

CERTIFICATE OF ANALYSIS

The Power to Question

Test	Specification	Result
Appearance	White to light yellow crystalline powder	White crystalline powder
Visual Impurities	Not exceed 6000 particles per 1g equal to or greater than 10um, and not exceed 600 particles per 1g equal to or greater then 25um	10um: 217 particles /g 25um: 0 particles/g
Visible Particles	Meets the requirements	Complies
Identification	1. UV: Absorption maximum at 272 2. HPLC: The retention time of the major peak in the chromatogram of the assay preparation correspond to that of the standard preparation obtained as specified in the Assay. 3. IR: Conforms to the reference spectrum. 4. Responds to the test for sodium	Complies
Purity (HPLC)	Not less than 90.0%, calculated on the anhydrous basis	95.2 %
рН	4.5 - 6.5	5.1
Residual Solvents	Methanol < 0.3 % Ethanol < 0.5 % Acetone < 0.5 % Methylene chloride < 0.06 % Isopropanol < 0.5 % Ethyl acetate < 0.5 % N,N-dimethylacetamide < 0.109 %	0.27 % 0.44 % 0.18 % ND ND ND
Solubility	Freely soluble in water, slightly soluble in methanol, practically insoluble in ethanol and in ether	Complies
Solution	Clear or not more than opalescent than reference suspension 1. Not more intensely coloured than reference solution Y or YG6	< 0.5 < Y1
Absorbance	270 - 300	286

Satisfaction Guarantee: We appreciate your business and are committed to providing the highest level of quality and service. Any product that does not meet the performance standards indicated in our product literature will be replaced at no charge. Our policy is valid for one year from the date of your purchase.

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Specific rotation	-5°9°	-8°	
Related Substances	Individual impurity < 1.0 % Total impurity < 1.5 %	0.11 % 0.36 %	
Ceftriaxone polymer	≤ 0.05 %	0.028 %	
Water Content	≤ 5.0 %	3.9 %	
Bacterial Endotoxins	< 0.075 EU/mg	< 0.060 EU/mg	
Sterility	Meets the requirements	Complies	

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