5. CONCLUSION

Two HPTLC and one LC/MS/MS methods have been developed for concurrent quantification of selected drugs in the marketed pharmaceutical formulation used in the research study as literature survey revealed no HPTLC and LC/MS/MS method for the simultaneous estimation of these drugs.

In the first densitometric method, a sensitive, precise, selective, robust and accurate high performance thin layer chromatography method for simultaneous quantification of paracetamol and tolperisone hydrochloride in pharmaceutical dosage form (tablet) with densitometric detection has been developed and validated. Chromatographic analysis was performed on precoated HPTLC aluminum plates. The solvent system [toluene: ethyl acetate: methanol (1: 7: 3, v/v/v)] with detection wavelength 256 nm. The retention factor for tolperisone hydrochloride was 0.39 ± 0.02 and for paracetamol was found to be 0.79 ± 0.02. Tolperisone hydrochloride was linear over a range of 50-800 ng/band and Paracetamol was linear over 100-800 ng/band with percentage assay for Tolperisone Hydrochloride and Paracetamol found to be 98.47, 99.23 %, respectively.

In the next method concurrent analysis of rosuvastatin Calcium and fenofibrate combined tablet formulation developed followed by validation by HPTLC method using (ICH-Q2 (R1) guideline. Aluminium pre-coated TLC plates of silica gel G F254 were used as a stationary phase and acetic acid: ethyl acetate (0.2: 20, v/v) as a mobile phase. Method quantification involved densitometric absorbance mode (246 nm). The Rf values for rosuvastatin and fenofibrate were 0.31 ± 0.02 and 0.76 ± 0.02, respectively. The results were linear in the range of 50-800 ng/band for both drugs with LOD and LOQ for rosuvastatin were found to be 11.07 and 33.56 ng/band and for Fenofibrate 12.76 and 38.68 ng/band. LC/MS/MS method for simultaneous estimation of paracetamol, guaifenesin, phenylephrine hydrochloride, chlorpheniramine maleate, and ambroxol hydrochloride in tablet pharmaceutical dosage formulation developed and validated in accordance with International
Conference on Harmonization guidelines. The method was developed using a mobile phase (gradient mode) of water: methanol with the fixed flow rate 0.3 mL/min. The analysis was done by multiple reactions monitoring (MRM) mode. The selected parent to product ion transition for paracetamol was m/z 152.0 ≥ 110.0, for guaifenesin m/z 199.0 ≥163.0, phenylephrine hydrochloride m/z 168.0≥ 150.0, chlorpheniramine maleate m/z 275.0 ≥ 230.0 and for ambroxol hydrochloride m/z 379.0 ≥ 263.8. For paracetamol, guaifenesin, phenylephrine hydrochloride, chlorpheniramine maleate, and ambroxol hydrochloride the retention times were found to be 1.76, 1.81, 1.90, 2.10, and 2.33 min, respectively. The method was linear in the range of 10-200 ng/ml for all drugs. Recoveries were found to be in the range of 99-101 %. Results obtained were reproducible and statistically validated.

Developed analytical methods (HPTLC and LC/MS/MS) methods were found to be robust, accurate, precise, rapid and can be used to analyze respective pharmaceutical formulations used in the study.