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



Certificate of Analysis

Product name	ACICLOVIR FINER EP Current Edition		Manufacturing date	30/03/2020
Product Code	65600		Re-test date	26/01/2025
Batch Number	2030000520		Certificate Nr.	100000009800
Order	1201211		Batch Size	255,000 KG
Quantity	25,000 KG		Ref. Order	PO 2020-1/204

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	%	0,01
Assay (HClO4)	EP monograph	98,5 - 101,0	% anh.	100,2
EP impurity A	EP monograph (HPLC)	<= 0,2	%	< Disregard limit (0,03)
EP Impurity B (guanine)	EP monograph (HPLC)	<= 0,30	%	0,09
EP impurity C	EP monograph (HPLC)	<= 0,1	%	< Disregard limit (0,03)
EP impurity F	EP monograph (HPLC)	<= 0,1	%	< Disregard limit (0,03)
EP impurity G	EP monograph (HPLC)	<= 0,2	%	< Disregard limit (0,03)
EP impurity I	EP monograph (HPLC)	<= 0,1	%	< Disregard limit (0,03)
EP impurity J	EP monograph (HPLC)	<= 0,2	%	0,04
EP impurity K and R	EP monograph (HPLC)	<= 0,2	%	< Disregard limit (0,03)
EP impurity N	EP monograph (HPLC)	<= 0,2	%	< Disregard limit (0,03)
EP impurity O and Q	EP monograph (HPLC)	<= 0,3	%	< Disregard limit (0,03)
EP impurity P	EP monograph (HPLC)	<= 0,2	%	< 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

Alessandra Barbieri QC Manager Approved May 27, 2020	Chiara Magnone Qualified Person Released May 28, 2020
'Emission'	Chiara Magnone Qualified Person May 28, 2020

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - R.E.A. Milano n. 1201640
Società Capogruppo P. & R. Principi Attivi S.p.A.
Società con Socio unico - Strada Rivoltana km. 6/7 - 20090 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v. - C.F. e P.IVA 11155530964

Modello: 65600_S / 1

May 28, 2020

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

May 28, 2020

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<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
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

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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ACV F 65600

CQ3
27/05/2020 CQ

OLON S.p.A. Dorno (PV)



Measurement Details

Operator Name bocca
Sample Name Average of 'ACV F 65600'
Lotto 2030000520
SOP File Name ACV_F_65600-Secco.msop

Measurement Details

Analysis Date Time 27/05/2020 08:50:35
Measurement Date Time 27/05/2020 08:50:35
Result Source Averaged

