



INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.
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Certificate of Analysis

Date

03.07.2015

Purchase Order No. / Date

B150935 / 09.06.2015

Delivery Note No.

5524001292 000010

Export No. / Date

5504004757 000010 / 12.06.2015

Customer's Code No.

472257

N. of Packages : 1 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 37 EUR.PH.8 ED. JP XVI

Code N.: 07480000

Lot N.: 15100146 Quantity Delivered: 50 KG

Manufacturing Date: 28.02.2015 Retesting Date: 27.02.2020

Analysis N.: 30000265638 Date 10.03.2015

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)	99.6 %	99.0	101.0 %
USP Assay (on dried basis)	100.4 %	98.5	100.5 %
Loss on drying	0.04 %		0.50 %
HPLC E.P.Imp.B(PAPAVERINOL)	< 0.05 %		0.10 %



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Tel.(39) 0692900010 - FAX.(39) 0692902016

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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%)	50 μ m	10	50 μ m
Particle size D(50%)	94 μ m	20	100 μ m
Particle size D(90%)	171 μ m	100	400 μ m
Bulk density Loose	0.71 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.79 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

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