ABSTRACT

QUALITATIVE AND QUANTITATIVE ANALYSIS OF P-AMINOPHENOL IN PARACETAMOL SYRUP BY HPLC METHOD

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A simple isocratic reversed-phase HPLC method was developed and validated for the determination of p-aminophenol, the major degradation impurity of paracetamol, in pharmaceutical syrups. The analytes were separated on a RP-18 LiChrospher® column (250 mm x 4.00 mm i.d., 5 μm particle size). A mobile phase of MeOH and 0.01M phosphate buffer pH 4.07 (26:74 v/v) at flow rate of 1 ml/min, with oven temperature set at 30°C was suitable for the separation and determination of p-aminophenol in simulation paracetamol syrups. The UV detection was carried out at 275.8 nm. The chromatographic parameters such as retention times, capacity factor, tailing factor, number of theoretical plates, %RSD of peak area and resolution factors were determined. The developed method was found to be linear over concentration ranges of 1.01 – 6.06 μg/ml for p-aminophenol ($r^2 = 0.9996$, $\text{Vxo} = 1.48\%$). The limit of detection (LOD) and limit of quantification (LOQ) for p-aminophenol were 0.18 μg/ml and 0.54 μg/ml, respectively. Validation acceptance criteria were met in all cases. Then the developed method was successfully applied to determine p-aminophenol in three generic paracetamol syrups in Indonesia, resulting that p-aminophenol were not detected in sample.

Keywords: Paracetamol, p-Aminophenol, HPLC, Syrup