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RESEARCH ARTICLE

Development and Validation of UV-Spectroscopic Method for Estimation of Formoterol in Bulk and Pharmaceutical Dosage Form

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ABSTRACT
This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of Formoterol in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.
Keywords: Formoterol, UV-spectrophotometric technique

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CONTENTS

1. Introduction

Formoterol is a long-acting (12 hours) beta2-agonist used in the management of asthma and/or chronic obstructive pulmonary disease (COPD). Inhaled formoterol works like other beta2-agonists, causing bronchodilatation through relaxation of the smooth muscle in the airway so as to treat the exacerbation of asthma. A white crystalline powder. It is freely soluble in methanol and in lower alcohol solvents, but is practically insoluble in water [1].

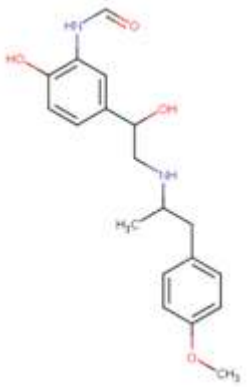

Figure 1. Formoterol

2. Materials and Methods

Material

Formoterol was a gift sample from Dr. Reddys Lab, Hyderabad. All chemicals (distilled water, methanol) and reagents used were of analytical grade and purchased from Qualigens Fine Chemicals, Mumbai, India [2-3].

Apparatus

A Labindia UV–visible spectrophotometer (UV-T60-India) was used for all absorbance measurements with matched quartz cells.

Methodology

Method Development

Preparation of standard stock solution

Accurately weighed 10 mg of Formoterol was transferred to a 100 ml volumetric flask, dissolved in 20 ml distilled water by shaking manually for 10 min. The volume was adjusted with the same up to the mark to give the final strength, i.e. 100 µg/ml.

Selection of wavelength for analysis of Formoterol

Appropriate volume 0.5 ml of standard stock solution of Formoterol was transferred into a 10 ml volumetric flask, diluted to a mark with distilled water to give concentration of 5 µg/ml(and also 10, 15µg/ml). The resulting solution was scanned in the UV range (200–400 nm). In spectrum Formoterol showed absorbance maximum at 287 nm [4-5].

Validation of the method

The method was validated in terms of linearity, accuracy, precision, and ruggedness.

Linearity study

Different aliquots of Formoterol in the range 0.5–3 ml were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with distilled water to get concentrations 5, 10, 15, 20, 25, and 30 µg/ml, respectively. The solutions were scanned on a spectrophotometer in the UV range 200–400 nm. The spectrum was recorded at 287 nm. The calibration plot was constructed as concentration vs. absorbance [6-7].

Accuracy

To the pre analysed sample solutions, a known amount of standard stock solution was added at different levels, i.e. 50%, 100%, and 150%. The solutions were reanalyzed by the proposed method [8-9].

Precision

Precision of the method was studied as intraday and interday variations. Intraday precision was determined by analyzing the 10, 15 and 20 µg/ml of Formoterol solutions for three times in the same day. Interday precision was determined by analyzing the 10, 15, and 20 µg/ml of Formoterol solutions daily for 3 days over the period of week [11-14].

Sensitivity

The sensitivity of measurements of Formoterol by the use of the proposed method was estimated in terms of the limit of quantification (LOQ) and limit of detection (LOD). The LOQ and LOD were calculated using equation LOD = 3 × N/B and LOQ = 10 × N/B, where 'N' is standard deviation of the peak areas of the drugs (n = 3), taken as a measure of noise, and 'B' is the slope of the corresponding calibration curve [15-16].

Repeatability

Repeatability was determined by analyzing 20 µg/ml concentration of Formoterol solution for six times.

Ruggedness

Ruggedness of the proposed method is determined for 20 µg/ml concentration of Formoterol by analysis of aliquots from a homogenous slot by two analysts using same operational and environmental conditions [17].

3. Results and Discussion

Selection of wavelength for analysis of Formoterol

During the development phase, the use of ethanol as the diluent resulted in preferable outcome in UV analysis. The pre-determined wavelength of maximum absorption (λmax) was 287 nm.

