

Aciclovirum

BT 130003

Stabilimento di Mulazzano
Via dell'Avventura, 89
26837 Fraz. Cassino d' Alberi (LO)

PEC: olon@pec.olonspa.it
Telefono 0302.8250.1
Fax 0302.812005

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



CERTIFICATE OF ANALYSIS

Product **ACYCLOVIR C EP7/USP34** Code N° **57560** Batch N° **1310101**

Manufacturing date **Jan 2013** Retesting date (where applicable) **Dec 2017** Expiration date (where applicable)

Analysis Number N1PF011801			
Test	Results	M.U.	Limits
Appearance			
- Appearance	White crystalline powder	--	White crystalline powder
- Colour	Not more coloured than Y7	--	Not more coloured than Y7
Solubility	Slightly soluble in water, freely soluble in dimethylsulfoxide, very slightly soluble in ethanol	--	Slightly soluble in water, freely soluble in dimethylsulfoxide, very slightly soluble in ethanol
Clarity	Clear solution	--	Clear solution
Identification			
- IR	Complies to Standard	--	Complies to Standard
- HPLC	Complies to Standard	--	Complies to Standard
Water content (K.F.)	5.0	%	4.0 + 6.0
Sulphated Ash	0.04	%	≤ 0.10
Heavy metals	<20	ppm	<20
Assay			
- Assay (HClO4) on anhydrous	99.9	%	98.5 + 101.0
- Assay (HPLC) on anhydrous	100.3	%anh	98.0 + 101.0
Related substances (HPLC)			
- Guanine	0.16	%	≤ 0.20
- Acyclovir N7 isomer	<0.0047	%	≤ 0.30
Related substances			
- EP Impurity A	<0.03	%	≤ 0.2
- EP Impurity B (Guanine)	0.14	%	≤ 0.20
- EP Impurity C	<0.03	%	≤ 0.1
- EP Impurity F	<0.03	%	≤ 0.1
- EP Impurity G	<0.03	%	≤ 0.2
- EP Impurity I + Imp. B OLON	<0.03	%	≤ 0.05
- EP J Impurity (Imp. A OLON)	<0.03	%	≤ 0.2
- EP Impurity K	<0.03	%	≤ 0.2
- EP Impurity N + Imp. C OLON	<0.03	%	≤ 0.05
- EP Impurity O	<0.03	%	≤ 0.3
- EP Impurity P (Imp. D OLON)	<0.03	%	≤ 0.2
- Each unknown impurity	<0.03	%	≤ 0.05
- Total impurities	0.2	%	≤ 1.0
Related Substances TLC			
- Acetylacyclovir	≤0.5	--	≤0.5
Density			
- Bulk density For information	0.48	g/ml	0.00 + 2.00
- Tapped density For information	0.78	g/ml	0.00 + 2.00
Residual solvents (GC)			
- Xilolo	<2	ppm	≤ 10
Foreign particles	≤ 6	ppm	≤ 6

Capitale Sociale € 40.000.000 i.v. - R.I. Milano, Cod. Fisc. e P. IVA n. 08101100157 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società Capogruppo P. & R. S.p.A.
Strada Rivoltana km 6/7 - 20060 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. n. P.I. 00551030151

Stabilimento di Mulazzano
Via dell'Avvilloria, 89
26837 Fraz. Cassino d' Alberi (LO)

PEC: olon@pec.olonspa.it
Telefono 0382.8260.1
Fax 0382.812006

Olon S.p.A.
Sede Legale
Strada Rivollana km. 6/7
Rodano (MI)



Microbiological purity			
- Total Aerobic Microbial Count (TAMC)	<5	cfu/g	≤ 500
- Total yeast and mould count (TYMC)	<5	cfu/g	≤ 50
- Bile tolerant gram negative bacteria	Absent/1g	cfu/g	Absent/1g
- P. aeruginosa	Absent/1g	u/c/g	Absent/1g
- E. coli	Absent/1g	u/c/g	Absent/1g
- S. aureus	Absent/1g	u/c/g	Absent/1g
- Salmonella	Absent/10g	u/c/g	Absent/10g

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. - Mulazzano

Date

28/01/2013

✓ CQ Manager (Roberto Quaglia)

Reviewed by Qualified Person

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
33804-340

Director Técnico