

Method, development and validation for simultaneous estimation of promethazine hydrochloride and pholcodine in bulk and marketed formulation (Linctus) by UV spectrophotometry

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Aim: Method development and validation for the simultaneous estimation of promethazine and pholcodine in marketed formulation (syrup) by UV spectrophotometry.

Objective:

- To develop different analytical methods to estimate promethazine hydrochloride and pholcodine in combined form by UV-visible spectrophotometer for pharmaceutical dosage form (syrup).
- To validate the developed methods by ICH guidelines.

Results: A novel, accurate and precise method for estimation of the promethazine hydrochloride and pholcodine in bulk and marketed formulation was developed and validated. The solvent used was distilled water and the λ max or the absorption maxima of the drug were found to be 248 nm for promethazine hydrochloride and 284 nm for pholcodine. The high values of correlation coefficients (r^2) indicated good linearity of calibration curve for both the drugs. The recoveries of Promethazine Hydrochloride and Pholcodine from the standard mixture solution were found to be 98.73% and 102.16% respectively. The method was then validated for different parameters as per ICH guidelines.

Conclusion: The proposed simultaneous method is very simple that can be performed by use of any spectrophotometer and does not require any costly instrument equipped with special package. It also shows good linearity values and sensitivity. The results demonstrated that absorbance maxima method and simultaneous equation method by Systronic 2202 UV/visible spectrophotometer could be useful technique for determination of promethazine HCl and pholcodine when they are given in same dosage form.

Keywords: Pholcodine, promethazine hydrochloride, method validation, and UV spectrophotometer

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