ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF TOLPERISONE HYDROCHLORIDE AND DICLOFENAC SODIUM IN THEIR PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A simple, accurate, rapid, economical UV spectrophotometry methods namely Simultaneous estimation equation, and RP-HPLC methods have been developed and validated for estimation of Tolperisone Hydrochloride and Diclofenac Sodium in combined tablet dosage form and can be used in routine analysis. In Simultaneous equation method absorbance measured at 261nm (correlation coefficient was found to be 0.997 and 0.997 for Tolperisone Hydrochloride and Diclofenac Sodium) and at 276 nm (correlation coefficient was found to be 0.998 and 0.998 for Tolperisone Hydrochloride and Diclofenac Sodium). Assay was found to be 99.26 % and 99.89% for Tolperisone Hydrochloride and Diclofenac Sodium respectively. The methods were found to be linear in the concentration range of 6-21µg/mL and 2-7µg/mL for Diclofenac Sodium both the drugs respectively.

In RP-HPLC, method was carried out by isocratic technique on a reversed-phase: Phenomenax luna ODS C18 (250mm X 4.6 mm i.d.,5µm particle size)and UV detection at 270 nm with mobile phase containing a mixture of Methanol : Water (90:10) **pH:3.0** (adjusted with orthophosphoric acid) at a flow rate of 1.0 mL/min. The average retention times for Tolperisone Hydrochloride and Diclofenac Sodium were 2.9 and 4.9 min respectively. The calibration curves were linear in the concentration range of 7.5-45 µg/mL and 2.5-15µg/mL for Tolperisone Hydrochloride and Diclofenac Sodium respectively. Correlation co efficient were found to be 0.999 and 0.998 for Tolperisone Hydrochloride and Diclofenac Sodium respectively. Mean assay was found to be 100.03% and 99.30% for Tolperisone Hydrochloride and Diclofenac Sodium respectively.

KEYWORDS: Tolperisone Hydrochloride and Diclofenac Sodium, Simultaneous equation, RP-HPLC