*The Pharmaceutical and Chemical Journal*, 2020, 7(4):75-79

*Available online www.tpcj.org*

**Research Article**

**ISSN: 2349-7092**
**CODEN(USA): PCJHBA**

# Spectrophotometric Determination of Sulpiride in Pharmaceutical Products

**Larisa Alagić-Džambić*, Minela Dacić, Kenan Bašić, Alija Uzunović, Maja Pašić-Kulenović, Ehlimana Osmanović Omerdić, Mirsad Džambić**

Quality Assuarance and Quality Control Department, Bosnalijek, 71000 Sarajevo, Bosnia and Herzegovina
*Email: larisatravnik@gmail.com

**Abstract** A simple spectrophotometric method was developed and validated for determination of Sulpiride in pharmaceutical products. The method was based using two different solvent: 0.1 mol/L sodium hydroxide and 0.1 mol/L hydrochloric acid. The absorbance maximum was at 291 nm. The correlation coefficient were r=0.9994 (in 0.1 mol/L sodium hydroxide as solvent) and r=1.0000 (in 0.1 mol/L hydrochloric acid as solvent). The method was validated and results obtained for the assay of three different brands of Sulpiride capsules, hard. The proposed method was successfully applied to the spectrophotometric determination of Sulpiride according to ICH guidelines (linearity, accuracy, precision).

**Keywords** Sulpiride, Method development, Spectrophotometry

## Introduction

Schizophrenia is a severe mental illness with "positive symptoms" such as hallucinations (sound and visual) and delusions (unusual beliefs). People with schizophrenia also suffer from disorganization and "negative symptoms" (such as fatigue, apathy and loss of emotions) [1]. People with schizophrenia have problems functioning in society and in employment. Schizophrenia is often considered one of the most serious diseases in the world. For some people, schizophrenia is a lifelong condition. People with schizophrenia are usually treated with antipsychotics. Newer antipsychotics (second generation or atypical) are more expensive and are thought to have fewer side effects than older ones (first generation or typical) [2]. These side effects may include movement disorders; as a result, many people find it difficult to tolerate older drugs and prefer second-generation drugs. However, in many developing countries, the cost of medicines can be a major factor in prescribing, so first generation drugs are the most used [3]. Sulpiride is a first-generation antipsychotic, but is thought to cause fewer side effects. Sulpiride is thought to be more effective than other older drugs (such as chloropromazine and haloperidol) for treating negative symptoms and withdrawal from a schizophrenic society [4]. Several analytical methods have been described for the determination of sulpiride such as HPLC [5, 6], but this is very simple and low cost spectrophotometric method. USP also gives method but for Sulpiride tablets as pharmaceutical products, not for capsules [7].

## Materials and Methods

### Materials and Equipment

Sulpiride 50 mg capsules, hard were commercial products from Bosnian market. The following reagents (sodium hydroxide and hydrochloric acid) and pure Sulpiride reference powder were obtained from Sigma-Aldrich, Germany. All the chemicals and reagents used were of analytical grade. The aqueous solutions (0.1 mol/L sodium

hydroxide and 0.1 mol/L hydrochloric acid) were freshly prepared with distilled water. A Shimadzu UV-Visible double beam spectrophotometer (Shimadzu, Japan) with matched 1 cm quartz cells was used for the measurements.

**Method**

***Preparation of 0.1 mol/L hydrochloric acid solution***

From 37% hydrochloric acid, 8.3 mL was pipetted in a 1 L volumetric flask and the volume made up to mark with distilled water.

***Preparation of 0.1 mol/L sodium hydroxide solution***

A 4 g mass of sodium hydroxide was weighed in a 1 L volumetric flask and the volume made up to mark with distilled water.

***Preparation of Sulpiride stock solution (a)***

A 25 mg mass of the pure reference material was weighed and dissolved in 0.1 mol/ L hydrochloric acid in a 25 mL volumetric flask and the volume made up to mark with same solvent (1 mg / mL). Working solutions were prepared by making appropriate dilutions of this standard Sulpiride stock solution (0.01 mg / mL – 0.06 mg / mL).

***Preparation of Sulpiride stock solution (b)***

A 25 mg mass of the pure reference material was weighed and dissolved in 0.1 mol/ Lsodium hydroxide in a 25 mL volumetric flask and the volume made up to mark with same solvent (1 mg / mL). Working solutions were prepared by making appropriate dilutions of this standard Sulpiride stock solution (0.01 mg / mL – 0.06 mg / mL).

