+Stabilimento di Dorno
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Lot: 0140517

Certificate of analysis

Product ACICLOVIR FINER EP9 **Code N°** 65600 **Batch N°** 1630001466

Manufacturing date OCT 2016 **Retest date (where applicable)** JUN 2021 Bidon Carton

Analysis Number Q2PF102602 **Bulletin** 2P1601452

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 H2O, 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 (HClO4)	EP monograph	99,7	%anh.	98,5 ÷ 101,0
EP impurity A	EP monograph	<0,03	%	≤ 0,2
EP Impurity B (Guanine)	EP monograph	0,19	%	≤ 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	0,2	%	≤ 1,0

Certificate of analysis

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Manufacturing date OCT 2016 Retest date (where applicable) JUN 2021

Analysis Number Q2PF102602 Bulletin 2P1601452

Test	References	Result	M.U.	Limits
Residual solvents: acetone	Internal method	11	ppm	≤ 200
Total solvents	Internal method	11	ppm	≤ 200
d(0,99)	Internal method	36	micron	< 50
d(0,9)	Internal method	16	micron	< 25
d(0,5)	Internal method	5	micron	< 10
d(0,1)	Internal method	2	micron	< 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

02/15/2017

QC Manager

Reviewed by Qualified Person

20/02/17

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

MALVERN INSTRUMENTS

MASTERSIZER

2/35 26/04/16 CS

Result: Analysis Report

User Name: bocca1

Security Level: 2

Sample Details

Sample ID: ACV F 1630001466
Sample File: ACV
Sample Path: C:\SIZERMU\DATA\
Sample Notes:

Run Number: 3
Record Number: 1101

Measured:
Analysed: Wed 26 Oct 2016 16.11
Result Source: Averaged

26/04/16

System Details

Sampler:
Presentation: 4PAE
Analysis Model: Polydisperse
Modifications: None

[Particle R.I. = (1.6800, 0.0000); Dispersant R.I. = 1.4000]

Measured Beam Obscuration: 14.2 %
Residual: 1.395 %

Result Statistics

Distribution Type: Volume
Mean Diameters:
D [4, 3] = 7.34 um

Concentration = 0.0065 %Vol
D (v, 0.1) = 1.86 um
D [3, 2] = 3.89 um

Density = 1.000 g / cub. cm
D (v, 0.5) = 4.92 um
Span = 2.845E+00

Specific S.A. = 1.5415 sq. m / g
D (v, 0.9) = 15.86 um
Uniformity = 9.015E-01

Size Low (um)	In %	Size High (um)	Under%
0.31	0.00	0.36	0.00
0.36	0.00	0.42	0.00
0.42	0.00	0.49	0.00
0.49	0.00	0.58	0.00
0.58	0.00	0.67	0.00
0.67	0.00	0.78	0.00
0.78	0.00	0.91	0.00
0.91	0.48	1.06	0.48
1.06	1.24	1.24	1.73
1.24	2.20	1.44	3.93
1.44	3.26	1.68	7.19
1.68	4.24	1.95	11.44
1.95	5.03	2.28	16.46
2.28	5.65	2.65	22.12
2.65	6.28	3.09	28.40
3.09	6.99	3.60	35.39
3.60	7.22	4.19	42.61
4.19	7.04	4.88	49.65
4.88	6.71	5.69	56.35
5.69	6.43	6.63	62.79
6.63	5.88	7.72	68.67
7.72	5.46	9.00	74.13
9.00	4.93	10.48	79.06

Size Low (um)	In %	Size High (um)	Under%
10.48	4.47	12.21	83.53
12.21	3.98	14.22	87.50
14.22	3.41	16.57	90.92
16.57	2.80	19.31	93.71
19.31	2.15	22.49	95.87
22.49	1.53	26.20	97.40
26.20	1.02	30.53	98.42
30.53	0.64	35.56	99.06
35.56	0.40	41.43	99.46
41.43	0.26	48.27	99.72
48.27	0.17	56.23	99.89
56.23	0.09	65.51	99.98
65.51	0.02	76.32	100.00
76.32	0.00	88.91	100.00
88.91	0.00	103.58	100.00
103.58	0.00	120.67	100.00
120.67	0.00	140.58	100.00
140.58	0.00	163.77	100.00
163.77	0.00	190.80	100.00
190.80	0.00	222.28	100.00
222.28	0.00	258.95	100.00
258.95	0.00	301.68	100.00