

**HUNAN YUXIN PHARMACEUTICAL CO., LTD.**

Address: Longxutang, Shaoyang City, 422001, Hunan Province, China

Tel: 86-731-82762659 Fax: 86-731-85551702 Email: info@steroidchem.com

CERTIFICATE OF ANALYSIS

Product name	Betamethasone valerate				
Batch No.	BTW-210301	Quantity	105.0kg		
Mfg. Date	Mar., 10, 2021	Expiry date	Mar., 09, 2024		
Specification	EP9				
Items	Standard	Results			
Appearance	White or almost white crystalline powder	almost white crystalline powder			
Solubility	practically insoluble in water ,freely soluble in acetone and in methylene chloride ,soluble in ethanol	Complies			
Melting point	About 192°C(188~196°C)	190.0~192.0°C			
Identification (A,B)	Complies with the Standard	Complies			
Specific optical Rotation	+77° ~+83°	+79.0°			
Related Substances					
- impurity A	Not more than 0.7%	0.10%			
- impurity D	Not more than 0.1%	0.02%			
- impurity E	Not more than 0.3%	0.20%			
- impurity G	Not more than 0.3%	0.01%			
- impurity C	Not more than 0.15%	n.d			
- impurity H	Not more than 0.15%	0.02%			
- impurity I	Not more than 0.15%	n.d			
-unspecified impurities	Not more than 0.10%	0.03%			
-total impurities	Not more than 1.5%	0.43%			
Loss on drying	Not more than 0.5%	0.04%			
Assay(UV, basis on drying)	97.0%~103.0%	100.5%			
Particle size	100%≤30um	complies			
Residual solvents					
THF	not more than 720ppm	n.d			
Methanol	not more than 3000ppm	n.d			
Acetone	not more than 5000ppm	1046ppm			
Pyridine	not more than 200ppm	n.d			
Packaging and storage: Preserve in tight, light-resistant containers.					
Conclusion: The test product complies with the requirements of EP9.					
Analyst	panyong	Checker	panwang	Approved by	yangmingcheng