DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF EPERISONE HYDROCHLORIDE AND PARACETAMOL IN THEIR TABLET DOSAGE FORM

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ABSTRACT

The present work involves the development and validation of a simple, accurate and precise first order derivative spectrophotometric method and RP-HPLC method for the assay of EPE and PCM.

Simple, specific, accurate, precise and reproducible method have been developed and validated for the simultaneous estimation of both drugs in their tablet dosage form.

UV- Spectrophotometric Method was a determination using the first order derivative spectrophotometric method at 243nm (ZCP of PCM) and 261.4nm (ZCP of EPE) over the concentration range 0.30-2.46µg/ml and 2-16µg/ml for EPE and PCM in Distilled water respectively. The % recoveries of the both the drugs (in sample preparation) were found to be 98.6-99.53% and 99.42-99.78% respectively.

The RP-HPLC Method has shown adequate separation of EPE and PCM in their tablet dosage form. The separation was achieved on a Enable C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with a isocratic system of (Methanol: Water) in the ratio of (60:40 v/v), pH

adjusted 3.4 with Ortho-Phosphoric acid. The mobile phase at a flow rate of 2.0 ml/min, Injection volume 20µl and wavelength of detection used was 254nm. The retention time for EPE and PCM was obtained as 1.44 ± 0.1min and 2.014 ± 0.1min, respectively. The linearity of the proposed method was investigated in the range of 5-25µg/ml and 32.5-162.5µg/ml for EPE and PCM respectively. Correlation coefficient was 0.995 and 0.996 for EPE and PCM, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ, robustness and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of EPE and PCM. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets. The % recoveries of the both the drugs (in sample preparation) were found to be 98.87-99.31% and 99.18-99.65% respectively.

Key words:EPE, PCM, UV-First order derivative Spectrophotometric Method, RP-HPLC Method, Analytical Method Validation.