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SPECTROPHOTOMETRIC ESTIMATION OF MONTELUKAST FROM BULK DRUG AND TABLET DOSAGE FORM

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ABSTRACT: Two Simple, accurate, precise and sensitive spectrophotometric methods for estimation of Montelukast sodium (MON) have been developed and validated. The zero order spectroscopic method (Method I) and area under curve method (Method II) have developed. The proposed methods are validated according to ICH Q2B guidelines. The Montelukast sodium gives maximum absorbance at 241nm in chloroform and observed linearity 2-20 µg/ml for zero order method and 4-20 µg/ml for area under curve method. The stability of drug in chloroform has been studied and drug shows good stability in Chloroform. The recovery by method I and method II are 99.52 ± 0.069, 101.93± 0.11 respectively. The both spectrophotometric methods can be applied for routine analysis of Montelukast sodium in tablet formulation and in bulk drug.

INTRODUCTION: Montelukast is a leukotriene receptor antagonist used as an alternative to anti-inflammatory medications in the management and chronic treatment of asthma and exercise-induced bronchospasm. The montelukast chemically (S, E)-2-(1-((1-(3-(2-(7-chloroquinolin-2-yl) vinyl) phenyl)-3-(2-(2-hydroxypropan-2-yl) phenyl) propylthio) methyl) cyclopropyl) acetic acid.Montelukast selectively antagonizes leukotriene D_4 (LTD_4) at the cysteinyl leukotriene receptor, $CysLT_1$, in the human airway. Montelukast inhibits the actions of LTD_4 at the $CysLT_1$ receptor, preventing airway edema, smooth muscle contraction, and enhanced secretion of thick, viscous mucus.

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The proposed methods are validated according to ICH Q2B guidelines for validation of analytical procedures in order to determine the linearity, sensitivity, precision, LOD, LOQ and accuracy for the analyte.

MATERIALS AND METHODS:

Instrument and chemicals: UV Spectrophotometer used was SHIMADZU model-1800 (Japan). Chemicals of Loba Chemicals Pvt. Ltd. of Analytical grade were used. A gift sample of montelukast sodium active pharmaceutical ingredient (API) from Smilex Laboratories Limited Hyderabad, Andhra Pradesh, was used. All operations were carried out in amber colour glassware.

Solvent selection: Chloroform of analytical reagent grade was selected as solvent for developing spectral characteristics of drug. The selection was made after assessing the solubility and stability of the drug in different solvents.

Preparation of Standard Drug Solution: Standard stock solution containing Montelukast were prepared by dissolving 10 mg of Montelukast in 20 ml of chloroform. It was then sonicated for 10 minutes and the final volume of the solution was made up to 100 ml with chloroform to get stock solutions containing100 µg/ml.

Determination of Absorption Maxima: By appropriate dilution of standard drug solution with chloroform, a solution containing 10 µg/ml of MONT was scanned in the range of 200- 400 nm to determine the wavelength of maximum absorption for the drugs. MONT showed absorbance maxima at 241nm.

Zero Order Method:

i) **Calibration Curve:** The absorbances were recorded for 2-20 µg/mL at 241 nm (λ_{max} of MONT). From this calibration curve was plotted (**Fig. 1**).

Area under Curve Method (Method II):

ii) **Calibration curve:** The absorbance was recorded for 4-20 µg/mL at 236 – 246 nm. From this, calibration curve were plotted. (**Fig. 2**).

