Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Lafutidine and Domperidone in Bulk and Pharmaceutical Dosage Form.

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ABSTRACT

A sensitive, accurate and precise method was developed and validate for the simultaneous estimation of Lafutidine and Domperidone in capsule dosage form. The RP-HPLC method had shown adequate separation for Lafutidine and Domperidone from its degradation products. The separation was achieved on Phenomenex Synergi 4u max RP 80 A C_{12} with TMS end capping (250 mm × 4.6 mm id, 4 µm particle size) using a gradient mixture of Ammonium phosphate buffer pH4.72 and acetonitrile at a flow rate of 1.5 ml/min, Injection volume 50µl with detection wavelength of 254 nm. The retention time for Lafutidine and Domperidone were 7.5±0.5min and 13.5±0.5min respectively. The described method was linear over a range of 10-200 µg/ml for Lafutidine and 30-600 µg/ml for Domperidone. The correlation coefficient for Lafutidine and Domperidone were 0.999, 0.999 respectively. The limit of detection for Lafutidine and Domperidone were 0.092µg/ml

and 0.082µg/ml respectively. The limit of quantification for Lafutidine and Domperidone were 0.27 µg/ml, 0.25µg/ml respectively. Force degradation study was carried out on dosage form as per ICH guideline and it was subjected to acid and base hydrolysis, oxidative, thermal and photolytic degradation. Proposed method was validated as per ICH guidelines for linearity, accuracy, precision, specificity and LOD and LOQ for estimation Lafutidine and Domperidone in capsule dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: Lafutidine and Domperidone, Stability indicating RP-HPLC method, Validation, Force degradation.