METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0097-TDS-ENG-2026

ACICLOVIR (EUR. PH.)		
DESCRIPTION DCI: ACICLOVIR	DESCRIPTION DOE: ACICLOVIR	
CAS Nº: 59277-89-3	EC Nº: 261-685-1	AEMPS CODE: 201A
MOL. WEIGHT: 225,21	MOL. FORMULA: C8H11N5O3	ARTICLE CODE: 0097

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 %), practically insoluble in heptane. It dissolves in dilute solutions of mineral acids and alkali hydroxides
Identification	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Related substances	
Impurity B	=< 0.7 %
Impurity J	=< 0.2 %
Sum of impurities K and R	=< 0.15 %
Sum of impurities O and Q	=< 0.15 %
Impurity C	=< 0.15 %
Impurity N	=< 0.15 %
Impurity P	=< 0.15 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 1.0 %
Water	=< 6.0 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Keep the containers tightly closed. Store in a cool and dry place, away from incompatible materials.

REMARKS

Aciclovir is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

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