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A Validated Stability Indicating HPTLC method for analysis of Febuxostat and Characterization of degradation product

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Abstract : A simple, sensitive, precise, specific and stability indicating high-performance thin-layer chromatographic (HPTLC) method for the determination of febuxostat, both in bulk drug and pharmaceutical dosage form was developed and validated. The method employed aluminium plates precoated with silica gel G 60 F_{254} as the stationary phase. The solvent system consisted of ethylacetate : methanol : acetic acid (7.5:2.8:0.01, v/v/v). The *Rf* value of febuxostat was found to be 0.65.Densitometric analysis of febuxostat was carried out in the absorbance mode at 315 nm. Linear regression analysis showed good linearity ($r2$ = 0.9976) with respect to peak area in the concentration range of 30–180 ng spot^{-1}. The method was validated in accordance with ICH guidelines. Febuxostat was subjected to acid and alkali hydrolysis, oxidation, photodegradation and dry heat and wet heat conditions.The degraded product peak was well resolved from the pure drug with significantly different *Rf* values. Statistical analysis proved that the method is repeatable and specific for the estimation of febuxostat. As the method could effectively separate the drug from its degradation product, it can be regarded as stability indicating. The degraded product was characterized by IR, NMR and mass spectroscopic methods. Febuxostat was found to decompose in alkaline conditions to 2-(3-Carboxy-4-isobutoxyphenyl)-4-methylthiazole-5-carboxylic acid.
Keywords : Febuxostat, Stability indicating, HPTLC, Degradation, Characterisation.

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