

Lote: 0160618

Certificate of analysis

Product **ACICLOVIR FINER EP9** Code N° **65600** Batch N° **1830000755**

Manufacturing date **MAY 2018** Retest date (where applicable) **APR 2023**

Analysis Number **S2PF051702** Bulletin **2P1800724**

Test	References	Result	M.U.	Limits
Description	EP monograph	White crystalline powder	--	White to almost white crystalline powder
Solubility	EP monograph	Conforme	--	Slight sol in H ₂ O, very slight sol in eth 96%, pract insol in heptane. Sol in dil sol of ac, alk hid
IR	EP monograph	Conform to standard	--	Conform to standard
Appearance of solution	EP monograph	clear, not more col. than Y7	--	clear, not more col. than Y7
Water content (K.F.)	EP monograph	5,2	%	≤ 6,0
Sulphated Ash	EP monograph	0,0	%	≤ 0,1
Heavy metals	EP 2.4.8 Meth. C	Complies	ppm	NMT 20
Assay (HClO ₄)	EP monograph	100,3	%anh	98,5 ÷ 101,0
EP impurity A	EP monograph	<0,03	%	≤ 0,2
EP Impurity B (Guanine)	EP monograph	0,09	%	≤ 0,30
EP impurity C	EP monograph	<0,03	%	≤ 0,1
EP impurity F	EP monograph	<0,03	%	≤ 0,1
EP impurity G	EP monograph	<0,03	%	≤ 0,2
EP impurity I	EP monograph	<0,03	%	≤ 0,1
EP impurity J	EP monograph	<0,03	%	≤ 0,2
EP impurity K and R	EP monograph	<0,03	%	≤ 0,2
EP impurity N	EP monograph	<0,03	%	≤ 0,2
EP impurity O and Q	EP monograph	<0,03	%	≤ 0,3
EP impurity P	EP monograph	<0,03	%	≤ 0,2
Highest impurity unknown	EP monograph	<0,03	%	≤ 0,05
Total impurities	EP monograph	0,1	%	≤ 1,0
Residual solvents: acetone	Internal method	5	ppm	≤ 200
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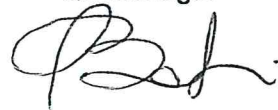
Analysis Number **S2PF051702** Bulletin **2P1800724**

Test	References	Result	M.U.	Limits
d(0,99)	Internal method	14	micro n	< 50
d(0,9)	Internal method	8	micro n	< 25
d(0,5)	Internal method	4	micro n	< 10
d(0,1)	Internal method	2	micro n	< 3
Total aerobic microbial count (TAMC)	EP 2.6.12	<5	cfu/g	≤ 500
Total yeast and mould counts (TYMC)	EP 2.6.12	<5	cfu/g	≤ 100
Bile tolerant gram negative bacteria	EP 2.6.13	Absent/g	--	Absent/g
Salmonella	EP 2.6.13	Assente/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

Analysis Date

06/15/2018

QC Manager



Reviewed by Qualified Person

 18/06/18

Notes: NOT TO BE USED IN STERILE PARENTERAL AND IN STERILE NON PARENTERAL PRODUCTS
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: Stabilimento di Dorno

Result: Analysis Report

2/35
16/06/18 CB Lynne 106/18

User Name: bocca1

Security Level: 2

Sample Details		
Sample ID: ACV F 1830000755	Run Number: 3	Measured:
Sample File: ACV	Record Number: 1489	Analysed: Thu 14 Jun 2018 12.30
Sample Path: C:\SIZER\MU\DATA\		Result Source: Averaged
Sample Notes:		

System Details		
Sampler:		Measured Beam Obscuration: 12.6 %
Presentation: 4PAE	[Particle R.I. = (1.6800, 0.0000); Dispersant R.I. = 1.4000]	
Analysis Model: Polydisperse		Residual: 1.041 %
Modifications: None		

Result Statistics			
Distribution Type: Volume	Concentration = 0.0046 %Vol	Density = 1.000 g / cub. cm	Specific S.A. = 1.8662 sq. m / g
Mean Diameters:	D (v, 0.1) = 1.76 um	D (v, 0.5) = 3.72 um	D (v, 0.9) = 8.37 um
D [4, 3] = 4.51 um	D [3, 2] = 3.22 um	Span = 1.775E+00	Uniformity = 5.505E-01

Size Low (um)	In %	Size High (um)	Under%	Size Low (um)	In %	Size High (um)	Under%
0.31	0.00	0.36	0.00	10.48	2.27	12.21	97.53
0.36	0.00	0.42	0.00	12.21	1.42	14.22	98.95
0.42	0.00	0.49	0.00	14.22	0.74	16.57	99.69
0.49	0.00	0.58	0.00	16.57	0.28	19.31	99.97
0.58	0.00	0.67	0.00	19.31	0.03	22.49	100.00
0.67	0.00	0.78	0.00	22.49	0.00	26.20	100.00
0.78	0.00	0.91	0.00	26.20	0.00	30.53	100.00
0.91	0.33	1.06	0.33	30.53	0.00	35.56	100.00
1.06	1.21	1.24	1.54	35.56	0.00	41.43	100.00
1.24	2.56	1.44	4.10	41.43	0.00	48.27	100.00
1.44	4.23	1.68	8.33	48.27	0.00	56.23	100.00
1.68	5.83	1.95	14.16	56.23	0.00	65.51	100.00
1.95	7.03	2.28	21.19	65.51	0.00	76.32	100.00
2.28	7.84	2.65	29.02	76.32	0.00	88.91	100.00
2.65	8.74	3.09	37.76	88.91	0.00	103.58	100.00
3.09	9.97	3.60	47.72	103.58	0.00	120.67	100.00
3.60	9.98	4.19	57.70	120.67	0.00	140.58	100.00
4.19	9.06	4.88	66.77	140.58	0.00	163.77	100.00
4.88	7.98	5.69	74.75	163.77	0.00	190.80	100.00
5.69	7.08	6.63	81.83	190.80	0.00	222.28	100.00
6.63	5.66	7.72	87.48	222.28	0.00	258.95	100.00
7.72	4.51	9.00	92.00	258.95	0.00	301.68	100.00
9.00	3.27	10.48	95.26				

