

Abstract

The HPLC and Microbiological assay methods are the standard methods available in the pharmacopoeia for the analysis of vitamins B1, B2 and B3 mixtures and Erythromycin Stearate respectively. Alternative analytical techniques for the above assay methods were studied considering the cost, the time of analysis per sample and the complexities involved. The FTIR analytical methods are convenient, rapid, and sufficiently accurate for the purpose of monitoring active ingredients in the pharmaceutical manufacturing industry. In the first part of this study the Erythromycin Stearate in tablets was quantitatively estimated, after extracting it from its excipients and the results were compared with the assay results of the standardized British Pharmacopoeia method, which was a microbiological assay testing method. A linear standard calibration curve was observed when pellets of Erythromycin Stearate were mixed in Potassium Bromide (KBr) between the concentrations of 5.00 g kg^{-1} to 20.00 g kg^{-1} . The samples were prepared by compressing 7.50 g kg^{-1} and 11.00 g kg^{-1} . The results of the Standard method and the FTIR method agreed within a $\pm 5\text{-}10\%$ range and it was sufficient for monitoring the incoming goods and the in-process goods. Data analysis to estimate the assay value for Erythromycin Stearate was done using the Multi Point (MP) method.

The second part of this study was quantitatively analyzing the Vitamin B (B1, B2 and B3) mixture, which was diluted with the excipient dextrose using the FTIR Technique without any chemical extractions. The standard calibration curve of the Vitamin B mixture was prepared by accurately weighing known concentrations of Vitamin B and dextrose. The above mixture was mixed with KBr in the range of 10.00 g kg^{-1} and 35.00 g kg^{-1} . The Multi Linear Regression (MLR) method was used to estimate the assay value for the Vitamin B mixture in dextrose and it was found that the estimated values agreed within a $\pm 7.5\%$ range with the calculated value.

Quantification of a sample could be performed in about 3 hours for Erythromycin Stearate tablets, whereas the standard microbiological method for the same sample took 48 hours. Quantification of the Vitamin B mixture could be performed in two and half hours whereas the same will take 10 hours in HPLC. Therefore, saving of chemicals, instrument time, and analysis time consequently cuts down the product cost for consumers.