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Development and validation of a stability indicating RP-HPLC method for the estimation of Troxepide in bulk and its pharmaceutical dosage forms

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A Simple, sensitive, selective and precise stability indicating reverse phase high-performance liquid chromatographic method for analysis of troxepide in pharmaceutical dosage forms. The method employed column agilent ZORBAX SB-CN (150 × 4.6 mm, 3.5 µm) as the stationary phase. The solvent system consisted of Phosphate buffer, 25 Mm (the pH was adjusted to 4.0 ± 0.05 with ortho-phosphoric acid) and Acetonitrile (40:60% v/v) at a flow rate of 0.8 ml/min. This system was found to give compact peak for troxepide (Retention time is 2.1 min). troxepide was carried out in the absorbance mode at 260 nm. The linear regression data for the calibration plots showed good relationship with $r^2 = 0.99 \pm 0.001$. The method was validated for precision, accuracy, robustness and recovery. System suitability tests essential for the assurance of quality performance of the method were performed. The method was statistically validated according to International Conference on Harmonization ICH guideline and % RSD was found to be less than 2 indicating high degree of accuracy and precision of the proposed RP-HPLC method. The drug was subjected to stress degradation studies under acidic, basic, oxidative and thermal conditions. Degradation products resulting from stress studies did not interfere with the detection of troxepide and the assay can thus be considered as stability-indicating. Due to its simplicity, rapidness, high precision and accuracy, the proposed HPLC method may be used for determining troxepide in bulk drug samples and in pharmaceutical dosage forms.

Key words: troxepide, Reverse phase stability indicating HPLC, Bulk and Pharmaceutical dosage forms.

Characterization and evaluation of solid lipid nanoparticles for oral delivery of poorly water soluble drug by spray drying technique

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The oral route remains the preferred route of drug administration due to its convenience, good patient compliance and low medicine production costs. In order for a drug to be absorbed into the systemic circulation following oral administration, the drug must be dissolved in the gastric fluids. For hydrophobic drugs, it is this dissolution process which acts as the rate-controlling step and, therefore, determines the rate and degree of absorption. Consequently, many hydrophobic drugs show erratic and incomplete absorption from the gastrointestinal tract of animals and humans. Thus, one of the major challenges to drug development today is poor solubility, as an estimated 40% of all newly developed drugs are poorly soluble or insoluble in water. The aim of this study was to improve the dissolution rate and subsequently the oral absorption and bioavailability of a model poorly water soluble drug,by formation of Spray-drying of solid lipid nanoparticles.SLN are interesting colloidal drug delivery systems, since they have all the advantages of fat emulsions and polymeric nanoparticles They open a broad field of applications including i.v.,oral and dermal administration. The less cost-intensive spray-drying technique was investigated for SLN as an alternative method to lyophilization. Spray-drying is widely used in the chemical, the food and the pharmaceutical industries. It is commonly used to process milk, eggs, ceramics and fertilizers. It converts a liquid into a dry system in a one-step process and can produce fine, dust-free powders as well as agglomerated ones, to precise specifications. In our laboratories, we have used spray drying in an attempt to enhance the dissolution rate of a model drug, In this paper, we report on the preparation and characterization of these particles and their in vitro dissolution.