

Certificate of Analysis

Date

12.10.2018

Purchase Order No. / Date

2018 6196 / 18.09.2018

Delivery Note No.

5835000055 000010

Export No. / Date

5815000042 000010 / 24.09.2018

Customer's Code No.

618600

N. of Packages: 1 DRUM/S**PAPAVERINE HYDROCHLORIDE**

USP 41 EUR.PH.9 ED. JP XVI

Code N.: 07480000**Lot N.:** 18100605 **Quantity Delivered:** 25 KG**Manufacturing Date:** 17.09.2018 **Retesting Date:** 16.09.2023**Analysis N.:** 30000374255 **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)	99.9 %	99.0	101.0 %
USP Assay (on dried basis)	100.4 %	98.5	100.5 %
Loss on drying	0.02 %		0.50 %
HPLC E.P.Imp.B(PAPAVERINOL)	< 0.05 %		0.10 %

Delivery Note No.

5835000055 000010

N. of Packages : 1 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 41 EUR.PH.9 ED. JP XVI

Code N.: 07480000

Lot N.: 18100605 Quantity Delivered: 25 KG

Manufacturing Date: 17.09.2018 Retesting Date: 16.09.2023

Analysis N.: 30000374255 Date 25.09.2018

Analytical Procedure: 148PAC-14

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		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	0.01 %	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	

Delivery Note No.

5835000055 000010

N. of Packages : 1 DRUM/S

PAPAVERINE HYDROCHLORIDE

USP 41 EUR.PH.9 ED. JP XVI

Code N.: 07480000

Lot N.: 18100605 Quantity Delivered: 25 KG

Manufacturing Date: 17.09.2018 Retesting Date: 16.09.2023

Analysis N.: 30000374255 Date 25.09.2018

Analytical Procedure: 148PAC-14

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Org.res.solv.Methanol	< 32 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%)	81 μ m	20	100 μ m
Particle size D(90%)	172 μ m	100	400 μ m
Bulk density Loose	0.62 gr/ml	0.60	0.80 gr/ml
Bulk density Tapped	0.72 gr/ml	0.70	0.90 gr/ml
Micr.pur.:Aerobe bacteria	< 10 fcu/g	100	fcu/g
Micr.pur.:Moulds and yeast	< 10 fcu/g	100	fcu/g
Bacterial endotoxins	< 2100 eu/g	2190	eu/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

.....