Simultaneous Determination of Pseudoephedrine Hydrochloride and Cetrizine Hydrochloride by Reverse Phase High Performance Liquid Chromatography

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A reversed phase high performance liquid chromatographic method has been developed using Shimadzu H PLC-VP series, LC-10 AT V pump, SPD 10 AVP and C8 column, for simultaneous determination of pseudoephedrine hydrochloride and cetrizine hydrochloride in three marketed tablet formulations (extended release). The mobile phase consists of phosphate buffer of pH 7.0 and acetonitrile HPLC grade in the ratio of 1:1. The flow rate was maintained at 1 ml/min and the ultraviolet detection was done at 242 nm, which is the isosbestic point. Linearity coefficients, assay values, recovery studies and repeatability studies showed that the method is accurate and precise.

Pseudoephedrine hydrochloride (PEH) is official in IP1. Cetrizine hydrochloride (CEH) is official in BP2. Fixed dose combinations of PEH and CEH are widely used for the symptomatic treatment of allergic rhinitis. Many methods have been reported in the literature for the determination of similar formulation with various other drugs using HPLC3-5, HPTLC6 and spectrophotometry7. However, a method for the simultaneous determination of PEH and CEH in tablets by HPLC has not been reported. In this present work, efforts have been made to develop an isocratic method using a simple mobile phase and UV detection for the simultaneous determination of the above drugs.

A high performance liquid chromatographic system from Shimadzu VP series, consisting of LC10 ATV Pump and SPD 10 AVP UV detector, was used for the analysis. C8 (150x4.6 mm, 5 µ) column was used in the analysis with a flow rate of 1 ml/min. A Rheodyne injector with a 20 µl loop was used for injecting the samples. Ammonium hydrogen phosphate (AR grade) and acetonitrile (HPLC grade) were used for mobile phase preparation. Working reference standards of PEH and CEH were obtained from Dr. Ceeal Analytical Lab, Chennai. Three marketed tablet formulations were selected for the study. The brand names of the tablets are Alerid (batch no. T10593, Cipla Ltd.), Cetrizet (batch no. SK 10893, Sun Pharmaceuticals) and Zyncet (batch no. 14086, Noble Medicure Pvt. Ltd.). Phosphate buffer (20 mM), pH 7.0 and acetonitrile in the ratio 1:1 was used as the mobile phase with a flow rate of 1 ml/min. The HPLC procedure was carried out at an ambient temperature.

A stock solution containing 6 mg/ml of PEH and 250 µg/ml of CEH was prepared. Standard solution containing PEH and CEH was prepared from stock solution by suitable dilution to get a concentration of 3.6 mg/ml and 150 µg/ml respectively.

Twenty tablets were weighed and crushed to a fine powder. A powder quantity equivalent to 7.5 mg of CEH was weighed and transferred to a 50 ml volumetric flask. The powder was dissolved in water by shaking for 15 min, filtered and then made up to the mark with mobile phase. Dilutions were made to get the concentration of 3.6 mg/ml of PEH and 150 µg/ml of CEH. A volume of 20 µl each of standard and sample solutions was injected into the stabilized HPLC system. Detection was kept at 242 nm, which is the isobestic point. The retention times of PEH and CEH were found to be 5.59 min and 3.57 min respectively. The chromatogram of PEH and CEH is given in Fig. 1. The respective peak areas of standard and sample for each ingredient were used for quantification.

The assays were carried out by the proposed method, and the results are tabulated in Table 1. Accuracy of the
The method was established by performing recovery studies. The study was carried out by spiking the known concentration of the samples with active ingredients at three levels (20, 40, 60 µg/ml for PEH and 2, 4, 6 µg/ml for CEH), and the results are tabulated in Table 2.

Linearity and range of the method was carried out by injecting five mixed standard solutions containing 1.2 to 6 mg/ml of PEH and 50 to 250 µg/ml of CEH. The calibration curves were plotted using peak area vs concentration. Linearity coefficients obtained are given in Table 3. Precision of the method was demonstrated by repeatability studies. This was assessed by using nine determinations for each tablet (3 concentrations/3 replicates each) covering the specified range for the procedure. Percentage RSD was calculated and given in Table 3. The system suitability studies were carried out to determine resolution factor, symmetry factor and precision of the instrument. Results are tabulated in Table 3. This systematic study revealed that the proposed method for the simultaneous determination of PEH and CEH is simple, sensitive, and with good precision and accuracy. This method can be used for the routine determination of pseudoephedrine hydrochloride and cetirizine hydrochloride simultaneously.
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REFERENCES


Wound Healing Activity of Cyperus rotundus Linn.

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The present study was aimed to evaluate the wound healing activity of extract of tuber parts of Cyperus rotundus. It is a well-known plant in Indian traditional medicine. On the basis of traditional use and literature references, this plant was selected for evaluation of wound healing potential. An alcoholic extract of tuber parts of Cyperus rotundus was examined for wound healing activity in the form of ointment in three types of wound models on rats: the excision, the incision and dead space wound model. The extract ointments showed considerable difference in response in all the above said wound models as comparable to those of a standard drug nitrofurazone ointment (0.2% w/w NFZ) in terms of wound contracting ability, wound closure time and tensile strength.

Wound may be defined as a loss or breaking of cellular and anatomic or functional continuity of living tissue. Wound healing is a complex phenomenon involving a number of processes, including induction of an acute inflammatory process, regeneration of parenchymal inflammatory process, migration and proliferation of both parenchymal and connective tissue cells, synthesis of extracellular matrix (ECM) proteins, remodelling of connective tissue and parenchymal components, and acquisition of wound strength. All these steps are orchestrated in a controlled manner by a variety of cytokines including growth factors. Some of these growth factors like platelet-derived growth factor B (PDGF), transforming growth factor B (TGF-B), fibroblast growth factor (FGF) and epidermal growth factor (EGF) have been identified in self-healing wounds. In chronic wounds, the normal healing process is disrupted due to some unknown reasons, and in such cases, exogenous application of certain growth-promoting agents or compounds which can enhance the in situ generation of these growth factors is required to augment the healing process. Several factors delay or reduce wound healing, including bacterial infection, necrotic tissue, interference with blood supply, lymphatic blockage and diabetes mellitus. Generally if the above factors could be inhibited/controlled by any agent, increasing healing rate could be achieved.

Cyperus rotundus Linn. (Family Cyperaceae), commonly