

ABSTRACT

The objective of the present work was to develop and validate a dissolution method for Levocetirizine dihydrochloride LCTZ tablet using ultraviolet spectrophotometry. The dissolution steps were based on the use of the paddle apparatus. The analytical assay was based on absorbance measurements at maximum absorption 236.5nm. Beer Lambert's law was obeyed in the concentration range 2 - 22 mg. The correlation coefficient was 0.9998 with a relative standard deviation of 0.62%. Results of analysis were validated statistically and by recovery studies. The method was validated according to the ICH guidelines with respect to specificity, linearity, accuracy, precision, and robustness, stability, limit of detection and limit of quantitation. The proposed method can be successfully applied in routine work for the determination of LCTZ in tablets.

ملخص الدراسة

الهدف من هذا العمل هو تطوير والتحقق من صحة طريقة اذابة حبوب ثائي هيدروكلوريد الليفوسترزين باستخدام طيف الأشعة فوق البنفسجية. واستندت خطوات الاذابة على استخدام جهاز الاذابه باستخدام البدلات كادوات. واستند التحليل على قياس الامتصاص عند الحد الأقصى للامتصاص عند 236.5 نانو متر وتم تطبيق قانون بيير و لامبرت في مجال تركيز 2 - 22 ملج. وبلغ معامل الارتباط 0.9998 مع انحراف معياري نسبي قدره 0.62%. تم التحقق من صحة هذه الطريقة وفقا للمبادئ التوجيهية العالمية فيما يتعلق بالخصوصية والخطية والمصدقية والدقة والمتانة والاستقرار وحد الكشف الادني و وحد التعيين الادني. يمكن تطبيق الطرق المقترحة بنجاح في التحليل الروتيني لتعيين ثائي هيدروكلوريد الليفوسترزين في حبوبها الصيدلانية.

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Abbreviations

Absorbance	A
Absorbance of Standard preparation	AS
Absorbance of Sample preparation	AT
Absorbance of placebo	AP
Concentration of standard in mg/ml	C
Intensity of transmitted light	I
Intensity of incident light	I_o
Labeled Claim	L
Limit of detection	LOD%
Limit of quantitation	LOQ%
Path length through the sample	b
Quantity released	Q %
Standard Assay	P
Standard weight	STD Wt.
Standard water content	WC
The absorptivity coefficient of the material	ε
Volume	V