

ble. 0200719



Certificate of Analysis

Product name **ACICLOVIR FINER EP9**

Product Code 65600
Batch Number 1930000917
Order 1191632
Quantity 5,000 KG

Manufacturing date 14/06/2019
Re-test date 07/04/2024
Certificate Nr. 100000004394
Batch Size 635,000 KG
Ref. Order PO 2019 - 1/273

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Appearance	EP monograph	Crystalline powder		Crystalline powder
Colour	EP monograph	White to almost white		White
Solubility 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	EP monograph	Complies		Complies
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	%	5,5
Sulphated ash	EP monograph	≤ 0,1	%	0,0
Heavy metals	EP 2.4.8 Method C	NMT 20 ppm		< 20 ppm
Assay (HClO ₄)	EP monograph	98,5 - 101,0	% anh.	100,7
EP impurity A	EP monograph (HPLC)	≤ 0,2	%	< Disregard limit (0,03)
EP Impurity B (guanine)	EP monograph (HPLC)	≤ 0,30	%	0,07
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	%	< Disregard limit (0,03)
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	%	0,1
Acetone	Internal Method (GC)	≤ 200	ppm	12
Total solvents	Internal Method (GC)	≤ 200	ppm	24
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

Gianmaria Testori
QC Deputy
Approved July 11, 2019

Claudia Maurogiovanni
Qualified Person
Released July 11, 2019

Emission July 17, 2019



Certificate of Analysis

Product name	ACICLOVIR FINER EP9	Manufacturing date	14/06/2019
Product Code	65600	Re-test date	07/04/2024
Batch Number	1930000917	Certificate Nr.	100000004394
Order	1191632	Batch Size	635,000 KG
Quantity	5,000 KG	Ref. Order	PO 2019 - 1/273

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

Gianmaria Testori
QC Deputy
Approved July 11, 2019

Claudia Maurogiovanni
Qualified Person
Released July 11, 2019

Emission July 17, 2019

ACV F 65600

CQ3

OLON S.p.A. Dorno (PV)



Measurement Details

Operator Name bocca
Sample Name Average of 'ACV F 65600'
Lotto 1930000917
SOP File Name ACV_F_65600-Secco.msop

Measurement Details

Analysis Date Time 28/06/2019 12:12:38
Measurement Date Time 28/06/2019 12:12:38
Result Source Averaged

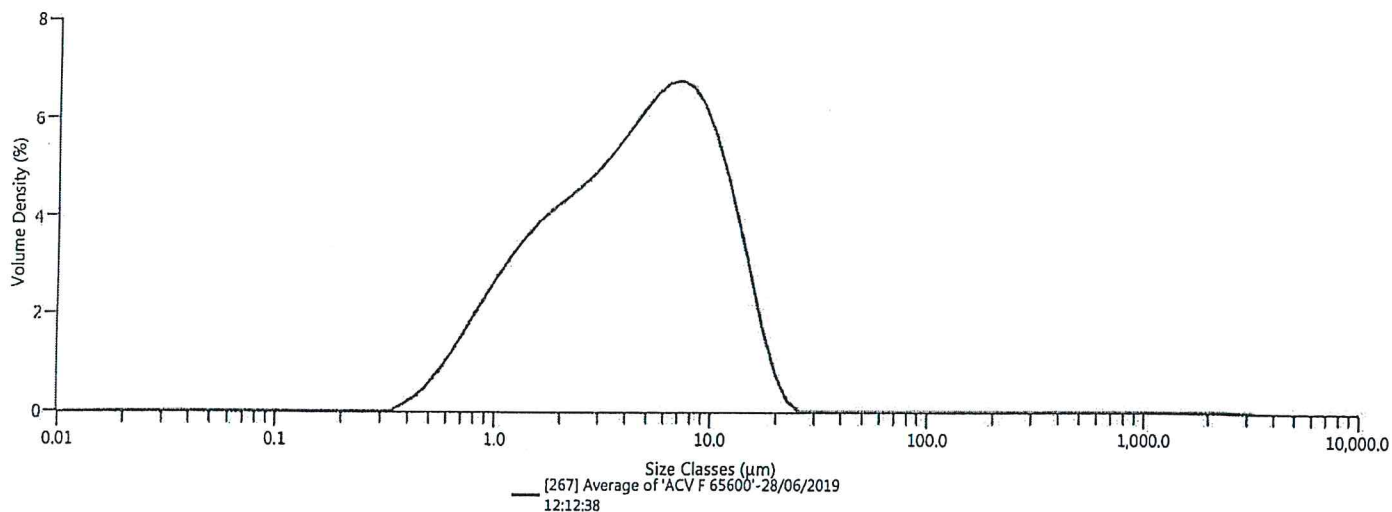
Analysis

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 1,56 %
Laser Obscuration 3,45 %

Result

Concentration 0,0009 %
Span 2,384
Uniformity 0,746
Specific Surface Area 2252 m²/kg
Dv (10) 1,13 µm
Dv (50) 4,44 µm
Dv (80) 8,98 µm
Dv (90) 11,7 µm
Dv (95) 14,0 µm
Dv (99) 18,2 µm
Dv (100) 24,0 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	0,12	2,13	3,73	12,7	3,14	76,0	0,00	454	0,00
0,0114	0,00	0,0679	0,00	0,405	0,25	2,42	3,90	14,5	2,21	86,4	0,00	516	0,00
0,0129	0,00	0,0771	0,00	0,460	0,44	2,75	4,09	16,4	1,32	98,1	0,00	586	0,00
0,0147	0,00	0,0876	0,00	0,523	0,69	3,12	4,32	18,7	0,60	111	0,00	666	0,00
0,0167	0,00	0,0995	0,00	0,594	0,99	3,55	4,58	21,2	0,15	127	0,00	756	0,00
0,0189	0,00	0,113	0,00	0,675	1,33	4,03	4,87	24,1	0,00	144	0,00	859	0,00
0,0215	0,00	0,128	0,00	0,767	1,60	4,58	5,16	27,4	0,00	163	0,00	976	0,00
0,0244	0,00	0,146	0,00	0,872	2,04	5,21	5,42	31,1	0,00	186	0,00	1110	0,00
0,0278	0,00	0,166	0,00	0,991	2,38	5,92	5,60	35,3	0,00	211	0,00	1260	0,00
0,0315	0,00	0,188	0,00	1,13	2,69	6,72	5,66	40,1	0,00	240	0,00	1430	0,00
0,0358	0,00	0,214	0,00	1,28	2,96	7,64	5,56	45,6	0,00	272	0,00	1630	0,00
0,0407	0,00	0,243	0,00	1,45	3,19	8,68	5,25	51,8	0,00	310	0,00	1850	0,00
0,0463	0,00	0,276	0,00	1,65	3,39	9,86	4,73	58,9	0,00	352	0,00	2100	0,00
0,0526	0,00	0,314	0,00	1,88	3,56	11,2	4,01	66,9	0,00	400	0,00	2390	0,00

28/06/19 C3

A 28/06/19



ACV F 65600

OLON S.p.A. Dorno (PV)



Signature

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

