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Development and validation of RP-HPLC method for an anticold formulation

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A simple, precise, and reproducible RP-HPLC (Reverse phase-High performance liquid chromatography) method has been developed for the simultaneous determination of an Anticold pharmaceutical tablet dosage form containing Phenylephrine HCl (PHEN), Paracetamol (PARA) and Caffeine (CAF). RP-HPLC separation of three drugs was achieved on a Thermo BDS Hypersil C18 column (250mm × 4.6mm, 5µm) using UV detection at 220 nm. The optimized mobile phase consisted of 65mM o-phosphoric acid and acetonitrile and in a proportion of 90:10 *v/v*. The flow rate was 1 ml min^{-1}. The three drugs were satisfactorily resolved with retention time values of 3.56±0.01, 5.61±0.01 and 8.03±0.01 mins for PHEN, PARA and CAF, respectively. The method was validated for linearity, accuracy, precision, robustness, limit of detection (LOD), limit of quantitation (LOQ) and specificity, as per ICH recommended guidelines. The method was found to be linear over concentration ranges of 5-17.5µg/ml, 500-1750µg/ml and 25-37.5 µg/ml for PHEN, PARA and CAF, respectively. All the three drugs showed more than 98% of recoveries. Recovery studies showed mean recoveries of 99.1 % for PHEN, 100.7 % for PARA and 99.04 % for CAF. The LOD values were found to be 0.57µg/ml, 0.219µg/ml and 0.264µg/ml for PHEN, PARA and CAF respectively and LOQ values were found to be 1.71µg/ml, 0.657µg/ml and 0.792µg/ml for PHEN, PARA and CAF respectively.

HPLC method proved to be simple and rapid for routine simultaneous estimation of PHEN, PARA and CAF in the bulk drug and in a tablet formulation.

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Simultaneous determination of Clopidogrel and Pantoprazole in rat plasma by HPLC method: Application to drug interaction

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It is increasingly recognised that Anti platelet agents such as Clopidogrel are associated with increased rates of gastro intestinal (GI) bleeding. Consequently proton pump inhibitors (PPI's) are frequently prescribed to reduce GI bleeding. Clopidogrel is a prodrug, which requires cytochrome P-450 metabolism (specifically via isoenzyme CYP2C19) to an active form. CYP2C19 can be inhibited by PPI's thereby reducing formation of active metabolite.

It is still not clear whether there is definitely a clinically relevant interaction between PPI's and clopidogrel as available data are conflicting. Although there is extrapolation from in vitro studies that some PPI's may be less likely to interact with clopidogrel there does not appear to be any evidence from clinical practice that any one PPI is better than another in this respect. There is a need to determine the interaction of clopidogrel and PPI's when administered concomitantly.

A reverse phase-liquid chromatographic method described for the simultaneous determination of Clopidogrel and Pantoprazole. Chromatographic separation of the two drugs was achieved on a reverse phase C-8 column using a mobile phase of a ternary mixture of phosphate buffer, methanol and acetonitrile adjusted to pH 3 with orthophosphoric acid in a ratio of 60:10:30v/v. The liquid chromatographic method developed offers symmetric peak shape, good resolution, and reasonable retention time for both drugs. Linearity, accuracy, and precision were found to be acceptable over the concentration ranges 10-50µg/ml for clopidogrel and pantoprazole. The liquid chromatographic method was successfully applied to the quality control of formulated products and drug interaction study between the drugs in rat plasma.

Biography

Sindhura Sama student of M.Pharm Pharmaceutical Analysis, JSS College of Pharmacy, Mysore. She is doing her dissertation work under the guidance of Dr. B.M.Gurupadayya, Professor, Dept. of Pharmaceutical Analysis, JSS College of Pharmacy, Mysore. Her current area of research is on study of drug interaction.

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