

Hangzhou Huarong Pharm Co., Limited

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CERTIFICATE OF ANALYSIS

Product : (3R,4R)-4-Methyl-3-(methyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamino)-beta-oxo-1-piperidinepropanenitrile 2-Hydroxy-1,2,3-propanetricarboxylate citrate (**Tofacitinib citrate**)

Quantity : 20 kg

Manufacturing Date : Jun. 14, 2020

CAS NO.: 540737-29-9

Suggest Retest Date : Jun. 14, 2022

Batch NO. : RD-TFB-202006141

Test Basis : SOP-T-API-002-3

Tests	Specifications	Results
Appearance	White to off-white powder	Off-white powder
Identification	A.IR:similar to Reference Substance	Complies
	B.Retention Time:similar to Reference Substance	Complies
Loss on Drying	≤ 0.5%	0.12%
Related substances	Acetyl impurity ≤ 0.15%	Undetected
	Chloroacetyl impurity ≤ 0.15%	Undetected
	Diastereomer ≤ 0.15%	Undetected
	Single impurity ≤ 0.10%	0.03%
	Total impurities ≤ 1.0%	0.08%
Enantiomer	≤ 0.15%	0.07%
Residual solvents	Methanol ≤ 3000ppm	Undetected
	Toluene ≤ 890ppm	30ppm
	Ethanol ≤ 5000ppm	595ppm
	Acetone ≤ 5000ppm	Undetected
	Dichloromethane ≤ 600ppm	Undetected
	Ethyl acetate ≤ 5000ppm	192ppm
	Hexane ≤ 290ppm	Undetected
Assay	98.0%~102.0% (Calculated on the dried basis)	100.8%

The results above meet all requirements under **Tofacitinib citrate** in **In-House Standard**

