

Research Article



Development and Validation of Analytical Method for the Estimation of Drugs Metoclopramide Hydrochloride and Dexamethasone Sodium Phosphate by FTIR

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ABSTRACT

The goal of this review to foster basic, exact, credible and practical logical technique for the assessment of antiemetic drugs as per ICH rules. To develop an accurate and validated method for estimating plenty of samples in short period of time. FTIR spectrophotometric method was used for the determination of the drugs (BRUKER ATR, Alpha interferometer attached to OPUS software). The simple method obeys Beers Lamberts law over a concentration range of 6.5-10.5mg for MET.HCl and 4.4-10.8 mg for DEX. MET shows a correlation coefficient of 0.998 and for DEX it is 0.997. The most important component of a pharmaceutical development programme is analytical method development, which is the process of demonstrating that the created technique can be used to measure the concentration or quantity of API in diverse formulations. The identification, purity, potency, and effectiveness of drug goods are ensured using the official test procedures that come from these procedures.

Keywords: Metoclopramide Hydrochloride, Dexamethasone Sodium Phosphate, FTIR, Method development, Validation.

QUICK RESPONSE CODE →

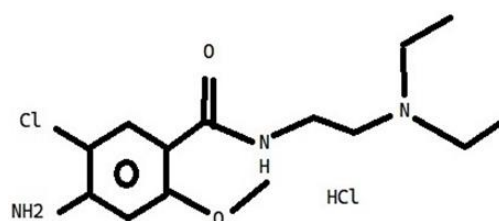
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MATERIALS AND METHODS

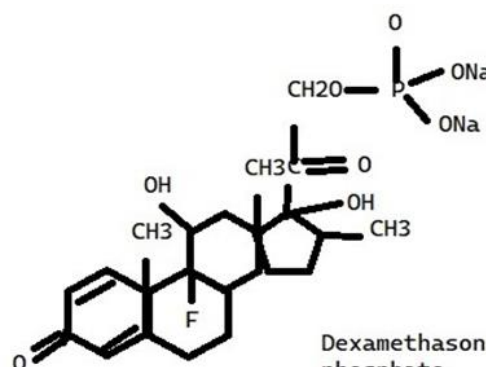
Metoclopramide hydrochloride



Metoclopramide hydrochloride

The spectrum was recorded between 4000 and 650 cm^{-1} by averaging 24 scans for spectrum using OPUS software of Bruker /ZnSe FTIR spectrophotometer with Reflection Top plate, and 100 mg of precisely weighed MET pure medication were maintained on top of ATR crystal. A pressure plate and clamp were employed to crush the sample against the crystal. Peak integral area for one isolated peak, 3408.81-3330.34 cm^{-1} , was estimated.

Dexamethasone sodium phosphate



Dexamethasone Sodium phosphate

INTRODUCTION

Nausea is a sensation of discomfort in the stomach with an involuntary urge to vomit. Emesis or vomiting is a physiological response to the presence of irritating and harmful substances in the gut or bloodstream.¹⁻¹² Nausea and vomiting occur frequently in patients undergoing general anesthesia¹³⁻¹⁴ for surgery. Metoclopramide is a dopamine antagonist¹⁵ used to treat nausea and vomiting that may be associated with diabetic gastroparesis in addition to gastroesophageal reflux disease. Dexamethasone sodium phosphate is a white or slightly yellow crystalline powder odorless, very hygroscopic substance.

MATERIALS AND METHODS

Reagents and chemicals

The standard Metoclopramide Hydrochloride were procured from Yarrow chem products, Mumbai. Dexamethasone Sodium phosphate from Yarrow chem Products, Mumbai.

Equipment's used

Electronic balance-Tandem T J series.

Bruker ATR, Alpha interferometer attached to OPUS software.



Accurately weighed 100mg of pure drug were kept in top of ATR crystal and spectra was recorded between 4000 and 650 cm^{-1} , by averaging 24 scans for spectrum using OPUS software of Bruker α /ZnSe FTIR spectrophotometer with reflection top plate. In order to compress the sample against the crystal a pressure plate and clamp provided were used. One isolated peak 2395.15 - 2277.43 cm^{-1} was defined and peak integral area was calculated.

Sample preparation

No sample treatment is required for FTIR except grinding and here the powdered sample is introduced in the top of ATR crystal and spectra was recorded between 4000 and 650 cm^{-1} , by averaging 24 scans for spectrum using OPUS software of Bruker α / ZnSe FTIR spectrophotometer with reflection top plate 14. In order to compress the sample against the crystal, a pressure plate and clamp were used.

Validation of FTIR

Accuracy

Accuracy of the method was expressed in terms of % recovery and are calculated by standard addition technique. Here the percentage spiking levels are 80,100 and 120 percentage.

Method precision

The precision of the instrument was checked by repeated scanning and measuring the absorbance of solution of (n=6) MET (10mg/ml) and DEX (5mg/ml) without changing the parameters of developed method.

Reproducibility

The intraday and interday precision was determined by analyzing corresponding responses 3 times on the same day and on 3 different days over a period of 1 week for 3 different concentrations of standard solutions of MET (8,5,9,10mg/ml) and DEX (5,6,7,5mg/ml). RSD was used to report the results.

Limit of detection and limit of quantification

The LOD and LOQ were calculated by the equation method

$$\text{LOD} = 3.3 \times \sigma / S$$

$$\text{LOQ} = 10 \times \sigma / S$$

Where, σ = the substandard deviation of the response

S = slope of the calibration curve

Linearity

Different weights of MET and DEX were taken using electronic balance with 0.001mg sensitivity and spectrum recorded and average of such determinations were plotted in calibration curve.

