



Certificate of analysis

Product name: Tofacitinib citrate

Cas number: 540737-29-9

Molecular Formula: C₁₆H₂₀N₆O·C₆H₈O₇

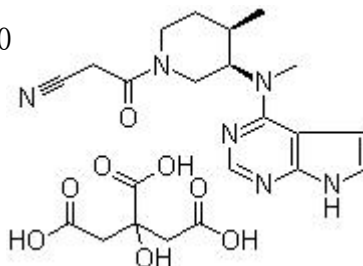
Molecular Weight: 504.50

Date of production: Sep. 15, 2020

Batch NO: 20200915

Exp Date: Sep. 14, 2022

Chemical structure:



Items	Specifications	Results
Appearance	White or off-white solid	Complies
Identification	HNMR MS, HPLC	Complies
Specific Rotation	+9.0°~ +13.0°(0.6g/100ml in DMSO)	+9.8°
Heavy Metal	≤10ppm	Complies
Loss on drying	≤0.50%	0.25%
Enantiomer	(SS) ≤0.1%	N.D
Citrate	36.2% ~ 40.0% (on dried basis)	38.3%
Related Substances	(RS+SR): ≤0.10%	0.01%
	Any single impurity: ≤0.10%	0.08%
	Total Impurities: ≤2.0%	0.20%
Residual Solvents	Petroleum ether: ≤3000ppm	N.D
	Ethanol: ≤5000ppm	N.D
	Ethyl ether: ≤5000ppm	N.D
	Acetone: ≤5000ppm	N.D
	n-Butyl alcohol: ≤5000ppm	N.D
	Dichloromethane: ≤600ppm	N.D
Assay	≥98.0%	99.8%

Conclusion: Complies with in house standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F