

Certificate of Analysis

Date

04.03.2015

Purchase Order No. / Date

229 / 15.01.2015

Delivery Note No.

5535000012 000010

Export No. / Date

5515000001 000010 / 15.01.2015

Customer's Code No.

618600

N. of Packages : 1 DRUM/S**ACYCLOVIR**

USP 37 EUR.PH.8 ED. IP 2015

Code N.: 00975500

Lot N.: 14100643 Quantity Delivered: 5 KG

Manufacturing Date: 07.10.2014 Retesting Date: 06.10.2019

C.E.P.: R1-CEP 2007-213-Rev 00

Analysis N.: 30000260289 Date 13.10.2014

Analytical Procedure: 148ACY-26

Solubility:

Slightly soluble in water; freely soluble in dimethyl sulphoxide; very slightly soluble in ethanol(96%); soluble in dilute solutions of mineral acids and alkali hydroxides; practically insoluble in heptane.

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Description	Complies	White or almost white crystalline powder	
IR Spectrum identification	Complies	Complies with the reference	
HPLC retention time identification	Complies	Complies with the reference	
Volumetric assay (on anhydrous)	100.1 %	99.0	101.0 %
Clarity of solution	Clear	Clear	
Colour of solution	Complies	< = 7th level EP	
HPLC Assay (on anhydrous)	99.2 %	98.0	101.0 %
HPLC Limit for guanine (acc. to US	0.06 %		0.50 %

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
HPLC Sum of impurit. excl.guanine	0.17 %		0.70 %
HPLC Eur.Ph.Imp.A	< 0.03 %		0.20 %
HPLC Eur.Ph.Imp.B	0.06 %		0.50 %
HPLC Eur.Ph.Imp.C	< 0.03 %		0.10 %
HPLC: Eur.Ph.Imp.F	0.03 %		0.10 %
HPLC: Eur.Ph.Imp.G	< 0.03 %		0.20 %
HPLC Eur.Ph.Imp. I	< 0.03 %		0.10 %
HPLC Eur.Ph.Imp. J	< 0.03 %		0.20 %
HPLC Sum of EP imp K & EP imp R	0.03 %		0.20 %
HPLC Eur.Ph.Imp. N	< 0.03 %		0.20 %
HPLC Sum of EP imp O & EP imp Q	0.04 %		0.30 %
HPLC Eur.Ph.Imp. P	< 0.03 %		0.20 %

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
HPLC Each max.unidentified	0.04 %	0.05	%
HPLC Total impurities	0.20 %	1.50	%
Water content (K.F.)	5.20 %	6.00	%
Sulphated ash	0.02 %	0.10	%
Particle size D(10%)	6 μ m	20	μ m
Particle size D(50%)	24 μ m	50	μ m
Particle size D(90%)	49 μ m	100	μ m
- Alpine sieve anal. <45 μ	80.5 %	60.0	%
- Bulk density Loose	0.53 gr/ml	0.40	0.70 gr/ml
- Bulk density Tapped	0.68 gr/ml	0.50	0.90 gr/ml
Bacterial endotoxins	< 170 eu/g	500	eu/g

No class 1 and class 3 solvents are used; class 2 solvent toluene used in the process is validated to be not present in the API hence not tested routinely

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7).

QUALITY CONTROL MANAGER

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