Dissertation abstract

COLLEGE: Faculty of Pharmacy  DEPARTMENT: Medicinal Chemistry  CALL NO.
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Dissertation Title:
Contribution to the analysis of certain drugs used in the treatment of respiratory tract disorders in pharmaceutical preparations

Dissertation Abstract

This thesis is devoted to the development of new methods for the analysis of certain drugs used in the treatment of respiratory tract disorders, namely: Formoterol Fumarate (FF), Budesonide (BUD), and Indacaterol Maleate (IND) in pure form and in pharmaceutical preparations.

A simple and rapid IPC method with UV detection was developed for simultaneous determination of binary mixture; Formoterol Fumarate and Budesonide in their raw materials as well as metered dose inhaler without pre-column derivatization or gradient elution.

Two simple, sensitive and reliable spectrophotometric and spectrofluorimetric methods were developed for the determination of Indacaterol. The methods depend on measurement of the absorbance and the native fluorescence of the drug for methods I and II, respectively. The two methods could be successfully applied to the determination of IND in capsule dosage form. The method was further applied to content uniformity testing according to USP guidelines. Stability indicating study was applied to method I.

A sensitive and specific reversed-phase liquid chromatographic method with ultraviolet and fluorescence detection was developed for determination of IND in raw material. Different chromatographic parameters were investigated and the methods were successfully applied for the determination of IND in pure form and in its capsule formulations.

Three simple, sensitive, and reliable spectrophotometric methods were developed for the determination of IND. Difference spectrophotometric method was established for determination of IND in method A. Methods B and C briefly performed by the reaction of IND with two different reagents namely MBTH and 4-AAP. The three methods could be successfully applied to the determination of IND in capsule dosage forms.

Key words:
Formoterol Fumarate - Budesonide - Indacaterol Maleate - pure form - pharmaceutical preparations.

ملحوظة:
1- يرقى هذا النموذج بالرسالة الورقية. 2- كما ينسخ على قرص CD الخاص بالرسالة في ملف يسمى (مستخلص)
Summary

This thesis is devoted to the development of new methods for the analysis of certain drugs used in the treatment of respiratory tract disorders, namely: Formoterol Fumarate (FF), Budesonide (BUD), and Indacaterol Maleate (IND) in pure form and in pharmaceutical preparations.

The thesis is divided into five main parts;

**Part I: Introduction**

This part provides a general introduction about respiratory tract diseases and classification of drugs used for their treatment.

**Part II: Simultaneous Determination of Formoterol Fumarate and Budesonide in Metered dose inhaler using ion-pair chromatography**

A simple and rapid IPC method with UV detection was developed for simultaneous determination of binary mixture; Formoterol Fumarate and Budesonide in their raw materials as well as metered dose inhaler without pre-column derivatization or gradient elution.

**Part III: Spectrophotometric and Spectrofluorimetric Determination of Indacaterol Maleate in Pure Form and Pharmaceutical Preparations: Application to Content Uniformity**

Two simple, sensitive and reliable spectrophotometric and spectrofluorimetric methods were developed for the determination of Indacaterol. The methods depend on measurement of the absorbance and the native fluorescence of the drug for methods I and II, respectively. The two methods could be successfully applied to the determination of IND in capsule dosage form. The method was further applied to content uniformity testing according to USP guidelines. Stability indicating study was applied to method I.
Summary

Part IV: HPLC Determination of Indacaterol Maleate in Pharmaceutical Preparations by high-performance liquid chromatography adopting ultraviolet and fluorescence detection

A sensitive and specific reversed-phase liquid chromatographic method with ultraviolet and fluorescence detection was developed for determination of IND in raw material. Different chromatographic parameters were investigated and the methods were successfully applied for the determination of IND in pure form and in its capsule formulations.

Part V: Spectroscopic study on Indacaterol maleate: Analytical applications for quality control of capsules

Three simple, sensitive, and reliable spectrophotometric methods were developed for the determination of IND. Difference spectrophotometric method was established for determination of IND in method A. Methods B and C briefly performed by the reaction of IND with two different reagents namely MBTH and 4-AAP. The three methods could be successfully applied to the determination of IND in capsule dosage forms.

The experimental parameters of the proposed procedures were optimized and the validation criteria of the developed methods were implied. The obtained results were statistically analyzed and compared with those obtained by comparison methods.

The thesis consists of five parts including (162) references, (26) tables, (27) figures, and (2) scheme and ends with an arabic summary.