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Certificate of Analysis

Date
06.12.2016
Purchase Order No. / Date
218397 / 05.07.2016
Delivery Note No.
5624002303 000010
Export No. / Date
5604009441 000010 / 17.10.2016
Customer's Code No.
718470

N. of Packages: 2 DRUM/S

PAPAVERINE HYDROCHLORIDE
USP 39 EUR.PH.8 ED. JP XVI
Code N.: 07480000

Lot N.: 16100743; Quantity Delivered: 100 KG
Manufacturing Date: 23.11.2016, Retesting Date: 22.11.2021 ✓

Analysis N.: 30000310228 Date 30.11.2016
Analytical Procedure: 148PAC-13

Solubility:

Sparingly soluble in water and in chloroform; slightly soluble
in alcohol; practically insoluble in ether.

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Description	Complies	White odorless crystalline powder	
IR Spectrum identification	Complies	Complies with the reference	
UV Spectrum Identification	Complies	Complies USP	
Chlorides identification	Positive	Positive	
Eur.Ph.Assay (on dried basis)	100.4 %	99.0	101.0 %
USP Assay (on dried basis)	99.9 %	98.5	100.5 %
Loss on drying	0.08 %		0.50 %
HPLC E.P.Imp.B(PAPAVERINOL)	< 0.05 %		0.10 %



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		MIN	MAX
HPLC E.P.Imp.C(DIHYDROPAPAV)	< 0.05 %	0.10	%
HPLC E.P.Imp.D(PAPAVERALD)	< 0.05 %	0.10	%
HPLC E.P.Imp.E(TETRAHYDROPAP)	< 0.05 %	0.10	%
HPLC E.P.Imp.F	< 0.05 %	0.10	%
HPLC Each other impurity	< 0.05 %	0.10	%
HPLC Total impurities	< 0.05 %	0.50	%
Sulphated ash	0.04 %	0.10	%
pH (2% in water)	3.2 -	3.0	4.0 -
Clarity of water solution	Clear	Clear	
Colour of water solution	Complies	<= 6th level EP	
Completeness of chloroform solut.	Complies	Complete	
Readily carbonisable sub.(USP/JP)	Complies	Complies with the reference	



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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Org.res.solv.Methanol	33 ppm	100	ppm
Org.res.solv.Dimethylcarbonate	< 10 ppm	50	ppm
Particle size D(10%)	35 µm	10	50 µm
Particle size D(50%)	74 µm	20	100 µm
Particle size D(90%)	128 µm	100	400 µm
Bulk density Loose	0.61 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.72 gr/ml	0.70	0.90 gr/ml

HPLC E.P. IMP.A (NOSCAPINE): Not applicable to our process

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

QUALITY CONTROL MANAGER