no colorimetric methods are reported estimation of metformin hydrochloride in bulk and in formulations.

The present work describes a new simple spectrophotometric method based on the reaction between amino groups of metformin hydrochloride with ninhydrin to form a violet colored complex, which shows absorption maxima at 572nm.

The reference standard of metformin hydrochloride was procured as gift sample from Micro Labs, Bangalore and tablets (Riomet 500 mg, Kare Labs Pvt. Ltd. Goa) were utilized for the study. Ninhydrin and all other chemicals, solvents utilized were of AR grade. A double beam spectrophotometer (Shimadzu-UV-1601) was employed for measurement of absorbance.

A standard solution of metformin hydrochloride was prepared by dissolving 100 mg of the drug in 100 ml of distilled water and further diluted with water to get concentration of 100 µg/ml. Twenty tablets were weighed, powdered and the powder equivalent to 100 mg of metformin hydrochloride was accurately weighed, dissolved in 100 ml of distilled water, filtered through Whatmann filter paper No: 41 and diluted further to get a concentration of 100µg/ml.

To a series of (S_1, S_2, S_3, S_4, S_5) 25 ml volumetric flasks, aliquots of 3.0 to 4.5 ml of the standard solution of metformin hydrochloride, 1.5 ml of 5M NaOH, 2.2

ml of 1% ninhydrin solution and 10 ml of water was added, heated on a water bath for 30 min, cooled and volume adjusted to 25 ml with water and the absorbance of the solution in each flask was measured at 572 nm against reagent blank. The absorbance of sample solution was also measured and the amount of metformin hydrochloride present in tablet formulation was determined by extrapolating from the calibration curve. The results are shown in the TABLE 1. In order to ascertain the suitability and reproducibility of the proposed method, recovery studies were carried out by adding known quantities of standard metformin hydrochloride to the previously analyzed sample and the mixtures were reanalyzed by the proposed method. The results are shown in the TABLE 2. The percentage recovery of metformin hydrochloride was found in the range of 97-100% indicating that there is no interference by the excipients in the method.

TABLE 1 : Analysis of metofrmin hydrochloride in tablets

Formulation (Tablets)	Labeled amount (mg)	Amount found	% recovery by proposed method
Riomet	500	487.51*	97.09
Riomet	500	493.75*	98.82
Riomet	500	497.23*	98.91

Table showing analysis of metformin hydrochloride in tablets by proposed spectrophotometric method. *Average of three determinations*.

TABLE 2 : Recovery studies of metformin hydrochloride

Vol. of standard (ml)	Vol. of sample	Concentration of sample (µg/ml)	Absorbance* at 572 nm	From standard graph (µg/ml)	Recovery of standard	% Recovery ± SD
3.0	1.0	04	0.082	15.00	10.00	100.0±0.99
3.5	1.0	04	0.093	16.01	11.82	98.50±0.98
4.0	1.0	04	0.099	17.72	13.64	97.42±0.97

Table showing % recovery of metformin hydrochloride by proposed spectrophotometric method. *Average of three determinations*.

The proposed method is simple, accurate, precise sensitive and can be successfully applied for routine quantitative estimation of metformin hydrochloride in bulk and solid dosage forms. The summary of the method developed is shown in the TABLE 3.

TABLE 3 : Summary of method developed

Parameters	Results
Absorption maxima (λmax)	572nm
Stability of colour	16 min
Beer's law range	9-19 µg/ml
Sandell's sensitivity	0.18543 µg/cm^2/0.001 absorbance units
Molar absorptivity	5.7X10/mol^{-1}cm^{-1}

Table showing summary of analytical parameters for proposed spectrophotometric method.

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