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Application of rapid and sensitive HPLC method for routine analysis of pharmaceutical injectable formulation

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A simple, sensitive reverse–phase high-performance liquid chromatographic method for analysis of a new calcium sensitizer in pharmaceutical formulations was developed.The separation in reverse phase HPLC method was achieved with Inertsil Phenyl5 µm column with a flow rate of mobile phase of 1.0 ml/min. The proposed method was validated as per ICH guidelines. Specificity was conducted for the interference of excipients in formulation. It was found that the parent peak was well separated from product degradant and excipients peaks. The linear regression analysis data for calibration plots showed good linear relationshipin the concentration range of 50-200 µg/ml. Intra and Inter-day precision were within the guideline specifications. The method showed the mean % recovery ranges from 99.80-100.12% in commercial injection formulations. This method can be employed for routine quality control analysis of the drug in commercial pharmaceutical formulations.

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Development and validation of RP-HPLC method for the estimation of levosimendan

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Levosimendan is chemically ({4-[4'R)-4-Methyl-6-oxo-1,4,5,6-tetrahydropyridazin-3yl]phenyl}hydrazono)propanedinitrile.It is chemically a pyridazone-dinitrile derivative and its primary action is to enhance cardiac contractility.The drug does not increase intracellular concentrations of free calcium.The separation in reverse phase HPLC method was achieved with Inertsil Phenyl, 250×4.6 mm, 5 µm column with 0.01Mammonium acetate solution, previously adjusted to pH 3.0 with glacial acetic acid and acetonitrile in the ratio of (40:60 v/v) as mobile phase. A well-defined chromatographic peak of the drug was exhibited with a retention time of about 4.30 min and tailing factor of 1.15 at the flow rate of 1.0 ml/min and at ambient temperature, using wavelength at 380 nm. The linear regression analysis data for calibration plots showed good linear relationshipwith r2=0.9999 in the concentration range of 50-150 µg/ml. Intra and Inter-day precision (% relative standard deviation)were less than 2%. The proposed method was validated and found to be specific, accurate, precise, reproducible, and robust.

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