



CERTIFICATE OF ANALYSIS

PRODUCT PHENTOLAMINE MESYLATE Ph.Eur. PRODUCT INTERNAL CODE: 5380	MANUFACTURE DATE: December 2022
MANUFACTURED AND RELEASED IN: Industriale Chimica S.R.L - Via E.H. Grieg, 13 - 21047 Saronno (VA) - Italy Tel. +39 02 964 26411 - Fax +39 02 962 1997 www.chemogroup.com	RELEASE DATE: January 2023 RETEST DATE: December 2027
BATCH: PR222995	

TESTS	SPECIFICATIONS	RESULTS
Description	White or almost white crystalline powder, slightly hygroscopic, practically insoluble in dichloromethane.	Conforms
Identification		
Melting point	Positive	Positive °C
UV	Positive	Positive
IR	Positive	Positive
Acidity	Conforms	Conforms
Loss on drying	<= 0.5 %	0.07 %
Sulphated ash/residue on ignition	<= 0.1 %	0.01 %
Related substances		
Impurity A (Ph. Eur.)	<= 0.2 %	< 0.05 %
Impurity B (Ph. Eur.)	<= 0.10 %	< 0.05 %
Impurity C (Ph.Eur.)	<= 0.10 %	< 0.05 %
Any unspecified impurities (max value) (Ph. Eur.)	<= 0.10 %	< 0.05 %
Total impurities (Ph. Eur.)	<= 0.5 %	< 0.05 %
Residual solvents		
Methanol	<= 1000 ppm	< 25 ppm
Isopropyl alcohol	<= 5000 ppm	2300 ppm
Ethyl acetate	<= 5000 ppm	1264 ppm
Toluene	<= 890 ppm	< 25 ppm
Xylene	<= 1000 ppm	< 25 ppm
n-Methyl pyrrolidone	<= 530 ppm	< 50 ppm
Total solvents	<= 5000 ppm	3564 ppm
Titrimetric assay	[98.0 - 101.0] % calculated on the dried basis	99.9 %

HANDLING PROCEDURES - Storage

Preserve in well-closed, light-resistant containers. Store at USP controlled room temperature.

The manufacturing, packaging, and testing of this batch was performed according to GMPs requirements (ref. ICH Q7 - EU GMP Guide Vol. 4 Part II)



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BATCH RELEASED BY
dr. Stefano Frattini ON
2023-01-11 10:07:31

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