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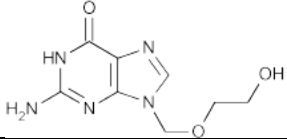
PRODUCT SPECIFICATION

ACYCLOVIR

(Nonsterile)

USP 40

Version No: DS01NS-USP-01

Product Name	ACYCLOVIR		
Molecular Formula	C ₈ H ₁₁ N ₅ O ₃	Formula Weight	225.20
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 1) IR 2) HPLC, Assay and limit for guanine	Spectrum of sample matches that of reference standard; The RT of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation		
Appearance of solution	Clear and not more intense coloured than Ref. Sol. Y ₇		
Water determination	≤ 6.0%		
Ordinary impurities, TLC	≤ 1%		
Residual Solvents No class I solvent used	Compliance with ICH Q3C limits		
Assay limit for guanine (on the anhydrous basis), HPLC	98.0%~101.0% of C ₈ H ₁₁ N ₅ O ₃		
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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