Table 1. Solubility studies

Solvent	Solubility(mg/ml)
Ehanol	1.5
Methanol	0.9
Alcohol	1.3
Chloroform	1.6
Acetone	1.2
Distilled water	0.4

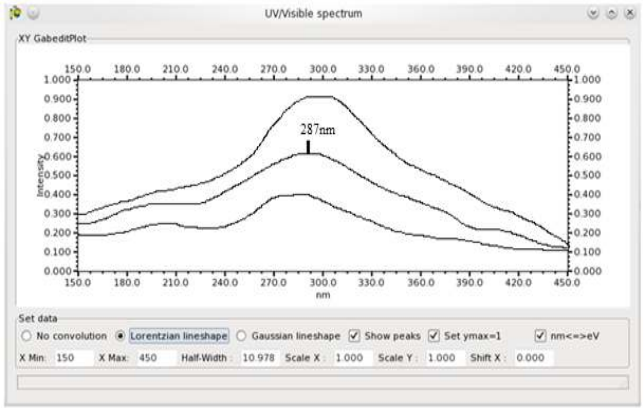

Figure 1. UV –visible spectrum

Linearity

Table 2 Results of Linearity

Concentration (ug/ml)	absorbance(nm)
0	0
5	0.143

10	0.274
15	0.403
20	0.532
25	0.658
30	0.792

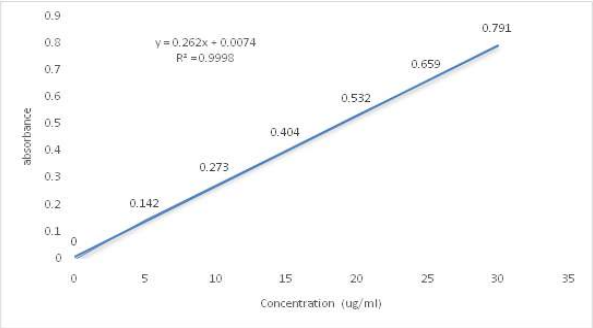

Figure 2. Results of Calibration graph

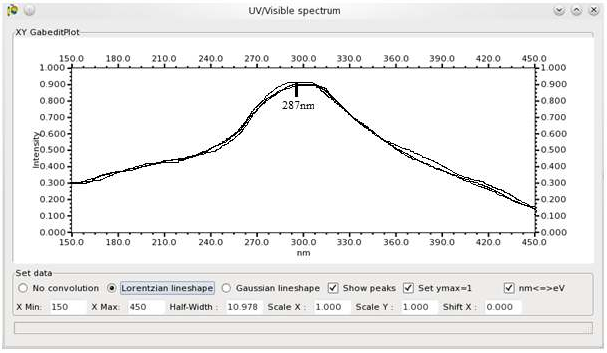

Figure 3. Accuracy (recovery) data for Formoterol

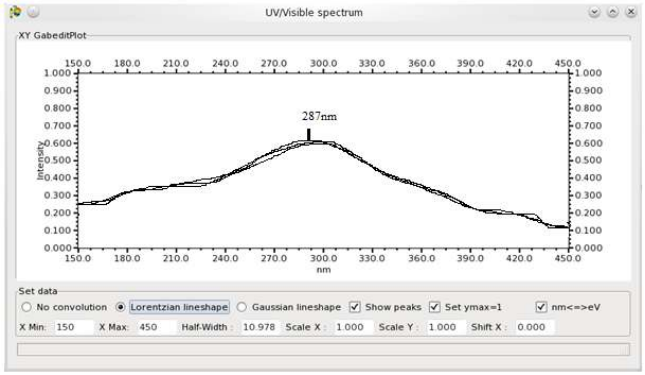

Figure 4. Accuracy 50%

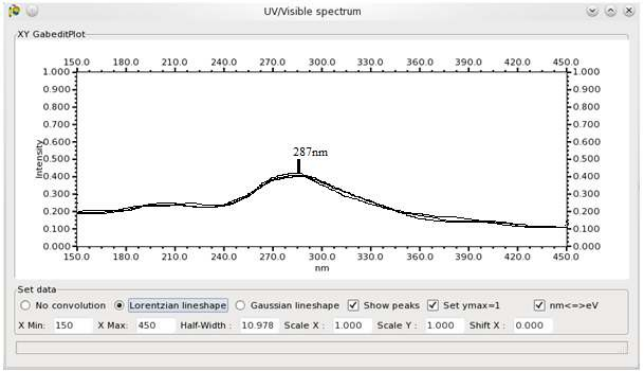

Figure 5. Accuracy 100%

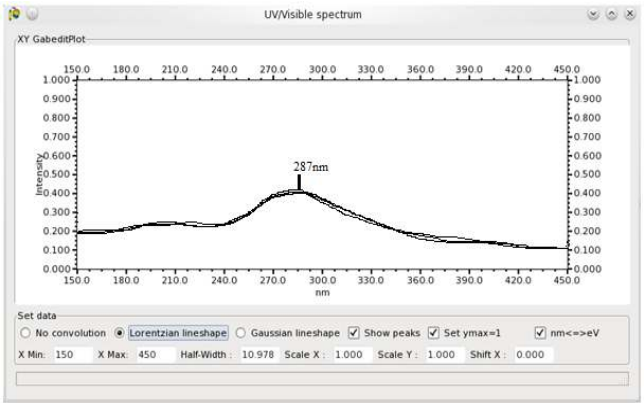

Figure 6. Accuracy 150%

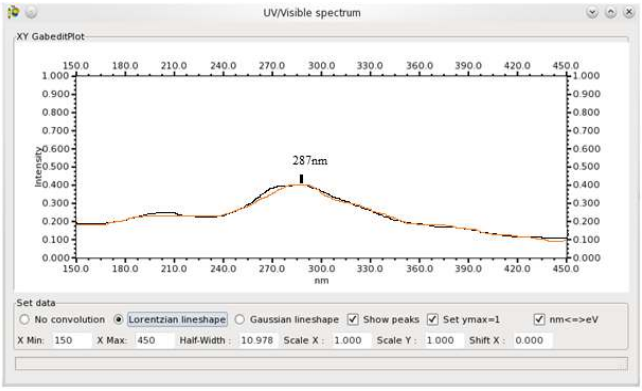

Figure 7. Intra-day and inter-day precision determined for three different concentrations of Formoterol (n=3).

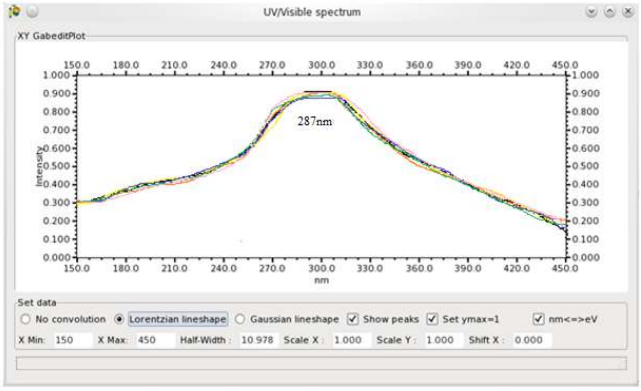

