Development and Validation of Green Method for Assessment of Clarithromycin in Pharmaceutical Formulation by Transmission Fourier Transform Infrared Spectroscopy

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Abstract

Clarithromycin is a semi-synthetic broad spectrum macrolide antibiotic widely used for the eradication of respiratory tract infections including atypical pneumonias and soft tissue infections. It is an important substitute for patients exhibiting penicillin sensitivity and allergy.

The methods reported previously for the detection of clarithromycin have mainly used lengthy sample preparation procedures involving liquid–liquid extraction or solid-phase extraction prior to chromatographic analysis and most of these methods suffer from long run times and require large sample volumes. Although these methods offer selective detection of clarithromycin but they are much more complex than the conventional ultraviolet (UV) detection. Clarithromycin has weak UV absorbance because it lacks a suitable chromophore which makes difficult to develop a specific, selective and sensitive method using spectrophotometry without complexation and derivatization. As a impact of such laboratory practice, large amounts of waste chemical are produced every day in industrial laboratories which is of great concern throughout the world since long. So it becomes necessary to develop alternative strategy which can substitute such traditional methods with clean and environmental friendly analytical means involving minimum consumption or replacement of toxic reagents with the reagents having no or less polluting effects.

A rapid, sensitive and environmental friendly analytical method for the direct determination of clarithromycin in tablet formulations through transmission Fourier Transform Infrared (FT-IR) spectroscopy has been successfully developed for routine quality control analysis. This method avoids any sample pretreatment except grinding or use of any solvent as extraction is no more required. Standards and samples were used in the form of KBr for recording FT-IR spectra. In the final step, chemometric method was used to filter out unmatched spectral features and the converted and filtered spectra were used to build a calibration model based on partial least square (PLS) using the FT-IR carbonyl region (C=O) from 2965-1662 cm^{-1}. The excellent correlation coefficient (R^2) was achieved (0.9999). This method gives maximum

recovery of 102% and is fully validated. This also fulfills the ever increasing demand of pharmaceutical industries for developing sensitive, economical, time consuming and environmental friendly analytical methods for the quantification of Active Pharmaceutical Ingredients (API) while monitoring quality of finished product with total analysis time of less than three minutes.

Key words: FT-IR spectroscopy; pharmaceutical formulation, clarithromycin

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