



INDUSTRIA CHIMICA E FARMACEUTICA S.p.A
VIA M. CIVITALI, 1 - 20148 MILANO, ITALIA
TEL. (39) 0248787.1

MANUFACTURING SITE: CAMPOVERDE
VIA MEDIANA CISTERNA, 4
04011 CAMPOVERDE DI APRILIA (LT), ITALY
Tel. (39) 0692900010 - FAX. (39) 0692902016

Certificate of Analysis

Date
03.04.2014
Purchase Order No. / Date
2014 1728 / 13.03.2014
Delivery Note No.
5435000030 000010
Export No. / Date
5415000019 000010 / 14.03.2014
Customer's Code No.
618600

N. of Packages : 1 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 36 EUR.PH.8 ED. JP XVI

Code N.: 07480000

Lot N.: 14100192 Quantity Delivered: 25 KG

Manufacturing Date: 17.03.2014 Retesting Date: 14.03.2019

Analysis N.: 30000255787 Date 21.03.2014

Analytical Procedure: 148PAC-12

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 USP	
UV Spectrum Identification	Complies	Complies USP	
Chlorides identification	Positive	Positive	
Eur.Ph.Assay (on dried basis)	100.1 %	99.0	101.0 %
USP Assay (on dried basis)	100.4 %	98.5	100.5 %
Loss on drying	0.05 %		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	0.02 %	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	< 32 ppm		100 ppm
Org.res.solv.Dimethylcarbonate	< 10 ppm		500 ppm
Particle size D(10%)	47 μ m	10	50 μ m
Particle size D(50%)	100 μ m	20	100 μ m
Particle size D(90%)	191 μ m	100	400 μ m
Bulk density Loose	0.67 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.77 gr/ml	0.70	0.90 gr/ml
Micr.pur.:Aerobe bacteria	fcu/g		100 fcu/g
Micr.pur.:Moulds and yeast	fcu/g		100 fcu/g

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

Giuseppe B...