

HANGZHOU DINGYAN CHEM CO.,LTD

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CERTIFICATE OF ANALYSIS

NO: DYC031805041

Product name	Betamethasone
CAS Number	378-44-9
Molecule Structure	HO OH
Molecule Formula	C22H29F05
Batch number	20180318
Manufacture date	2018-03-18
Testing date	2018-03-18
Expiry date	2020-03-17

Items	Standard	Results
Appearance	White or almost white crystalline powder	almost white
		crystalline powder
Solubility	Practically insoluble in water ,sparingly	Complies
	soluble in anhydrous ethanol, very	1
	slightly soluble in methylene chloride.	
Identification (B,C)	Complies with the Standard	Complies
Specific optical Rotation	+118° ~+126°	+119.7°
Related Substances		
-Impurity A	Not more than 1.0%	0.03%
-Impurity B	Not more than 1.0%	N.d
-Impurity C	Not more than 1.0%	N.d
-Impurity D	Not more than 1.0%	0.02%
-Impurity E	Not more than 1.0%	N.d
-Impurity F	Not more than 1.0%	N.d
-impurity G	Not more than 1.0%	N.d
-impurity H	Not more than 1.0%	<0.05%
-impurity I	Not more than 1.0%	<0.05%
-Impurity J	Not more than 1.0%	0.15%
-Not more than one of such	More than 0.50%	Complies
-Each unknown impurity	Not more than 0.10%	0.07%
-total impurities	Not more than 2.0%	0.43%
Loss on drying	Not more than 0.5%	0.08%
Assay(HPLC, basis on drying)	97.0%~103.0%	99.8%
Organic volatile substances		
Methanol	Not more than 3000ppm	Complies
Ethyl acetate	Not more than 5000ppm	Complies
Acetone	Not more than 5000ppm	Complies

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DMF	Not more than 880ppm	Complies		
Dichloromethane	Not more than 600ppm	Complies		
Chloroform	Not more than 60ppm	Complies		
Particle size	100%≤30um	complies		
Packaging and storage: Preserve in tight, light-resistant containers.				
Conclusion: The test product complies with the requirements of EP8.				

CHECK:姚仙娟 INSPECTOR: 刘清风

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