***General Procedure***

A blank solution was prepared in the same way but excluding the analyte (Sulpiride), for both selected solvents. The above solutions were all prepared in triplicates. The absorbance of each solution was measured at 291 nm against a blank (0.1 mol / L sodium hydroxide and 0.1 mol / L hydrochloric acid).

***Validation of the proposed method***

The calibration curve for the drug was constructed in both selected solvents. Regression equation for the data was derived with the aid of Microsoft Excel software program. Each concentration of standard solution was assayed in triplicates and the mean absorbance obtained was then plotted versus concentration [8].

***Determination of accuracy and precision of the proposed method***

The precision and accuracy of the method were investigated based on inter-day variation (repeatability) assessment by analyzing Sulpiride using six replicates. The precision and accuracy of the method were expressed as % RSD and recovery of the measured concentration, respectively.

***Determination of Sulpiride content in capsules, hard formulation using the proposed method***

Three different brands of Sulpiride 50 mg capsules, hard formulation were assayed using the developed method. For each brand, the contents of 20 capsules, hard were weighed, ground into a fine powder. An accurately weighed portion of the powder equivalent to 25 mg Sulpiride was transferred into a 25 mL volumetric flask. Samples were dissolved in two different solvents. First solvent was of 0.1 mol/ L hydrochloric acid was added and after some minutes of mechanical shaking, the solution was made up to mark with the solvent. After filtration, 0.5 mL was pipette into a 10 mL volumetric flask. The content of each label claim was verified by comparing the concentrations obtained from the validated curves with the actual concentrations of the drug taken. Second solvent was 0.1 mol/L sodium hydroxide. The analytical procedure was same as is described for first solvent.

**Results & Discussion**

The content of sulpiride in the tested samples was determined by spectrophotometric method using a solvent of 0.1 mol/L hydrochloric acid (solvent a) and 0.1 mol / L sodium hydroxide (solvent b). For the purpose of method verification, the linearity of the standard solution in both solvents was done, due to the poor solubility of sulpiride, by preparing solutions in concentrations of 0.01 mg / mL - 0.06 mg / L in relation to the working concentration of the standard solution 0.05 mg / mL (Figure 1 and Figure 2).

