

ACICLOVIR (EUR. PH.)

PRODUCT CODE: 0097	CAS Nº: 59277-89-3	ANALYSIS Nº: 307/25
MANUFACTURER BATCH: ACYCII125002	CERTIFICATE ID: 48.496	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/08/2025	
METAPH BATCH: 0380925	EXPIRY DATE: 30/07/2030	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	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	Complies (*)
Identification	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
Related substances		
Impurity B	=< 0.7 %	0.3 %
Impurity J	=< 0.2 %	0.03 %
Sum of impurities K and R	=< 0.15 %	< 0.03 %
Sum of impurities O and Q	=< 0.15 %	< 0.03 %
Impurity C	=< 0.15 %	Not Detected
Impurity N	=< 0.15 %	< 0.15 %
Impurity P	=< 0.15 %	0.1 %
Unspecified impurities	=< 0.05 %	< 0.03 %
Total impurities	=< 1.0 %	0.4 %
Water	=< 6.0 %	5.2 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	98.5 - 101.0 %	100.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 06/11/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000520
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