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(SHORT COMMUNICATION)



Spectrophotometric method for dissolution analysis of pioglitazone from capsules

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Abstract

Pioglitazone, an anti-diabetic molecule have been analyzed from a marketed capsule consisting of glimepiride and pioglitazone using spectrophotometric method. The method was developed at 270 nm using 0.1 N HCl as diluent. The method was found to be highly specific for pioglitazone in presence of glimepiride and other constituents of the capsule. The developed method is simple, precise, robust and stands validated as per ICH guidelines.

Keywords: Pioglitazone; Anti-diabetic; Spectrophotometer; Glimepiride

1. Introduction

Pioglitazone is a diabetes drug (thiazolidinedione-type, also called "glitazones") used along with a proper diet and exercise program to control high blood sugar in patients with type 2 diabetes. It works by helping to restore your body's proper response to insulin, thereby lowering your blood sugar.

Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke.

Pioglitazone is used either alone or in combination with other diabetes medications (such as metformin or a sulfonylurea such as glyburide).

2. Material and methods

2.1. Chemicals

Hydrochloric acid AR grade and Purified water were procured from Merck India Pvt Ltd.

2.2. Standard solution preparations

Weigh pioglitazone HCl equivalent to 30 mg of pioglitazone in 1000 ml volumetric flask. Add 300 ml of methanol to the flask, sonicate, cool and make the content of the flask to 1000 ml using 0.1 N HCl.

2.3. Sample solution

Weigh powdered pellets accurately equivalent to 30 mg of pioglitazone in 1000 ml volumetric flask. Add about 300 ml of methanol, sonicate for 10 minutes. Add about 500 ml 0.1 N HCl and sonicate for about 20 minutes. Cool and make up

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the volume with 0.1N HCl. Filter the solution through 0.45 μ membrane filter. Determine the absorbance of the standard and test solution at 270 nm using 0.1 N HCl as blank.

2.4. Dissolution conditions

The dissolution was carried out *in vitro*.

Table 1 Dissolution parameters of the experiment

Parameter	Description
Dissolution Apparatus	USP XXV Type II (paddle)
RPM	75
Temperature	37 \pm 0.5 $^{\circ}$ C
Media Volume	900 ml
Dissolution Media	N HCl

In each of the 6 vessels, place 900 ml of dissolution medium and allow to equilibrate to 37 $^{\circ}$ C. Immerse the paddle, put weighed tablet in each of the jars & start rotation at 75 RPM. At the end of the 30 min, 1, 4 and 8th hour of rotation, withdraw with a pipette 10 ml of solution. Replace the withdrawn solution with 10 ml of dissolution medium. Dilute the aliquots of 30 min as 5 ml to 10 ml with diluting solvent & filter through 0.45 μ filter.

2.5. Method validation

2.5.1. System Suitability

System suitability tests were carried out to ensure reproducibility of the equipment. The test was carried out by measuring of standard solution in 5 replicates.

2.5.2. Precision

Precision is the measure of either the degree of reproducibility or of repeatability of the analytical method under normal conditions. The test were carried out with 6 assay samples in replicate of standard solutions.

2.5.3. Linearity

The linearity of an analytical procedure is its ability to obtain test results which are directly proportionally to the concentration of analyte in the sample.

Linearity of pioglitazone is carried out in the range 1.25 μ g/ml to 7.5 μ g/ml.

3. Results and discussion

3.1. System suitability

The method was found to be suitable for the proposed analysis as the relative standard deviation of average peak area of system suitability test is not more than 2.0 %.

3.2. Precision

Precision measured at all level was within the acceptable criterion of NMT 6.0 % indicating the efficiency of method for the proposed analysis.

4. Conclusion

The method developed for analysis of pioglitazone in presence of Glimepiride and other matrix stands to be validated as per ICH guidelines. The limits for all the parameters were met with no interference from the placebos of the capsules and hence this method can be used as quality control tool for analysis of the capsules.

Compliance with ethical standards

Disclosure of conflict of interest

The authors, Patankar-Jain Kalpana, Gadkari Parag and Pradhan Pushkar, hereby declare that there is no conflict of interest whatsoever.

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