



INDUSTRIA CHIMICA E FARMACEUTICA S.p.A
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MANUFACTURING SITE: CAMPOVERDE
VIA MEDIANA CISTERNA, 4
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Certificate of Analysis

Date
23.11.2015
Purchase Order No. / Date
BI151872 / 18.11.2015
Delivery Note No.
5524002225 000010
Export No. / Date
5504009437 000010 / 18.11.2015
Customer's Code No.
472257

N. of Packages : 2 DRUM/S

PAPAVERINE HYDROCHLORIDE
USP 38 EUR.PH.8 ED. JP XVI
Code N.: 07480000
Lot N.: 15100671 Quantity Delivered: 50 KG
Manufacturing Date: 19.10.2015 Retesting Date: 17.10.2020

Analysis N.: 30000278651 Date 23.10.2015
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 with the reference	
UV Spectrum Identification	Complies	Complies USP	
Chlorides identification	Positive	Positive	
Eur.Ph.Assay (on dried basis)	100.5 %	99.0	101.0 %
USP Assay (on dried basis)	100.3 %	98.5	100.5 %
Loss on drying	0.02 %		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%)	40 μ m	10	50 μ m
Particle size D(50%)	100 μ m	20	100 μ m
Particle size D(90%)	190 μ m	100	400 μ m
Bulk density Loose	0.63 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.70 gr/ml	0.70	0.90 gr/ml

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

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

JK 27-BOJ

Director Técnico

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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