

Available online at [GSC Online Press Directory](http://www.gsonlinepress.com)

GSC Biological and Pharmaceutical Sciences

e-ISSN: 2581-3250, CODEN (USA): GBPSC2

Journal homepage: <https://www.gsonlinepress.com/journals/gscbps>

(SHORT COMMUNICATION)



## Rapid, simple and validated reverse phase method for analysis of glimepiride from capsules

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Publication history: Received on 05 November 2018; revised on 28 November 2018; accepted on 10 December 2018

Article DOI: <https://doi.org/10.30574/gscbps.2018.5.3.0132>

### Abstract

Glimepiride, a blood sugar controlling molecule have been analyzed from a marketed capsule consisting of glimepiride and pioglitazone using a reversed phase isocratic method. The method was developed on 150 mm × 4.6 mm, 5 μ C18 column. The mobile phase consisted of sodium dihydrogen o-phosphate pH 6.0: acetonitrile (60:40 v/v). The compounds gave a good UV response at 220 nm, hence the detection wavelength. The method was found to be highly specific for glimepiride in presence of Pioglitazone and other constituents of the capsule. The developed method is simple, precise, robust and stands validated as per ICH guidelines.

**Keywords:** Glimepiride; Anti-diabetic; Reverse phase; Liquid chromatography

### 1. Introduction

Glimepiride is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes. It may also be used with other diabetes medications. 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 attacker stroke. Glimepiride belongs to the class of drugs known as sulfonylureas. It lowers bloodsugar by causing the release of your body's natural insulin.

Glimepiride belongs to a class of drugs called sulfonylureas. A class of drugs is a group of medications that work in a similar way. These drugs are often used to treat similar conditions.

Glimepiride helps your pancreas to release insulin. Insulin is a chemical that your body makes to move sugar (glucose) from your bloodstream into your cells. Once the sugar enters your cells, they can use it as fuel for your body.

With type 2 diabetes, your body doesn't make enough insulin, or it can't properly use the insulin that it makes, so the sugar stays in your bloodstream. This causes high blood sugar levels (hyperglycemia).

The more common side effects that can occur with glimepiride include, low blood sugar (hypoglycemia), trembling or shaking, nervousness or anxiety, irritability, sweating, lightheadedness or dizziness, headache, fast heart rate or palpitations, intense hunger, fatigue or tiredness, nausea, weakness and unexplained weight gain. If these effects are mild, they may go away within a few days or a couple of weeks.

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Serious side effects and their symptoms can include, severe low blood sugar (less than 35 to 40 mg/L), mood changes, such as irritability, impatience, anger, stubbornness, or sadness, confusion, including delirium, lightheadedness or dizziness, sleepiness, blurred or impaired vision, tingling or numbness in your lips or tongue, weakness or fatigue, lack of coordination, nightmares or crying out in your sleep, seizures and unconsciousness.

## 2. Material and methods

### 2.1. Chemicals

Sodium dihydrogen ortho phosphate AR grade, orthophosphoric acid AR grade, acetonitrile HPLC grade and purified water were procured from Merck India Pvt Ltd.

### 2.2. Standard solution preparation

Weigh pioglitazone HCl equivalent to 75 mg of pioglitazone in 100 ml volumetric flask. Add 50 ml of methanol to the flask, sonicate, cool and make the content of the flask to 100 ml using methanol. This is solution A. 33.06 mg of pioglitazone HCl is equivalent to 30 mg of pioglitazone. Weigh about 25 mg of glimepiride WS in 500 ml volumetric flask. Add 100 ml of acetonitrile to the flask, sonicate, cool and make the content of the flask to 500 ml using Tris buffer. This is solution B. Dilute 5 ml of solution A and 5 ml of solution B to 250 ml with Tris buffer to get a final concentration of 1 µg/ml for glimepiride and 15 µg/ml for pioglitazone. Inject 100 µl of this solution onto the system under the conditions mentioned and calculate content.

### 2.3. Sample solution

5 capsules were weighed and their average weight was determined. Powder the pellets & transfer powder equivalent to average content of capsule (i.e. 200 mg of powdered pellets) to a dry 1000 ml volumetric flask. Add about 200 ml Acetonitrile. Sonicate for 15 minutes. Shake well. Cool the solution. After the solution attains the room temperature dilute to volume with Tris buffer. Filter the solution through 0.45 µ before injecting into HPLC chromatograph under the following condition.

### 2.4. Instrumentation and chromatographic conditions

**Table 1** Chromatographic parameters of the experiment

Parameter	Description
Instrument	Shimadzu UFLC Prominence System
Pump	LC – 20 AD binary pumps
Injector	Auto sampler (SIL – 20 AC HT)
Injection volume	100 µl
Column oven	CTO – 20 AC at 25°C
Column	C18 (5 µ, 4.6 mm id ×150 mm)
Mobile Phase	Isocratic system of 1.6g of Sodium dihydrogen o-phosphate per liter : acetonitrile (60: 40) Run time: 20 min.
Flow Rate	2.0 mL/min
Detector	UV Detector- UV-4075
Detection Wavelength	220 nm

### 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 injecting standard solution in 5 replicates, single injection of blank solution and test solution.

### 2.5.2. Specificity

Specificity is the ability to assess unequivocally the analyte in the presence of other components which may be expected to be present. The tests were carried out by injecting diluent blank, resolution standard solution, placebo solution, standard solution, placebo + standard solutions and sample solution.

### 2.5.3. 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 injections of standard solutions.

### 2.5.4. 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 glimepiride is carried out in the range 3 µg/ml to 24 µg/ml.

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## 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. Specificity

Retention time obtained with test sample is comparable to the retention time obtained for the standard. All peaks are well separated from each other indicating the specificity of the analytical method for glimepiride.

### 3.3. Precision

Precision measured at all level was within the acceptable criterion of NMT 2.0 % indicating the efficiency of method for the proposed analysis.

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## 4. Conclusion

The method developed for analysis of glimepiride in presence of pioglitazone 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.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

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

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## How to cite this article

Patankar-Jain K, Gadkari P and Pradhan P. (2018). Rapid, simple and validated reverse phase method for analysis of glimepiride from capsules. GSC Biological and Pharmaceutical Sciences, 5(3), 43-45.

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