

Hangzhou Huarong Pharm Co., Limited

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CERTIFICATE OF ANALYSIS

Product Name	Acalabrutinib	CAS	1420477-60-6
Batch No.	230501	Mfg Date:	2023.05.08
Quantity	10kg	Report Date	2023.05.12
Standard	In house	Retest Date	2025.05.07
Items	Specifications	Results	
Appearance	White to light yellow powder	Conforms	
Solubility	Soluble in 0.5N HCl and practically insoluble in water	Conforms	
Identification	HPLC: The principal peak in the chromatogram obtained with the test solution is similar in position to the principal peak in the chromatogram obtained with reference solution.	Conforms	
	IR: Conform to the spectrum obtained with the reference standard.		
Polymorphic form	Form I	Conforms	
Water (KF)	≤0.5%	0.3%	
Residue on ignition	≤0.10%	0.07%	
Melting point	212-217°C	Conforms	
Heavy metal	≤20ppm	Conforms	
Related substances	Any individual impurity ≤0.15%	0.12%	
	Total impurities ≤1.0%	0.45%	
Chiral purity	(R)-Optical isomer ≤0.15%	N.D.	
Residual solvents	Methanol ≤ 3000ppm	Conforms	
	Ethyl acetate ≤ 5000ppm	Conforms	
	Dichloromethane ≤ 600ppm	Conforms	
Microbial limit	Total Aerobe Bacteria ≤1000cfu/g	Conforms	
	Total molds and yeast ≤100cfu/g	Conforms	
Bulk Density	0.3-0.5g/ml	Conforms	
Tapped Density	0.4-0.6g/ml	Conforms	
Particle size	D90 ≤100μm	Conforms	
Assay	98.5%~102.0% (anhydrous substance)	99.5%	
Conclusion:	The product conforms to In house Standard.		

