

11TH WORLD DRUG DELIVERY SUMMIT

October 16-18, 2017 Baltimore, USA

Stability-indicating HPTLC method for simultaneous determination of ketoprofen, methyl paraben and propyl paraben in gel formulation

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Aim: A novel and quick HPTLC-densitometric method was developed for the simultaneous determination of ketoprofen, methyl paraben and propyl paraben.

Methods: Chromatographic separation of the drugs was performed on pre-coated silica gel 60 F254 Merck plates using toluene: ethyl acetate: glacial acetic acid (6.5:2.5:1.0 v/v/v) as a mobile phase. A TLC scanner set at 265 nm was used of ketoprofen, methyl paraben, propyl paraben respectively were validated according to ICH guidelines. Forced degradation conditions of hydrolysis (neutral, acidic and alkaline) oxidation, photolysis and thermal stress, as suggested in the ICH guideline Q1A (R2).

Results: The three drugs were satisfactorily resolved with Rf values of 0.33-0.05, 0.54-0.05, 0.71-0.05 for ketoprofen, methyl paraben, propyl paraben respectively. Calibration curves were polynomial in the range 200-1000 ng/band, 200-1500 ng/band, 100-600 ng/band, for ketoprofen, methyl paraben, and propyl paraben respectively. Correlation coefficient (r) values were 0.9917, 0.9927, 0.9906 for ketoprofen, methyl paraben, propyl paraben respectively. The percentage recovery ranges from 99 to 101%.

Conclusion: A low relative standard deviation (<2%) was found for both precision and robustness study showing that the proposed method was precise and robust. The method had an accuracy of 99.95%, 99.85% and 100.07% of ketoprofen, methyl paraben, propyl paraben respectively were validated according to ICH guidelines. The drug showed instability in oxide, heat and UV light, while it remained stable in neutral conditions.

Biography

Pallavi Mangesh Patil has completed her PhD from Tamil Nadu University and she is working as an Assistant Professor of Pharmaceutical Chemistry, a premier Modern College of Pharmacy, Nigdi Pune organization. She has her expertise in development and validation parameter quantity evaluation and passion in improving the method optimization which help in health and wellbeing. She has published more than 35 papers in reputed international journals and also presented her research work in national and international conference and has been serving as a Reviewer of reputed journals.

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