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Validation of Four Different Spectrophotometric Methods for Simultaneous Determination of Domperidone and Ranitidine in Bulk and Pharmaceutical Formulation

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7 Abstract

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Four simple, specific, accurate and precise spectrophotometric methods were developed and 8 validated for simultaneous determination of Domperidone (DP) and Ranitidine hydrochloride 9 (RT) in bulk powder and pharmaceutical formulation. The first method was simultaneous ratio 10 subtraction (SRS), the second was ratio subtraction (RS) coupled with zero order 11 spectrophotometry (D^0) , the third was first derivative of the ratio spectra (^1DD) and the fourth 12 method was mean centering of ratio spectra (MCR). The calibration curve is linear over the 13 concentration range of 0.5-5 and $1-45\mu$ g.mL⁻¹ for DP and RT, respectively. The proposed 14 spectrophotometric methods can analyze both drugs without any prior separation steps. The 15 16 selectivity of the adopted methods was tested by analyzing synthetic mixtures of the investigated drugs, also in their pharmaceutical formulation. The suggested methods were validated according 17 to International Conference of Harmonization (ICH) guidelines and the results revealed that; they 18 were precise and reproducible. All the obtained results were statistically compared with those of 19 the reported method, where there was no significant difference. 20

21 Keywords

Domperidone, Ranitidine HCl, Simultaneous ratio subtraction, Ratio subtraction, Derivative ratio, Mean centering.

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