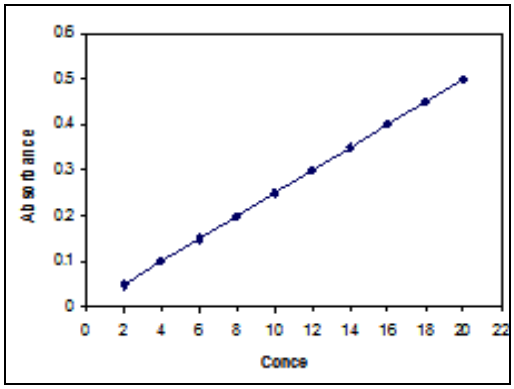

FIG. 1: CALIBRATION CURVE OF MONTELUKAST FOR ZERO ORDER METHOD

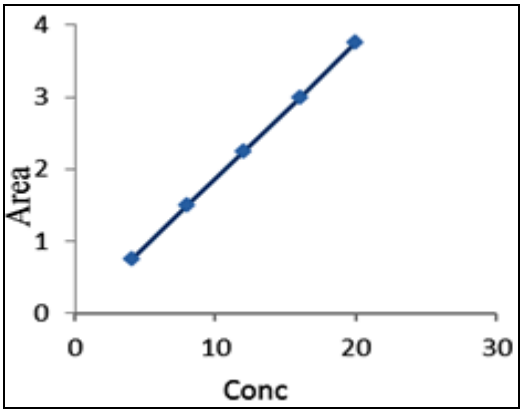

FIG 2: CALIBRATION CURVE OF MONTELUKAST FOR AREA UNDER CURVE METHOD II

TABLE 1: LINEAR REGRESSION ANALYSIS OF CALIBRATION CURVES WITH THEIR RESPECTIVE ABSORPTIVITY VALUES

Parameters	Method I	Method II
Beer's law limit (µg/mL)	2-20	4-20
Correlation coefficient (r)	0.999483	0.99456
Molar absorptivity (lit/mole/cm)	24816.89	0.5971
Sandell's sensitivity (mcg/Sq.cm/0.001)	0.018576	0.2345
Slope	0.035703	1.32
Intercept	0.002267	2.12
LOD (µg/mL)	0.6	1.2
LOQ (µg/mL)	3.5	2

TABLE 2: RESULTS OF ANALYSIS OF MONT IN THE LABORATORY PREPARED MIXTURE

Analyte	Method I	Method II
% Conc. Estimated *(Mean ± S.D.)	98.45± 0.3321	99.39 ± 0.00207
Coefficient of variance	0.0546	0.009

*Average of six determinations; R.S.D.; Relative Standard Deviation

TABLE 3: RESULTS OF ANALYSIS OF TABLET SAMPLES AND RECOVERY STUDIES

	Label Claim (mg/ tab)	% Label Claim (Mean ± R. S. D.)	Coefficient of variance	%Recovery* (Mean ± R. S. D)
Method I	12	103.45 ± 1.224	0.0155	99.52 ± 0.069
Method II	12	100.00	0.0257	101.93± 0.11

*Average of three determinations; R.S.D.; Relative Standard Deviation.

TABLE 4: RESULTS OF INTERMEDIATE PRECISIONS

Day	% Label claim estimated* (Mean ± % R.S.D.)	
	Method I	Method II
Intra day	105.83 ± 0.73	99.65 ± 0.83
Inter day	106.86 ± 1.27	99.24 ± 0.23

* Average of three determinations; R.S.D.; Relative Standard Deviation

RESULTS AND DISCUSSION: The absorbance method is simple, rapid and requires only the accurate values of absorptivities of the drug solution at maximum absorbing wavelengths. The method requires recording of absorbance and few calculations that can be used with any model of spectrophotometer. The maximum absorbance observed at 241nm in chloroform.

In Area under curve method, the absorptivity values of the drug were determined at 236 – 246 nm wavelength range. Total area under curve of a mixture at wavelength range is equal to the sum of area under the individual component at that wavelength range. The correlation coefficient (**Table 1**) is 0.999483 for Method I and 0.99456 for Method II. The results of Recovery study (**Table 3**) and precision (**Table 4**) are in acceptable limit.

TABLE 5: ONE WAY ANOVA (TUKEY -KRAMER MULTIPLE COMPARISON TEST)

Comparison	Mean difference	P value	P Value
Method I Vs Method II	1.14	0.3737	ns P > 0.05

The P value was found to be greater than 0.05. The results of the ANOVA indicate no significant difference between all methods.

CONCLUSION: The developed methods were statistically compared using one way ANOVA. The method used for the comparison was Tukey-Kramer Multiple comparison test.

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