RESULTS AND DISCUSSIONS

Spectrophotometric methods for the simultaneous determination of MET and DEX were developed and validated according to ICH Q2B guidelines which are used

for validation of analytical procedures in order to determine the linearity, sensitivity, precision and accuracy for the analytes and data complying with the standards were obtained. The results of validation parameters for the developed methods are reported.

Table 1: Validation parameters

	Metoclopramide hydrochloride	Dexamethasone
Accuracy (%RSD)	0.640	0.171
Limit of detection	0.6	1.2
Limit of quantification	1.2	2.5
Precision (%RSD)	0.695	1.03
Correlation coefficient	0.998	0.997

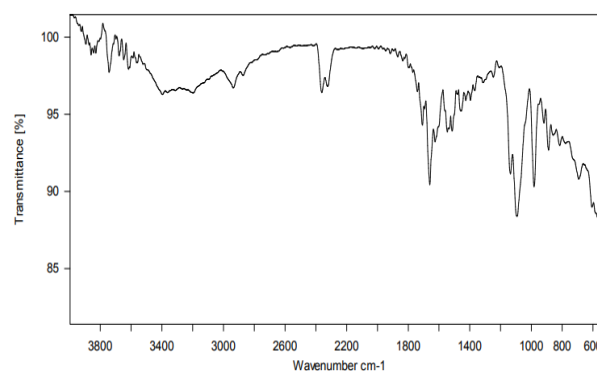


Figure 1: FTIR spectra of Metoclopramide hydrochloride

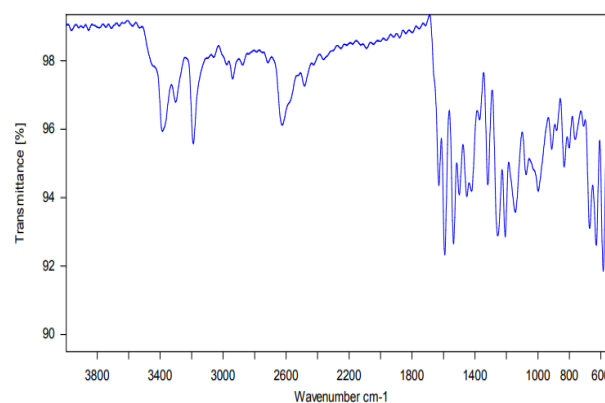


Figure 2: FTIR spectra of Dexamethasone sodium phosphate

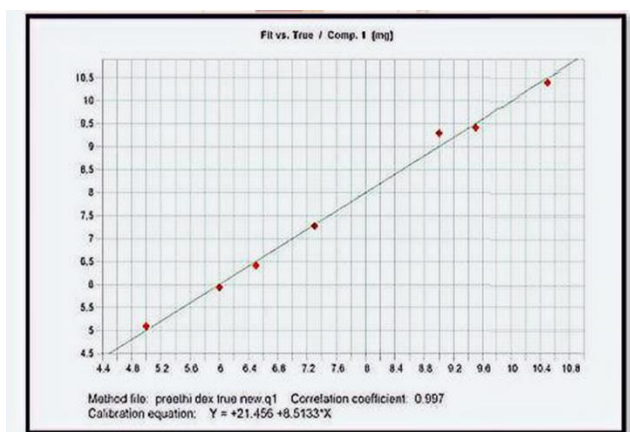


Figure 3: True v/s Fit curve of MET

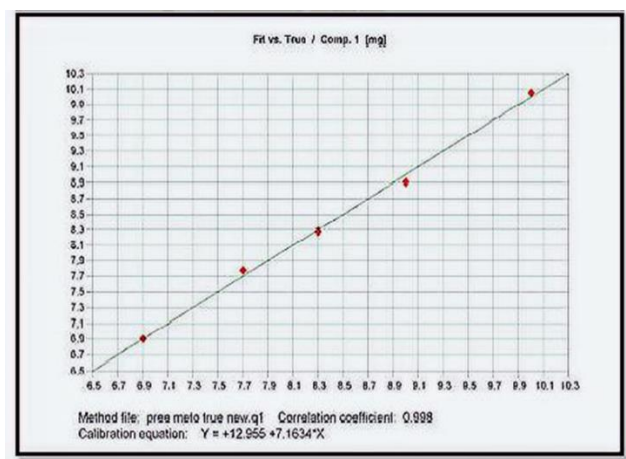


Figure 4: True v/s Fit curve of DEX

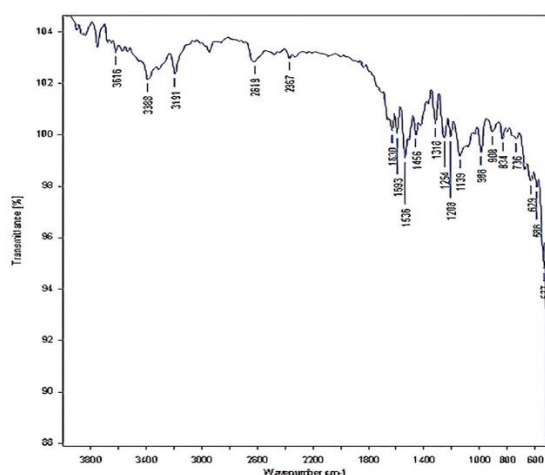


Figure 5: FTIR spectra of sample

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