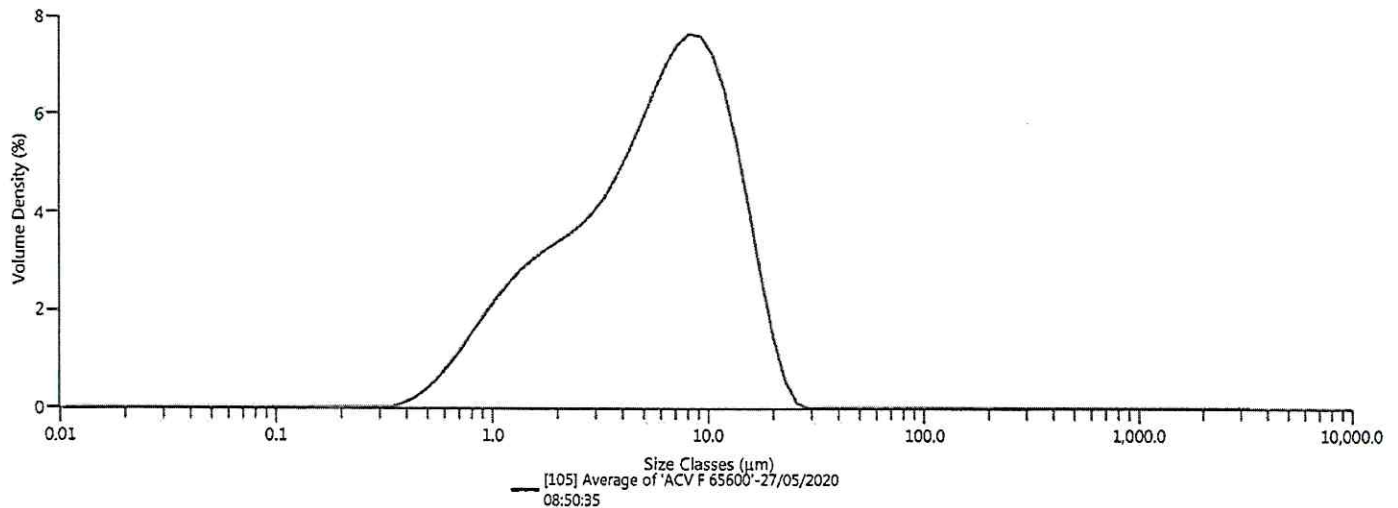
Analysis

Particle Name Aciclovir
Particle Refractive Index 1,700
Particle Absorption Index 0,000
Dispersant Name Dry dispersion
Dispersant Refractive Index 1,000
Scattering Model Mie
Analysis Model General Purpose
Weighted Residual 1,60 %
Laser Obscuration 1,84 %

Result

Concentration 0,0006 %
Span 2,144
Uniformity 0,671
Specific Surface Area 1909 m²/kg
Dv (10) 1,29 µm
Dv (50) 5,67 µm
Dv (80) 10,6 µm
Dv (90) 13,5 µm
Dv (95) 15,8 µm
Dv (99) 20,1 µm
Dv (100) 27,1 µm

Frequency (compatible)



Result

Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In
0,0100	0,00	0,0597	0,00	0,357	0,07	2,13	2,96	12,7	4,53	76,0	0,00	454	0,00
0,0114	0,00	0,0679	0,00	0,405	0,16	2,42	3,12	14,5	3,44	86,4	0,00	516	0,00
0,0129	0,00	0,0771	0,00	0,460	0,31	2,75	3,32	16,4	2,28	98,1	0,00	586	0,00
0,0147	0,00	0,0876	0,00	0,523	0,51	3,12	3,59	18,7	1,22	111	0,00	666	0,00
0,0167	0,00	0,0995	0,00	0,594	0,75	3,55	3,93	21,2	0,44	127	0,00	756	0,00
0,0189	0,00	0,113	0,00	0,675	1,03	4,03	4,36	24,1	0,05	144	0,00	859	0,00
0,0215	0,00	0,128	0,00	0,767	1,33	4,58	4,84	27,4	0,00	163	0,00	976	0,00
0,0244	0,00	0,146	0,00	0,872	1,62	5,21	5,34	31,1	0,00	186	0,00	1110	0,00
0,0278	0,00	0,166	0,00	0,991	1,90	5,92	5,82	35,3	0,00	211	0,00	1260	0,00
0,0315	0,00	0,188	0,00	1,13	2,16	6,72	6,19	40,1	0,00	240	0,00	1430	0,00
0,0358	0,00	0,214	0,00	1,28	2,37	7,64	6,40	45,6	0,00	272	0,00	1630	0,00
0,0407	0,00	0,243	0,00	1,45	2,55	8,68	6,37	51,8	0,00	310	0,00	1850	0,00
0,0463	0,00	0,276	0,00	1,65	2,70	9,86	6,05	58,9	0,00	352	0,00	2100	0,00
0,0526	0,00	0,314	0,00	1,88	2,83	11,2	5,43	66,9	0,00	400	0,00	2390	0,00

Si 27/05/2020



ACV F 65600

OLON S.p.A. Dorno (PV)



Signature				
Record Number	Sample Name	Signature State	Signatory	Signature Date
105	Average of 'ACV F 65600'	Unsigned		

