

RECORDATI
 INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.
 VIA M. GEMELLI 1 - 20148 MILANO (ITALY)
 TEL. (02) 60767
 MANUFACTURING SITE: CAMPOVERDE
 VIA MEDIANA CISTERNA 2
 01011 CAMPOVERDE DI APULIA (ITALY)
 TEL. (075) 9250010 FAX (075) 9250016

Certificate of Analysis

Date
 05.11.2018
 Purchase Order No. / Date
 3726 / 12.07.2018
 Delivery Note No.
 5824001934 000010
 Export No. / Date
 5804007808 000010 / 18.07.2018
 Customer's Code No.
 718470

N. of Packages: 4 DRUM/S

PAPAVERINE HYDROCHLORIDE
 USP 41 EUR.PH.9 ED. JP XVI
 Code N.: 07480000

Lot N.: 18100608 Quantity Delivered: 100 KG

Manufacturing Date: 22.09.2018 Retesting Date: 21.09.2023

Analysis N.: 30000375202 Date 25.09.2018

Analytical Procedure: 148PAC-14

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)	100.6 %	99.0	101.0 %
USP Assay (on dried basis)	100.5 %	98.5	100.5 %
Loss on drying	0.01 %		0.50 %
HPLC E.P.Imp.B(PAPAVERINOL)	< 0.05 %		0.10 %

**RECORDATI**

RECORDATI PHARMACEUTICALS S.p.A.
VIA M. CIVITALE 11 - 20145 MILANO (ITALY)
TEL. (02) 676771
MANUFACTURING SITE: CAMPOVERDE
VIA MEDIANA CISTERNALE 4
34071 CAMPOVERDE DI APRILIA (UD), ITALY
TEL. (0432) 9900210 - FAX (0432) 9900216

Delivery Note No.
5824001934 000010

N. of Packages : 4 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 41 EUR.PH.9 ED. JP XVI

Code N.: 07480000

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
HPLC E.P.Imp.C(DIHYDROPAPAV)	0.06 %		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	0.06 %		0.10 %
HPLC Total impurities	0.12 %		0.50 %
Sulphated ash	0.04 %		0.10 %
pH (2% in water)	3.3 -	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	



RECORDATI

RECORDATI CHIMICA FARMACEUTICA S.p.A.
VIA M. CIVITATI, 1 - 20146 MILANO (ITALY)
TEL. (02) 60000000
MANUFACTURING SITE: CAMPOVERDE
VIA MEDIANA CISTERNA, 4
06031 CAMPOVERDE DI APRILIA (LT), ITALY
TEL. (0773) 60000000 FAX (0773) 60000000

Delivery Note No.

5824001934 000010

N. of Packages : 4 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 41 EUR.PH.9 ED. JP XVI

Code N.: 07480000

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Org.res.solv.Methanol	47 ppm		100 ppm
Org.res.solv.Dimethylcarbonate	< 30 ppm		50 ppm
Particle size D(10%)	38 μ m	10	50 μ m
Particle size D(50%)	87 μ m	20	100 μ m
Particle size D(90%)	169 μ m	100	400 μ m
Bulk density Loose	0.61 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.71 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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