



INDUSTRIA CHIMICA E FARMACEUTICA S.p.A  
VIA M. CIVITALI, 1 - 20148 MILANO, ITALIA  
TEL. (39) 0248787.1

MANUFACTURING SITE: CAMPOVERDE  
VIA MEDIANA CISTERNA, 4  
04011 CAMPOVERDE DI APRILIA (LT), ITALY  
Tel.(39) 0692900010 - FAX.(39) 0692902016

## Certificate of Analysis

Date  
23.11.2015  
Purchase Order No. / Date  
BI151872 / 18.11.2015  
Delivery Note No.  
5524002225 000010  
Export No. / Date  
5504009437 000010 / 18.11.2015  
Customer's Code No.  
472257

N. of Packages: 2 DRUM/S

**PAPAPERINE HYDROCHLORIDE**  
USP 38 EUR.PH.8 ED. JP XVI  
Code N.: 07480000  
Lot N.: 15100671 Quantity Delivered: 50 KG  
Manufacturing Date: 19.10.2015 Retesting Date: 17.10.2020

Analysis N.: 30000278651 Date 23.10.2015  
Analytical Procedure: 148PAC-12

### 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) | 100.5 %  | 99.0                              | 101.0 % |
| USP Assay (on dried basis)    | 100.3 %  | 98.5                              | 100.5 % |
| Loss on drying                | 0.02 %   |                                   | 0.50 %  |
| HPLC E.P.Imp.B(PAPAPERINOL)   | < 0.05 % |                                   | 0.10 %  |



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| 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                     | 0.02 %   | 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 |       |



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| ANALYTICAL TESTS               | RESULTS     | SPECIFICATIONS |             |
|--------------------------------|-------------|----------------|-------------|
|                                |             | MIN            | MAX         |
| Org.res.solv.Methanol          | < 32 ppm    |                | 100 ppm     |
| Org.res.solv.Dimethylcarbonate | < 10 ppm    |                | 500 ppm     |
| Particle size D(10%)           | 40 $\mu$ m  | 10             | 50 $\mu$ m  |
| Particle size D(50%)           | 100 $\mu$ m | 20             | 100 $\mu$ m |
| Particle size D(90%)           | 190 $\mu$ m | 100            | 400 $\mu$ m |
| Bulk density Loose             | 0.63 gr/ml  | 0.60           | 0.80 gr/ml  |
| Bulk density Tapped            | 0.70 gr/ml  | 0.70           | 0.90 gr/ml  |

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

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