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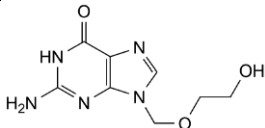
PRODUCT SPECIFICATION

ACICLOVIR

(Nonsterile)

Ph. Eur. 9.0

Version No: DS01NS-EP-01

Product Name	ACICLOVIR		
Molecular Formula	C ₈ H ₁₁ N ₅ O ₃	Formula Weight	225.2
Structure Formula			
CAS No	59277-89-3		
Origin	Chemical synthesis		
ITEMS	SPECIFICATIONS		
Appearance	White or almost white, crystalline powder		
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in heptane. It dissolves in dilute solutions of mineral acids and alkali hydroxides.		
Identification			
IR	Spectrum of sample matches that of reference standard		
Appearance of solution	Clear and not more intense coloured than Ref. Sol. Y ₇		
Water	≤ 6.0%		
Sulfated ash	≤ 0.1%		
Related Substances			
Impurity B	≤ 0.7%		
Sum of impurities O and Q	≤ 0.3%		
Sum of impurities K and R	≤ 0.2%		
Impurity A, G, J, N, P	≤ 0.2%		
Impurities C, F, I	≤ 0.1%		
Unspecified impurities	≤ 0.05%		
Total	≤ 1.5%		
Residual Solvents			
No class I solvent used	Compliance with ICH Q3C limits		
Assay (anhydrous substance)	98.5%~101.0%		
Retest Period	TBD		
Batch size	TBD		
Packing size	25kg/drum		
Storage	Preserve in tight containers. Store at room temperature. Protect from light and moisture.		

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