



## Validation of UV Spectrophotometric Method for Telithromycin in Pharmaceutical Formulations and Comparison with HPLC and Microbiological Assay

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**SUMMARY.** An ultraviolet (UV) spectrophotometric method was developed for the analysis of telithromycin, member of the ketolides, in drug substance and coated tablets. The method validation yielded good results, such as the range, linearity, intra and inter-day precision, accuracy, recovery specificity, and robustness. UV spectrophotometric determinations were performed at 258 nm. Good linearity was obtained between 10.0 and 70.0/  $\mu\text{g mL}$ . A prospective validation showed that the method is linear ( $r = 1$ ) with precise relative standard deviation (RSD) of 0.4 %. The intra and inter-day precision values were  $< 2$  % for all samples analyzed. The comparison between UV spectrophotometric, high performance liquid chromatography (HPLC) and microbiological assay showed no significant difference between the methodologies. The proposed method is appropriate for the determination of telithromycin in tablets and can be used in routine quality control.

**KEY WORDS:** quality control, spectrophotometry, telithromycin.

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