



Analytical Methods for the Estimation of Ruxolitinib – A Review

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Mukthinuthalapati Mathrusri Annapurna and Tangeti Nischala Sai.**Abstract**

Ruxolitinib is used to manage and treat myelofibrosis, polycythemia vera, and steroid-refractory acute graft-versus-host disease. It belongs to janus kinase inhibitor class. medications. It is an inhibitor of the JAK1 and JAK2 protein kinases and works by competitively inhibiting the ATP-binding catalytic site on JAK1 and JAK2. In the present study the authors have reviewed and summarised the analytical methods so far developed for the estimation of Ruxolitinib in pharmaceutical formulations as well as biological fluids.

Keywords: Ruxolitinib; Dosage**Introduction**

Ruxolitinib (CAS: 941678-49-5) (Mol wt: 306.37 g/mol) Ruxolitinib is used to manage and treat myelofibrosis [1], polycythemia vera, and steroid-refractory acute graft-versus-host disease [2,3]. The solubility of Ruxolitinib in ethanol is approximately 13 mg/ml and approximately 5 mg/ml in DMSO and DMF. Ruxolitinib is sparingly soluble in aqueous buffers and the pKa values are found to be 4.3 and 11.8. Ruxolitinib is available as tablets with label claim 15 mg and as cream 1.5% (Brand names: Opzelura, Rutinib).

The analytical methods such as LC-MS/MS [4,5], UPLC [6], RP-HPLC [7-9] were developed for the estimation of Ruxolitinib and the combination of Ruxolitinib with other drugs was studied by different authors with the help of LC-MS/MS [10-15] in pharmaceutical dosage forms as well as biological fluids and some of the parameters were discussed in detail in Table 1.

Table 1: Review of analytical methods.

Method	Mobile Phase (v/v)	Linearity(µg/ml)	Column	Reference
LC-MS/MS (Human plasma)	2.0 mM Ammonium acetate: Acetonitrile (Gradient mode)	0.0005-0.4	-	[4]
LC-MS/MS (Internal standard: Ruxolitinib-13C9)	0.1% aq. Formic acid: 0.1% Formic acid in Methanol (Gradient mode)	0.01-2.0	Thermo Hypersil GOLD C18	[5]
RP-UPLC	Glacial acetic acid: Methanol: Acetonitrile (pH 6.2) (40:30:30)	50-150	C ₈	[6]
RP-HPLC	Acetonitrile: Water: THF (60: 30: 10)	-	Symmetry Chromosil C ₁₈	[7]
RP-HPLC	Acetonitrile: Methanol: 1% Ortho phosphoric acid (70:25:5)	5-200	Symmetry ODS RP C18	[8]
RP-HPLC (Chiral analysis)	Water: Acetonitrile (70: 30) with 0.1% aq. Formic acid	24-144	Robusta C18	[9]

Conclusion

The authors have briefly reviewed the analytical methods for the estimation of Ruxolitinib as well as its combination with other drugs in pharmaceutical dosage forms as well as biological fluids.

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