

Novel Spectrophotometric methods for the determination of Leflunomide and Diacerein in binary mixtures

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Abstract

Two novel spectrophotometric methods were presented in this work using ethanol as a solvent. The first method was the ratio difference spectrophotometric method [RDSM], in which the amplitude difference between two selected wavelengths on the ratio spectra were recorded and used for estimation of each of Leflunomide LEF in mixture with its alkaline induced degradate DEG and also for Diacerein DIA determination in mixture with Aceclofenac ACEC without interference from the other component in the mixture. The second method is the ratio subtraction coupled with constant multiplication [RS-CM], where LEF was determined in its mixture with its alkaline degradate DEG at 261 nm indicating assay. In addition to simultaneous determination of Diacerein DIA and Aceclofenac ACEC in their mixtures at 257 and 277 nm method without previous separation.

Linearity was shown over the concentration range of [1.5-15 µg/ml] for LEF, [1-11 µg/ml] for DIA and [2.5-25 µg/ml] for ACEC, by both proposed methods. Leflunomide was found to be completely degraded when subjected to alkaline degradation producing one alkaline product. Validation of the suggested methods was conducted according to ICH guidelines, concerning precision, accuracy, repeatability. The suggested spectrophotometric methods were statistically compared to reference methods showing no significant difference. The suggested spectrophotometric methods are considered to be simple, sensitive and could be easily applied in quality control laboratories instead of LC methods.

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