Simultaneous Determination of Thalidomide and Dexamethasone in Rat Plasma by Validated HPLC and HPTLC With Pharmacokinetic Study

Mohamed Mohamed ,Marco M Zaki, Souty M Z Sharkawi, Nada S Abdelwahab , Nouruddin W Ali

Abstract

Two validated chromatographic methods have been developed for the simultaneous determination of thalidomide (THD) and dexamethasone (DEX) in rat plasma using paracetamol (PAR) as an internal standard (IS). Chromatographic analysis was achieved firstly by HPLC method on C18 column (150 × 4.6 mm2 i.d., 5 μm) and a mobile phase composed of ethanol:water (containing 0.1% acetic acid) (70:30, v/v) at the flow rate of 0.6 mL min−1. The second method was HPTLC method which depended on using a developing system of methylene chloride:acetone:ethyl acetate (7:4:1, by volume). In both methods, PAR was used as an IS. The developed methods have been validated as per FDA guidelines. All parameters were tested using quality control samples (LQC, MQC and HQC). All the obtained parameters were within the acceptance criteria. In the same way, the two methods were successfully used to study the pharmacokinetic parameters of both THD and DEX after their intra-peritoneal administration. Moreover, results obtained after administration of each drug alone were compared to those obtained after their administration together. The drugs showed drug–drug interactions when administered in combination, meaning that monitoring of such combination is very important

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