

# CERTIFICATE OF ANALYSIS

|                                                                                                                                                                                      |                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| PRODUCT <b>PHENTOLAMINE MESYLATE Ph.Eur.</b><br>PRODUCT INTERNAL CODE: <b>5380</b>                                                                                                   | MANUFACTURE DATE:<br>May 2024                         |
| MANUFACTURED AND RELEASED IN:<br>Industriale Chimica S.R.L - Via E.H. Grieg, 13 - 21047 Saronno<br>(VA) - Italy<br>Tel. +39 02 964 26411 - Fax +39 02 962 1997<br>www.chemogroup.com | RELEASE DATE:<br>May 2024<br>RETEST DATE:<br>May 2029 |
| BATCH: <b>PR241212</b>                                                                                                                                                               |                                                       |

| 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 %                                                                                                  | 0.32 %      |
| Sulphated ash/residue on ignition                 | <= 0.1 %                                                                                                  | 0.06 %      |
| 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                                                                                               | 2409 ppm    |
| Ethyl acetate                                     | <= 5000 ppm                                                                                               | 309 ppm     |
| Toluene                                           | <= 890 ppm                                                                                                | < 25 ppm    |
| Xylene                                            | <= 1000 ppm                                                                                               | < 25 ppm    |
| n-Methyl pyrrolidone                              | <= 530 ppm                                                                                                | < 50 ppm    |
| Total solvents                                    | <= 5000 ppm                                                                                               | 2718 ppm    |
| Benzene                                           | <= 2 ppm                                                                                                  | < 2 ppm     |
| Isopr. methansulf. ester                          | <= 5 ppm                                                                                                  | < 5 ppm     |
| Titrimetric assay                                 | [98.0 - 101.0] %<br>calculated on the dried basis                                                         | 99.4 %      |

## 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)

**METAPHARMACEUTICAL**

N DE LOTE:

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CERTIFICATE GENERATED AUTOMATICALLY

rinted by B. Di Vincenzo on 2024-08-28 17:13:00

*[Signature]*  
16/09/2024  
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| BATCH: <b>PR241212</b>                                                                                                                                                               |                                                       |

| TESTS | SPECIFICATIONS | RESULTS |
|-------|----------------|---------|
|-------|----------------|---------|

BATCH RELEASED BY  
dr. Stefano Frattini ON  
2024-05-20 15:58:10

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