



SYNNAT PHARMA PRIVATE LIMITED
Plot No.60A, Jawaharlal Nehru Pharma City,
Parawada Mandal, Visakhapatnam District-531019,
Andhra Pradesh, India.

Format No. : QC/GEN/34/FT-03
Effective date: 02.01.2020

CERTIFICATE OF ANALYSIS

Product Name :	Papaverine Hydrochloride Ph.Eur (Papaverine Hydrochloride Ph.Eur 10.0)	Report Date :	26.05.2022
Batch / Lot No. :	64010522	Mfg. Date :	May-22
Quantity. :	25.0 Kg	Expiry/Retest Date :	Apr-27

Test Parameter	Specification		Result
CHARACTERS			
Appearance	White or almost white, crystalline powder or white or almost white crystals.		White Powder, Complies
Solubility			
In water	Sparingly soluble in water.		Complies
In Ethanol (96%)	Slightly soluble in Ethanol (96%).		Complies
IDENTIFICATION			
A. Infrared absorption Spectrophotometry	Sample spectrum should be concordant with the spectrum of Papaverine HCl Working Standard.		Complies
B. Thin-layer chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.		Complies
C. Melting point (⁰ C)	Between 146.0 °C and 149.0 °C		146.9°C, Complies
D. Reaction of chlorides	A curdled, white precipitate is formed.		Complies
TESTS			
Appearance of solution	Solution S is clear and not more intensely colored than reference solution BY ₆ .		Complies
pH	Between 3.0 and 4.0.		3.19, Complies
Related substances, by Liquid chromatography (% w/w)	Impurity-A	Not more than 0.1 %.	*ND, Complies
	Impurity-B	Not more than 0.1 %.	*BDL, Complies
	Impurity-C	Not more than 0.1 %.	*BDL, Complies
	Impurity-D	Not more than 0.1 %.	*ND, Complies
	Impurity-E	Not more than 0.1 %.	*ND, Complies
	Impurity-F	Not more than 0.1 %.	*ND, Complies
	Any unknown impurity	Not more than 0.1 %.	*BDL, Complies
	Total Impurities	Not more than 0.5 %.	*BDL, Complies
Loss on drying (% w/w)	Maximum 0.5 %.		0.10%, Complies
Sulphated ash (% w/w)	Maximum 0.1 %.		0.01%, Complies
Assay (% w/w)	Between 99.0 % and 101.0 % (dried substance).		100.1%, Complies



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CERTIFICATE OF ANALYSIS

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Test Parameter	Specification		Result
ADDITIONAL TESTS			
Residual solvents (by GC-MS)	Chloroform	Not more than 60 ppm.	*BQL, Complies
	Toluene	Not more than 100 ppm.	3 ppm, Complies
	Mesitylene	Not more than 70 ppm.	*BQL, Complies

STORAGE: Preserve Papaverine Hydrochloride in a well-closed containers and protected from light.

REMARKS: The above batch complies/does not comply with the prescribed standards of quality as described above.

For HSGC:

*LOQ: Limit of Quantification

*BQL: Below Quantification Limit

For HPLC:

*BQL: Below Quantification limit: 0.05 %

*ND: Not Detected

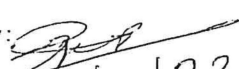
*BDL: Below detection limit

Name of the Solvent LOQ Value


Mesitylene : 2 ppm

Chloroform : 7 ppm

Toluene : 3 ppm

Prepared by: 

Date : 15/11/22

Reviewed by: 

Date : 15/11/22

Approved by: 

Date : 15/11/2022

