

Certificate of Analysis

Product	Trimethoprim	Batch Number	TNJ20160116015
CAS No.	738-70-5	Packing	25kg /drum
M F	C ₁₄ H ₁₈ N ₄ O ₃	MFG Date	Jan.16, 2016
N.W.	500.00kg	Analysis Date	Jan.16, 2016
G.W.	509.00kg	Retest Date	Jan.15, 2021
Items	Specification	Testing Results	
Chacters	Appearance	White or yellowish-white powder	
	Solubility	Very slightly soluble in water, slightly soluble in alcohol	
Identification			
A: Melting point	199-203 °C	200-201 °C	
B: Specific absorbance	Max 287nm: 240-250	245	
C: IR-spectrum	Complies with the reference spectrum	Confirms	
D: Chemical reaction	Green fluorescence at 365nm	Confirms	
Appearance of solution	Not more intensely colored than Reference Solution BY ₇	Less intensely colored than reference solution BY ₇	
Related substance Method A by HPLC:			
Impurity F	≤0.1%	Undetected	
Any single impurity	≤0.1%	<0.1%	
Total impurities	≤0.2%	<0.2%	
Method B by HPLC:			
Any single impurity	≤0.1%	<0.1%	
Total impurities	≤0.2%	<0.2%	
Heavy metals	≤20ppm	<20ppm	
Residual methanol	≤3000ppm	Not detected	
Residual DMSO	≤5000ppm	Not detected	
Impurity K(Aniline)by GC	≤5ppm	<5ppm	
Loss on drying	≤1.0%	0.1%	
Sulphated ash	≤0.1%	0.05%	
Assay	98.5%~101.0%	99.5%	
Prepared by	Dong Mei	Checked by	Wang Tianyi
		Approved by	Liu Wu
Conclusion	The Quality of the above said is in conformity with the standard of BP2016		
Storage	Stored in dry and ventilation place, far from heat and water.		
COA Issuer	Quality Control Team-Technology Department		

