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Development and validation of HPTLC method for an anticold formulation

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Phenylephrine hydrochloride (PHEN), Paracetamol (PARA), and Caffeine (CAF) are frequently associated in pharmaceutical formulations against the common cold. A simple, precise and robust High Performance Thin Layer Chromatography method for the simultaneous quantification of PHEN, PARA and CAF in tablet was developed and validated. The method employed three drugs on Merck Aluminium based silica gel 60 F_{254} plates as stationary phase and Methylene chloride: Ethyl acetate: Ethanol: Formic acid (3.5:2:4:0.5v/v) as mobile phase. Spectrodensitometric scanning was performed at 220 nm. The developed method gave well resolved spots for Phenylephrine hydrochloride ($R_{\rm f}$ 0.31 \pm 0.01), Paracetamol ($R_{\rm f}$ 0.63 \pm 0.01) and Caffeine ($R_{\rm f}$ 0.81 \pm 0.02). The developed method was validated for linearity, accuracy, precision, robustness and specificity studies as per the ICH guidelines. It was found to be linear over concentration ranges of 10-70 ng/ μ l, 150-1050 ng/ μ l and 50-350 ng/ μ l for PHEN, PARA and CAF respectively. The limit of detection and limit of quantification values were found to be 2.32 ng/ μ l, 10.2 ng/ μ l and 8.2 ng/ μ l; and 7.72 ng/ μ l, 33.96 ng/ μ l and 27.97 ng/ μ l for, PHEN, PARA and CAF respectively. The accuracy of the developed method was estimated by performing recovery studies. The method enabled average recoveries of 97.93 % for PHEN, 98.96 % for PARA and 98.05 % for CAF. No chromatographic interference from the tablet excipients was seen in this method. The method proved to be simple and rapid for routine simultaneous estimation of Phenylephrine HCl, Paracetamol and Caffeine in the bulk drug and in a tablet formulation.

Biography

Gouri Gajanan Joshi has completed her B. Pharm from S. R. T. M. University, Nanded and now purusing M. Pharm course in Pharmaceutical Chemistry Department, from Pune University. She has participated in the various state and college level poster presentation contests at B. Pharm and M. Pharm level. She has been also the part of the various cultural activities held at the college level.

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Method development and validation of valacyclovir by RP-HPLC in pharmaceutical dosage form

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A simple, specific, accurate, precise and stability-indicating reverse phase high performance liquid chromatography (RP-HPLC) method is developed for estimation of Valacyclovir in pharmaceutical dosage form. Valacyclovir is an antiviral drug used in the management of herpes simplex, herpes zoster(shingles) and herpes B. It is a prodrug, being converted invivo into Acyclovir. It is chemically (S)-2-[(2-amino-6-oxo-1, 6-dihydro-9H-purin-9-yl)methoxy]ethyl-2-amino-3-methylbutanoate. Chromatography was carried out using the instrument Waters HPLC 2998 mode with empower software on a Hypersil BDS C₁₈, 150mm×4.6mm, 5μ column with mobile phase sodium dihydrogen phosphate buffer (P^H 3.51) and 60 volumes of acetonitrile and 40 volumes of methanol run in gradient mode. The flow rate was 1.5ml/min, with injection volume 10μl detection done by using PDA detector at 254nm. The method was validated in terms of linearity, accuracy, precision, range, specificity, solution stability and robustness in accordance with ICH guidelines. Linear regression analysis data for the calibration plot showed that there was a linear relationship between response and concentration in the range of 50-200 mcg/ml and the correlation coefficient is 0.999 respectively. No chromatographic interference from tablet excipients was found. The proposed method was successfully used for estimation of Valacyclovir in pharmaceutical dosage form.

Biography

K. Lalitha Annapoorna is pursuing M. Pharmacy (Analysis) from School of Pharmacy, Anurag Group of Institutions, JNTU-H. She completed her graduation from RGRS College of pharmacy, JNTU-H. She presented a poster on Floating Microspheres of Lansoprazole in a National level seminar competition.

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