Figure 8. Results of Repeatability

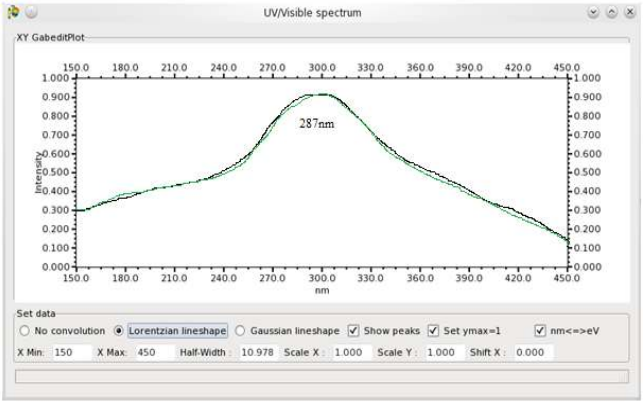

Figure 9. Results of Ruggedness

Table 3 Results of Accuracy

%Concentration (at specification Level) N=3	absorbance	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	0.4215	2.5	2.497	99.93	99.68
100%	0.6214	5.0	4.990	99.07	
150%	0.9199	10	9.995	99.95	

Table 4 Intra-day and inter-day precision determined for three different concentrations of Formoterol (*n*=3)

Concentration (µg/mL)	Intra-day precision			Inter-day precision		
	Absorbance measured	RSD (%)	Average (%)	Absorbance measured	RSD (%)	Average (%)
10	0.4112	0.140	98.97	0.4120	0.242	98.95
15	0.6148	0.095	98.60	0.6154	0.095	98.72
20	0.9212	0.123	98.78	0.8215	0.071	98.84

4. Conclusion

This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of Formoterol in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

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