

Lote: 0190719



Certificate of Analysis

Product name **ACICLOVIR FINER EP9**

Product Code 65600
Batch Number 1930000507
Order 1191632
Quantity 4,940 KG

Manufacturing date 03/04/2019
Re-test date 09/01/2024
Certificate Nr. 100000004393
Batch Size 625,000 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	%	5,1
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.	99,9
EP impurity A	EP monograph (HPLC)	<= 0,2	%	0,0
EP Impurity B (guanine)	EP monograph (HPLC)	<= 0,30	%	0,08
EP impurity C	EP monograph (HPLC)	<= 0,1	%	0,0
EP impurity F	EP monograph (HPLC)	<= 0,1	%	0,0
EP impurity G	EP monograph (HPLC)	<= 0,2	%	0,0
EP impurity I	EP monograph (HPLC)	<= 0,1	%	0,0
EP impurity J	EP monograph (HPLC)	<= 0,2	%	0,0
EP impurity K and R	EP monograph (HPLC)	<= 0,2	%	0,0
EP impurity N	EP monograph (HPLC)	<= 0,2	%	0,0
EP impurity O and Q	EP monograph (HPLC)	<= 0,3	%	0,0
EP impurity P	EP monograph (HPLC)	<= 0,2	%	0,0
Highest impurity unknown	EP monograph (HPLC)	<= 0,05	%	0,03
Total impurities	EP monograph (HPLC)	<= 1,0	%	0,1
Acetone	Internal Method (GC)	<= 200	ppm	10
Total solvents	Internal Method (GC)	<= 200	ppm	10
Total aerobic microbial count (TAMC)	EP 2.6.12	<= 500	CFU/g	< 5
Total yeast and mould counts (TYMC)	EP 2.6.12	<= 100	CFU/g	< 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 April 29, 2019

Claudia Maurogiovanni
Qualified Person
Released April 29, 2019

Emission July 17, 2019



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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
Bacterial endotoxins (LAL test)	EP 2.6.14	<0,50	IU/mg	

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 April 29, 2019

Claudia Maurogiovanni
Qualified Person
Released April 29, 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 1930000507
SOP File Name ACV_F_65600-Secco.msop

Measurement Details

Analysis Date Time 29/04/2019 10:36:09
Measurement Date Time 29/04/2019 10:36:09
Result Source Averaged

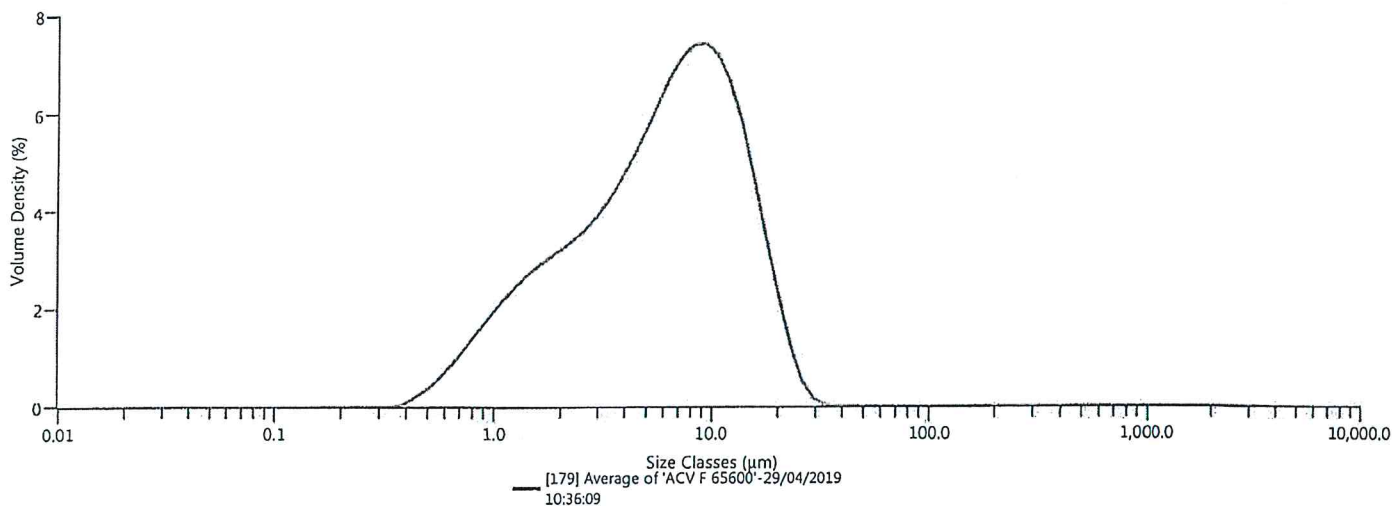
Analysis

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 1,68 %
Laser Obscuration 1,79 %

Result

Concentration 0,0006 %
Span 2,204
Uniformity 0,691
Specific Surface Area 1801 m²/kg
Dv (10) 1,36 µm
Dv (50) 6,04 µm
Dv (80) 11,4 µm
Dv (90) 14,7 µm
Dv (95) 17,5 µm
Dv (99) 22,9 µm
Dv (100) 34,6 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	0,02	2,13	2,82	12,7	4,87	76,0	0,00	454	0,00
0,0114	0,00	0,0679	0,00	0,405	0,14	2,42	3,00	14,5	3,96	86,4	0,00	516	0,00
0,0129	0,00	0,0771	0,00	0,460	0,27	2,75	3,21	16,4	2,94	98,1	0,00	586	0,00
0,0147	0,00	0,0876	0,00	0,523	0,46	3,12	3,49	18,7	1,92	111	0,00	666	0,00
0,0167	0,00	0,0995	0,00	0,594	0,68	3,55	3,83	21,2	1,04	127	0,00	756	0,00
0,0189	0,00	0,113	0,00	0,675	0,94	4,03	4,23	24,1	0,43	144	0,00	859	0,00
0,0215	0,00	0,128	0,00	0,767	1,21	4,58	4,68	27,4	0,12	163	0,00	976	0,00
0,0244	0,00	0,146	0,00	0,872	1,49	5,21	5,15	31,1	0,03	186	0,00	1110	0,00
0,0278	0,00	0,166	0,00	0,991	1,75	5,92	5,59	35,3	0,00	211	0,00	1260	0,00
0,0315	0,00	0,188	0,00	1,13	1,99	6,72	5,96	40,1	0,00	240	0,00	1430	0,00
0,0358	0,00	0,214	0,00	1,28	2,20	7,64	6,19	45,6	0,00	272	0,00	1630	0,00
0,0407	0,00	0,243	0,00	1,45	2,38	8,68	6,23	51,8	0,00	310	0,00	1850	0,00
0,0463	0,00	0,276	0,00	1,65	2,53	9,86	6,03	58,9	0,00	352	0,00	2100	0,00
0,0526	0,00	0,314	0,00	1,88	2,67	11,2	5,57	66,9	0,00	400	0,00	2390	0,00

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ACV_F_65600-2019

Created: 05/09/2018
Printed: 29/04/2019 10:40

ACV F 65600

OLON S.p.A. Dorno (PV)



Signature

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