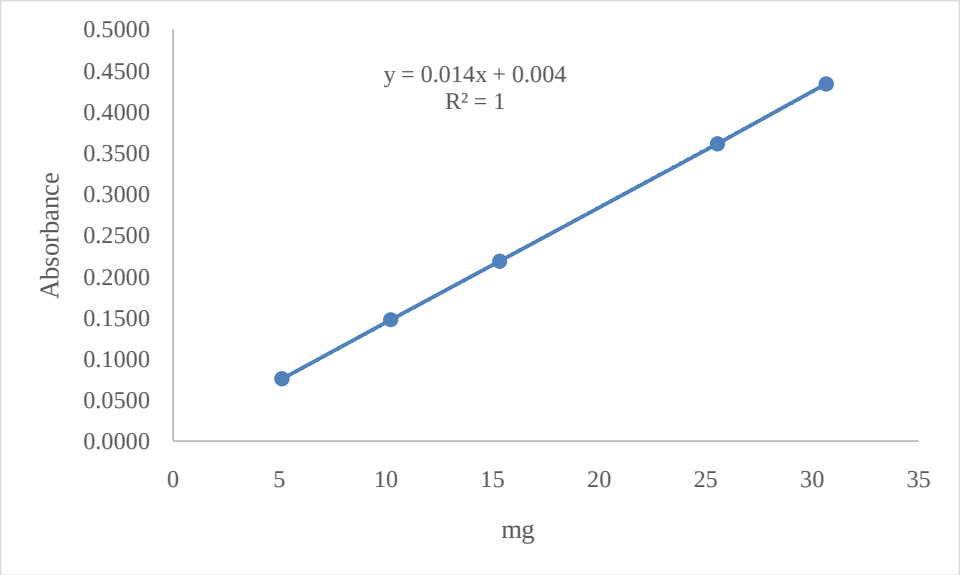


*Figure 1: Linearity for Sulpiride in solvent (a)*

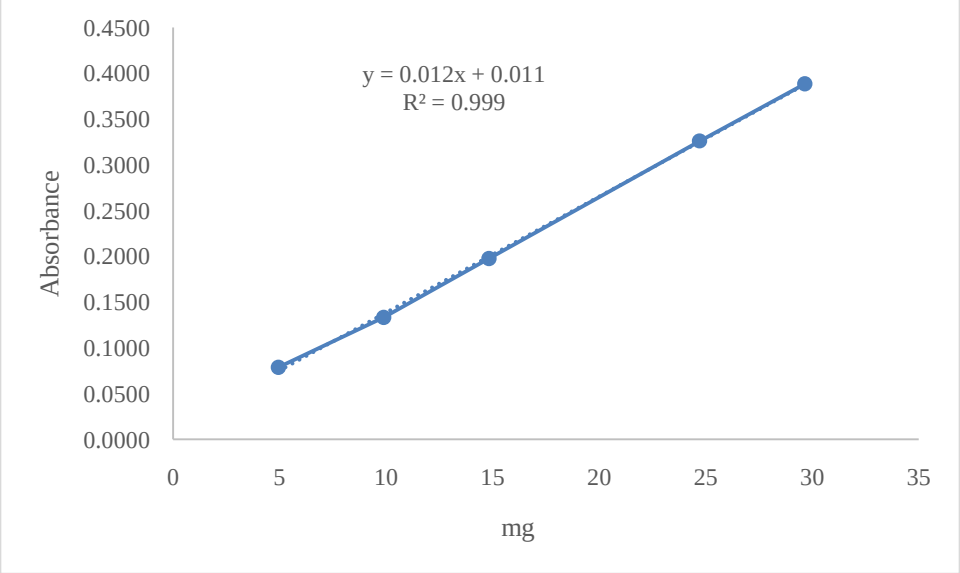


*Figure 2: Linearity for Sulpiride in solvent (b)*

Table 1 shows all validation results in both solvent.

**Table 1:** Validation results

| **Results** | **0.1 mol / L hydrochloric acid (solvent a)** | **0.1 mol / L sodium hydroxide (solvent b)** |
|---|---|---|
| Correlation coefficient ($r^2$) | 1.0000 | 0.9994 |
| Accuracy, RSD | 0.41 | 0.84 |
| Precision (n=6) | 1.90 | 1.04 |
| Limit of detection | 2 µg/mL | 0.3 µg/mL |
| Limit of quantification | 6 µg/mL | 0.9 µg/mL |

Table 2 obtained for the analysis of three brands of Sulpiride 50 mg capsules, hard using the developed method and compared between two solvents. The results obtained from comparisons that there are no significant differences between the proposed two solvents (Figure 3 and Figure 4).

**Table 2:** Percentage Content (%) of Sulpiride in 50 mg capsules, hard using proposed method comparison between solvents

| Samples | % of content sulpiride in solvent a | % of content sulpiride in solvent b |
|---|---|---|
| Sample A | 99.19 | 98.17 |
| Sample B | 97.48 | 103.81 |
| Sample C | 102.99 | 108.14 |

