



山东八方化工科技有限公司

SHANDONG OCTAGON CHEMICALS LIMITED



CERTIFICATE OF ANALYSIS

Product name	<u>Hydrocortisone (Cas 50-23-7)</u>		
Batch No.	TA0621	Mfg. Date	2025.05.15
Rep. Date	2025.05.31	Retest Date	2028.05.14
Packaging	1kg/Bag/Tin	Quantity	50G
Test Items	Standards: EP/USP		Results
Appearance	A white to almost white crystalline powder		White crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in acetone and in ethanol (96 Percent), slightly in methylene chloride		conforms
Specific optical rotation	+162°~+168° (EP: on the dried basis) +150°~+156° (USP)		+163.5° +151.8°
Identification	A: IR (EP) B: HPLC (EP) A: IR (USP) B: UV (USP)		Conforms
Loss on drying	NMT1.0% (EP) NMT1.0% (USP)		0.04% 0.06%
Residue on ignition	NMT0.5% (USP)		0.00%
Related substances(EP)	Impurity D:NMT0.5% Impurity H:NMT0.15% Impurity I:NMT0.5% Impurity G:NMT0.4% Impurity E: NMT0.5% Impurity A: NMT0.2% Impurity B: NMT0.2% Impurity F: NMT0.3% Impurity C: NMT0.5% Impurity N: NMT0.15% Any unspecified impurity: NMT0.10% Sum of impurities: NMT1.0%		ND ND ND 0.11% ND BDL ND ND 0.06% ND <0.10% 0.17%
Organic impurities (USP)	Individual impurity: NMT0.5% Total impurities: NMT2.0%		0.14% 0.35%
Residual solvents	Methanol: NMT3000ppm Ethanol: NMT2000ppm Acetone: NMT5000ppm DMF: NMT800ppm Methylene chloride: NMT600ppm		99ppm ND ND ND ND
Assay	97.0%~103.0% (On the dried basis by EP) 97.0%~102.0% (On the dried basis by USP)		100.1% 100.5%
Particle size	90% not more than 15 microns		conforms
Conclusion	It meets the requirements of EP/USP Standards		
Storage	Store in an air-tight container at ambient temperatures		
Reporter: LI	Reviewed By: WEI		

