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Development and validation of single analytical method for the simultaneous estimation of nine drugs proton pump inhibitors and their combinations with prokinetic agents and non-steroidal anti inflammatory drugs

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Drugs belong to the class like proton pump inhibitors, e.g., Omeprazole (OMP), Pantaprazole (PNP), Lansaprazole (LNP) and Rabeprazole (RBP) are used along with the prokinetic agents like Levosulpride (LSP), Domperidone (DMP), Itopride (ITP) and Ondansetron (OND) to improve the patient compliance in gastric esophageal reflux disease. They are also used in combination with the NSAIDS like Naproxen (NAP) for the prevention of NSAID induced gastric ulcers. In the present study, a single reverse phase liquid chromatographic method for the separation and quantification of all the mentioned nine drugs was developed and validated as per ICH guidelines. The chromatographic separation of nine drugs was achieved with an isocratic mobile phase consisting of phosphate buffer (pH 6.2), methanol and acetonitrile in the ratio of 70:22:8 v/v at a flow rate of 1.2 mL.min⁻¹ on Kinetix C18 non-porous core shell technology column (4.6×250 mm, 5 µm) maintained at 30 °C. The eluate was monitored at two different wavelengths, i.e., 232 nm for LSP, NAP and ITP and 285 nm for OND, DMP, OMP, RBP, LNP and PNP. The retention time of LSP, ITP, NAP, OND, PNP, OMP, RBP, LNP and DMP was 1.75, 3.35, 4.75, 6.46, 7.97, 9.21, 10.32, 14.94 and 19.95, respectively. The linearity of calibration curves is good ($r^2 > 0.999$) in the desired concentration range for all the nine drugs. The method was accurate and precise with recoveries in the range of 98-102% and %RSD < 2%. The proposed method was simple, precise and accurate and hence was successfully applied for the reliable quantification of drugs in commercial formulations.

Biography

Vijayalakshmi Atla is pursuing her PhD in Andhra University. She was awarded Senior Research Fellowship from Council of Scientific and Industrial Research (CSIR), India, a premier national R&D organization. She has published 4 papers in reputed journals.

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