

NOTE**Spectrophotometric Estimation of
Sisomicin and Olanzapine**

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A simple and sensitive spectrophotometric method has been developed for the estimation of sisomicin and olanzapine in pure and pharmaceutical formulations. This method is based on the formation of blue coloured species with Folin-Ciocalteu reagent under alkaline conditions exhibiting maximum absorbance at 725 nm and 655 nm. Beer's law is obeyed at the concentration range of 10–50 µg/mL for sisomicin and 1.5–7.5 µg/mL for olanzapine. The method has been statistically evaluated and is found to be precise and accurate.

Key Words: Spectrophotometric estimation, Sisomicin, Olanzapine.

Sisomicin (SMS)¹ is an amino glycoside antibiotic, that is used for the treatment of systemic infections and is chemically D-streptomine, (2*S-cis*)-4-*o*-[3-amino-6-(aminomethyl)-3,4-dihydro-2H-pyran-2-yl]-2-deoxy-6-*o*-[3-deoxy-4-C-methyl-3-(methyl amino)-β-L-arabinopyranosyl]-sulphate. Olanzapine (OZP)² is a tricyclic anti-psychotic agent and belongs to the thieno benzodiazepine class. Chemically, it is 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-*b*] [1,5]-benzodiazepine. Literature survey reveals that a few methods have been reported for the determination of SMS^{3,4} and OZP⁵ which include HPLC and colorimetry. The present method describes the reaction of sisomicin or olanzapine with Folin-Ciocalteu reagent in alkaline medium to develop blue-coloured species, which exhibits absorption maximum at 725 or 655 nm.

Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells.

Preparation of standard and sample solutions

Sisomicin: Accurately weighed 100 mg of drug was dissolved and diluted with distilled water stepwise so as to obtain a concentration of 200 µg/mL.

Formulation (cream) equivalent to 50 mg of sisomicin (SMS) was accurately weighed and transferred to a 250 mL separating funnel containing 50 mL of solvent ether to dissolve the additive materials. Sisomicin (non-extractable portion) was then treated with 5 mL of 0.1 N NaOH and then extracted with 3 × 15 mL portions of chloroform. The combined chloroform extract was adjusted to the volume 50 mL to get 1 mg/mL solution.

From the above solution (10 mL), the solvent chloroform was evaporated and the residue was dissolved in minimum volume of 0.1 N H₂SO₄ and then diluted and distilled water to get the concentration of 200 µg/mL.

Olanzapine: Accurately weighed 100 mg of drug was dissolved in 10 mL of 0.1 N HCl and made up to 100 mL with distilled water. This solution was further diluted with distilled water so as to obtain a concentration of 30 $\mu\text{g/mL}$.

An accurately weighed amount of tablet powder of olanzapine equivalent to 100 mg was dissolved in 10 mL of 0.1 N HCl, diluted to 100 mL with distilled water and filtered. This solution was further diluted with distilled water so as to obtain a concentration of 30 $\mu\text{g/mL}$.

Assay procedure

Aliquots of standard drug solution ranging from 0.5 to 2.5 mL were transferred to a series of 10 mL graduated test tubes. To each tube, 1.0 mL of Folin-Ciocalteu reagent and 3.0 mL NaOH (for sisomicin) or 2.0 mL NaOH (for olanzapine) were added and kept aside for 5 min at room temperature. The solutions were made up to volume with distilled water. The absorbance of the blue colour (stable for 1 h for sisomicin or 3 h for olanzapine) was measured at 725 or 655 nm against a reagent blank. The amount of the drug in the sample was computed from the Beer-Lambert plot.

The Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limits), regression equation, correlation coefficients, detection limits, % range of error (0.05 and 0.01 confidence limits) obtained are shown in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHODS
FOR SISOMICIN AND OLANZAPINE

Parameter	Method A	Method B
λ_{max} (nm)	725	655
Beer's law limits ($\mu\text{g/mL}$)	10–50	1.5–7.5
Detection limits ($\mu\text{g/mL}$)	1.107	0.033
Molar absorptivity ($\text{L mol}^{-1} \text{cm}^{-1}$)	1.26×10^4	2.40×10^4
Sandell's sensitivity ($\mu\text{g cm}^{-2}/0.001$ absorbance unit)	0.110	0.013
Regression equation ($Y = a + bC$):		
Slope (b)	9.03×10^{-3}	7.69×10^{-2}
Intercept (a)	1.70×10^{-3}	1.12×10^{-4}
Correlation coefficient (r)	0.9998	0.9999
Relative standard deviation (%)*	0.580	0.505
% Range of error (Confidence limits)*:		
0.05 level	0.486	0.422
0.01 level	0.718	0.625

* Average of eight determinations.

Pharmaceutical formulations of sisomicin and olanzapine were successfully analyzed by the proposed methods. The results obtained by the proposed method

and reported method are presented in Table-2. To evaluate validity and reproducibility of the method, known amounts of pure drug were added to previously analyzed samples and the mixtures were analyzed by the proposed method; there is no interference of other ingredients present in formulations. These results indicate that the method is simple, rapid, with reasonable precision and accuracy, and applicable to various formulations of sisomicin and olanzapine.

TABLE-2
ASSAY AND RECOVERY OF SISOMICIN AND OLANZAPINE IN DOSAGE FORMS

Name of the dosage form	Labelled amount (mg)	Content of drug found		% Recovery by proposed method*
		Proposed method (mg)	Reported method ^R (mg)	
Sisomicin				
Creams I	100	99.88	100.22	99.20
Creams II	100	99.90	100.06	99.70
Olanzapine				
Tablets I	5	4.99	5.03	99.85
Tablets II	5	4.89	5.00	99.48

*Recovery amount is the average of five determinations.

R Reference was UV method developed in the laboratory.

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REFERENCES

1. United States Pharmacopoeia, USP XXIV and NF IXX (2000) and 4 Addenda, USP Convention Inc., Rockville (2002).
2. PDR: Physician's Desk Reference, 54th Edn. (2000).
3. Tawa, Ritchi, Matsunaga, Hirokazu, Fujimoto and Takashi, *J. Chromatogr.*, **812A**, 141 (1998).
4. R. Evangelista, Cesar, Schaporal, Elfrides and Eva Scherman, *Rev. Cienc. Farm.*, **5**, 21 (1983).
5. V. Pucci, M. Raggi and E. Kenndler, *J. Chromatogr. B, Biomed. Sci. Appl.*, **728**, 263 (1999).

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