

Olon Spa Stab. Dorno
Via Scaldasole 33
27020 Dorno (PV)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
Tel. Plant: +39 0382 82501

Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)



METAPHARMACEUTICAL

N DE LOTE:

0130524

Certificate of Analysis

Product name **ACICLOVIR COARSE EP Current Edition**

Product Code 65500
Batch Number 0024300344
Order 1240859
Quantity 10,000 KG

Manufacturing date 05/03/2024
Re-test date 19/01/2029
Certificate Nr. 100000033639
Batch Size 500,000 KG
Ref. Order 2024 -1/202

Signature 15/05/2024

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	%	0,03
Assay (HClO ₄)	EP monograph	98,5 - 101,0	% anh.	100,9
EP Impurity B (guanine)	EP monograph (HPLC)	≤ 0,7	%	0,13
EP impurity C	EP monograph (HPLC)	≤ 0,15	%	< Disregard limit (0,03)
EP impurity J	EP monograph (HPLC)	≤ 0,2	%	< Disregard limit (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	%	0,13
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

Simone Stringa QC Manager Approved May 08, 2024	Andrea Cervati Qualified Person Released May 08, 2024		
'Emission'	Federica Finotti	QA Specialist	May 10, 2024

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

Modello: 65500_S / 1

May 10, 2024

This CoA is electronically dated and signed by authorized personnel of the Quality Unit

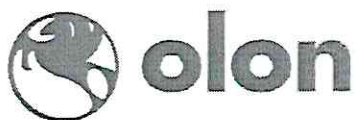
May 10, 2024

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Certificate of Analysis

Product name	ACICLOVIR COARSE EP Current Edition	Manufacturing date	05/03/2024
Product Code	65500	Re-test date	19/01/2029
Batch Number	0024300344	Certificate Nr.	100000033639
Order	1240859	Batch Size	500,000 KG
Quantity	10,000 KG	Ref. Order	2024 -1/202

<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

Simone Stringa QC Manager Approved May 08, 2024	Andrea Cervati Qualified Person Released May 08, 2024		
'Emission'	Federica Finotti	QA Specialist	May 10, 2024

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