



CERTIFICATE OF ANALYSIS

C220920002

PRODUCT PHENTOLAMINE MESYLATE Ph.Eur. PRODUCT INTERNAL CODE: 5380	MANUFACTURE DATE: July 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: September 2022
BATCH: PR221853	RETEST DATE: July 2027

TESTS	SPECIFICATIONS	RESULTS
Description	White or almost white crystalline powder, slightly hygroscopic, practically insoluble in dichloromethane.	Conforms
Melting point	Positive	Positive °C
UV	Positive	Positive
IR	Positive	Positive
Acidity	Conforms	Conforms
Loss on drying	≤ 0.5 %	0.27 %
Sulphated ash/residue on ignition	≤ 0.1 %	0.01 %
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 %
Methanol	≤ 1000 ppm	< 25 ppm
Isopropyl alcohol	≤ 5000 ppm	101 ppm
Ethyl acetate	≤ 5000 ppm	1813 ppm
Toluene	≤ 890 ppm	< 25 ppm
Xylene	≤ 1000 ppm	< 25 ppm
n-Methyl pyrrolidone	≤ 530 ppm	< 50 ppm
Total solvents	≤ 5000 ppm	1914 ppm
Benzene	≤ 2 ppm	< 2 ppm
Isopr. methansulf. ester	≤ 5 ppm	< 5 ppm
Titrimetric assay	[98.0 - 101.0] % calculated on the dried basis	98.4 %

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)

CERTIFICATE GENERATED AUTOMATICALLY

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BATCH: PR221853		
TESTS	SPECIFICATIONS	RESULTS

BATCH RELEASED BY
dr. Marco Radice ON
2022-09-16 14:12:39

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 GMP requirements (ref. ICH Q7 - EU GMP Guide Vol. 4 Part II)