



Anhui Ailead Pharmaceutical Co., Ltd.
Certificate of Analysis

Tofacitinib Citrate

Cas # 540737-29-9

Report No. :Y2021120501

Batch No.	211205	Quantity	15.0 kg
Package	LDPE	Test Date	Dec. 5. 2021
Storage	Preserve in tight containers	Retest Date	Dec. 4. 2023

Test Standards: In-house Standards

Items	Specification	Results
【Appearance】	White to off-white powder	White powder
【Solubility】	Slightly soluble in water,very slightly soluble in Ethanol,not soluble in ACN	Conforms
【Optical rotation】	It should be +9° to +15°	11°
【HPLC Identification】	The retention time of the main peak of the solution should be consistent with the retention time of the main peak of the reference solution	Conforms
【IR Identification】	The IRS should be consistent with that of standard sample	Conforms
【Chloride】	Not more than 0.01%	Conforms
【Sulphate】	Not more than 0.03%	Conforms
【Related Substance】	Impurity A not more than 0.15 %	0.02%
	Impurity B not more than 0.15 %	Not detected
	Impurity C not more than 0.15 %	Not detected
	Impurity D not more than 0.15 %	0.02%
	Other unknown single impurity not more than 0.10 %	0.03%
	Total Impurity not more than 1.00%	0.18%
【Residual Solvents】	Methanol not more than 0.30%	Not detected
	Ethanol not more than 0.50 %	0.06%
	Ethyl Acetate not more than 0.50 %	Not detected
	Tetrahydrofuran not more than 0.072 %	Not detected
	Acetone not more than 0.50 %	Not detected
	N,N-Dimethylformamide not more than 0.053 %	Not detected
【Enantiomer】	Not more than 0.15%	Not detected
【Water】	Not more than 1.00%	0.45%
【Residue on Ignition】	Not more than 0.10 %	0.02%
【Palladium】	Not more than 10 ppm	Not detected
【Heavy metal】	Not more than 10 ppm	Conforms
【Microbial limits】	Total aerobic bacteria count (TAMC) not more than 1000 cfu/g	Conforms

	Total Yeast and Mold count (TYMC) not more than 100 cfu/g	
	Escherichia coli not detected	
【Citric Acid】	It should contain $C_6H_8O_7$ 36.2 %~40.0 %	36.90%
【Assay】	On dry basis, it should contain $C_{16}H_{20}N_6O \cdot C_6H_8O_7$ 98.0% ~102.0%	99.20%
Analyst/Date	Dec.5. 2021	
Checker/Date:	Dec.6. 2021	
Supervisor/Date	Dec.6. 2021	
FINAL BATCH DISPOSITION		
Approved (√) <input type="checkbox"/> By/Date: _____		