



METAPHARMACEUTICAL

N DE LOTE:

0140323

Certificate of Analysis

Product name **ACICLOVIR COARSE EP Current Edition**

Product Code 65500
Batch Number 2130001312
Order 1230363
Quantity 10,000 KG

Manufacturing date 18/10/2021
Re-test date 27/02/2026
Certificate Nr. 100000027086
Batch Size 500,000 KG
Ref. Order 2023-1/84

afn 22/03/2023

Test	References	Specification	M.U.	Result
Appearance	EP monograph	Crystalline powder		Crystalline powder
Colour	EP monograph	White to almost white		White
Solubility	EP monograph	Complies		Complies
Slightly soluble in H ₂ O, very slightly soluble in ethanol 96%, practically insoluble in heptane. Soluble in diluted solutions of acid and alkaline hydroxide				
IR identification	EP monograph	Complies with standard		Complies with standard
Appearance of solution	EP monograph	Clear		Clear
Colour of solution	EP monograph	NMT Y7		NMT Y7
Water content (KF)	EP monograph	<= 6,0	%	5,0
Sulphated ash	EP monograph	<= 0,1	%	0,02
Assay (HClO ₄)	EP monograph	98,5 - 101,0	% anh.	99,4
EP Impurity B (guanine)	EP monograph (HPLC)	<= 0,7	%	0,16
EP impurity C	EP monograph (HPLC)	<= 0,15	%	< Disregard limit (0,03)
EP impurity J	EP monograph (HPLC)	<= 0,2	%	0,03
EP impurity K and R	EP monograph (HPLC)	<= 0,15	%	< Disregard limit (0,03)
EP impurity N	EP monograph (HPLC)	<= 0,15	%	< Disregard limit (0,03)
EP impurity O and Q	EP monograph (HPLC)	<= 0,15	%	< Disregard limit (0,03)
EP impurity P	EP monograph (HPLC)	<= 0,15	%	< Disregard limit (0,03)
Highest impurity unknown	EP monograph (HPLC)	<= 0,05	%	< Disregard limit (0,03)
Total impurities	EP monograph (HPLC)	<= 1,0	%	0,19
Acetone	Internal Method (GC)	<= 200	ppm	< RT (60)
Total solvents	Internal Method (GC)	<= 200	ppm	< RT (60)
Total aerobic microbial count (TAMC)	EP 2.6.12	<= 500	CFU/g	< LOQ (5)
Total yeast and mould counts (TYMC)	EP 2.6.12	<= 100	CFU/g	< LOQ (5)
Bile tolerant gram negative bacteria	EP 2.6.13	Absent/g		Absent/g
Salmonella	EP 2.6.13	Absent/10g		Absent/10g
Escherichia coli	EP 2.6.13	Absent/g		Absent/g
Pseudomonas aeruginosa	EP 2.6.13	Absent/g		Absent/g
Staphylococcus aureus	EP 2.6.13	Absent/g		Absent/g

Gianmaria Testori QC Deputy Approved February 09, 2022	Marco Pietro Fazio Qualified Person Released February 10, 2022		
'Emission'	Federica Finotti	QA Specialist	March 13, 2023

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640

Società Capogruppo P. & R. Principi Attivi S.p.A

Società con Socio unico - Strada Rivoltana km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v.- C.F. e P.IVA 11155530964



Certificate of Analysis

Product name	ACICLOVIR COARSE EP Current Edition	Manufacturing date	18/10/2021
Product Code	65500	Re-test date	27/02/2026
Batch Number	2130001312	Certificate Nr.	100000027086
Order	1230363	Batch Size	500,000 KG
Quantity	10,000 KG	Ref. Order	2023-1/84

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
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This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICH Q7A).

Manufacturing site of the Active Pharmaceutical Ingredient: Olon S.p.A - Dorno Not to be used in sterile parenteral and in sterile non-parenteral products

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