Development and validation of an ion-pair HPLC chromatography for simultaneous determination of lactone and carboxylate forms of SN-٣٨ in nanoparticles

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Abstract

A simple and reproducible reversed-phase ion-pair high performance liquid chromatography (HPLC) method using isocratic elution with UV absorbance detection was developed and validated for the simultaneous determination of carboxylate (C) and lactone (L) forms of SN-٣٨ (active metabolite of irinotecan) in nanoparticles (NPs). Reversed phase (RP) chromatography was performed on a C١٨ column with an ion-pair solution, KH $_2$PO $_4$ buffer solution and acetonitrile, under a mobile phase ٣٠:٣٠:٤٠ (v/v) and at a flow rate of ١ mL/min. Detection was performed at ٢٦٥ nm and sharp peaks were obtained for C and L forms of SN-٣٨ at retention times of ٢٫٩ ± ٠٫٠١ and ٥٫١ ± ٠٫٠١ min respectively. Linear regression analysis data for the calibration plot showed a good linear relationship between response and concentration in the range of ٤ to ١٠٠ μg/mL; the regression coefficient was ٠٫٩٩٩٩ for L form and ٠٫٩٩٩٨ for C form. The optimized method showed good performance in terms of specificity, linearity, detection and quantitation limits, precision and accuracy in accordance with the International Conference on Harmonization (ICH) Q٢ (R١) guidelines. This assay was demonstrated to be applicable for routine quantitation of SN-٣٨ in PLGA NPs.

Reaxys Database Information

Author keywords

HPLC; Ion-pair; Irinotecan; Nanoparticles; SN-٣٨

Indexed Keywords

EMTREE drug terms: ٧ ethyl ١٠ hydroxycamptothecin; acetonitrile; carboxylic acid; lactone; nanoparticle; polyglactin

EMTREE medical terms: accuracy; article; drug determination; drug formulation; drug release; drug stability; drug structure; flow rate; ion pair chromatography; light absorption; reversed phase high performance liquid chromatography; validation study