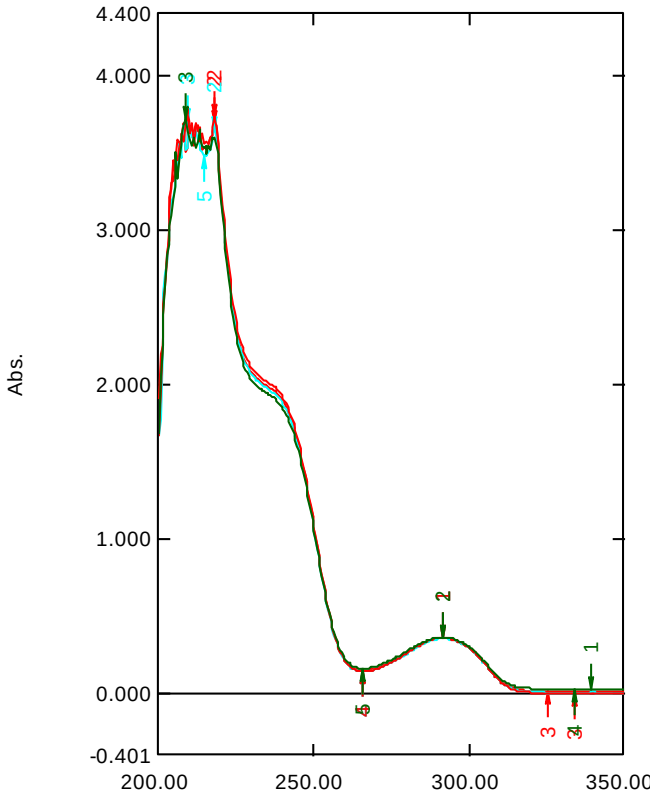


*Figure 3: Spectrograms of standard and sample solutions in solvent (a)*

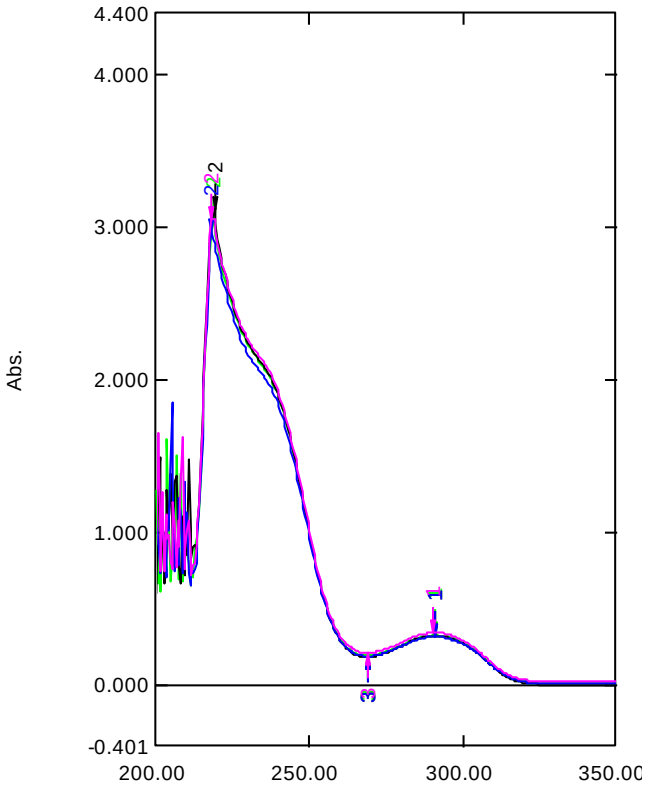


*Figure 4: Spectrograms of standard and sample solutions in solvent (b)*

## Conclusion

This is quite simple, accurate and precise method for determination of Sulpiride in capsules and it can therefore be concluded that the developed method is suitable for routine analysis of Sulpiride. All results have been demonstrated to be suitable for the spectrophotometric analysis of Sulpiride in formulated products, using both solvents. The method has the advantage of being simple, accurate, precise and suitable for routine quality control of Sulpiride in dosage form without any interference from excipients.

## References

[1]. Patel KR, Cherian J, Gohil K, Atkinson D. (2014). Schizophrenia: Overview and Treatment Options. PharmacolTher. 39: 638-645.

[2]. Zhornitsky S, Stip E. 2012. Oral versus Long-Acting Injectable Antypsychotics in the Treatment of Schizophrenia and special Populations at Risk for Treatment Nonadherence: A Systematic Review. Hindawi Publishing Corporation, Schizoph Res Treatment. 407171: 1-12.

[3]. Miyamoto S, Miyake N, Jarskog LF, Fleischhacker WW, Lieberman JA. 2012. Pharmacological treatment of schizophrenia: a critical review of the pharmacology and clinical effects of current and future therapeutic agents. Mol Psychiatry. 17: 1206 – 1227.

[4]. Altamura C, Fagiolini A, Galderisi S, Rocca P, Rossi A. 2011. Schizophrenia today: epidemiology, diagnosis, cpurse and models of care. J Psychopharmacol. 20: 223-243.

[5]. Fawzia A Ibrahim, Amira F El-Yazbi, Mira M. Wagih& Magda A. Barary. 2017. Chromatographic determination of zonisamide, topiramate and sulpiride in plasma by a fluorescent 'turn-on' chemosensor. Bioanalysis. 1049.

[6]. Mohamed I. Walash, Mohie M. Kh. Sharaf El-din, Nahed M. El-enany, Manal I. Eid, and Shereen M. Shalan. 2012. Simultaneous determination of sulpiride and mebeverine by HPLC method using fluorescence detection: application to real human plasma. Chemistry Central Journal. 6 (1):13.

[7]. USP Monograph for Sulpiride Tablets.

[8]. ICH Q2R1. Validation of Analytical Procedures. Textandmethodology.