

Certificate of Analysis No. 01/25/LT/Armila/K

Product: PROCAINE HYDROCHLORIDE

Batch No.: 2404056

Quantity: 1 x 100 g

Producer: CHONGQING SOUTHWEST

Methods of analysis: Ph. Eur. 11.0 (01:2017:0050)

Expiry date: 24.04.2028

Results of analysis:

| Parameter | | Specification | Result |
|----------------|-------------------------------------|--|-----------|
| Characters | | A white or almost white, crystalline powder or colourless crystals, very soluble in water, soluble in ethanol (96 per cent). | Confirmed |
| Identification | A. Melting point [°C] | 154 – 158 | 155.1 |
| | B. IR absorption | Positive | Confirmed |
| | C. Colour reaction | Positive | Confirmed |
| | D. Colour discharged reaction | Positive | Confirmed |
| | E. Reaction of chlorides | Positive | Confirmed |
| | F. Primary aromatic amines reaction | Positive | Confirmed |

Decision:

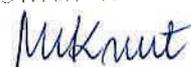
This batch of pharmaceutical raw material meets/does not meet the requirements of Ph. Eur. 11.0*

Check
(Laboratory Manager):

Z-ca Kierownika Laboratorium

mgr Grzegorz Piątek

Accept
(Quality Manager):

Kierownik Kontroli Jakości

mgr inż. Katarzyna Mikuł

* cross out needless

Certificate of Analysis No. 01/25/LT/Armila

Product: PROCAINE HYDROCHLORIDE

Batch No.: 2404056

Quantity: 50.0 kg

Producer: CHONGQING SOUTHWEST

Methods of analysis: Ph. Eur. 11.0 (01:2017:0050)

Expiry date: 24.04.2028

Results of analysis:

| Parameter | | Specification | Result |
|----------------|-------------------------------------|--|-----------|
| Characters | | A white or almost white, crystalline powder or colourless crystals, very soluble in water, soluble in ethanol (96 per cent). | Confirmed |
| Identification | A. Melting point [°C] | 154 – 158 | 155.3 |
| | B. IR absorption | Positive | Confirmed |
| | C. Colour reaction | Positive | Confirmed |
| | D. Colour discharged reaction | Positive | Confirmed |
| | E. Reaction of chlorides | Positive | Confirmed |
| | F. Primary aromatic amines reaction | Positive | Confirmed |
| Tests | Appearance of solution | Solution S is clear and colourless | Confirmed |
| | pH | 5.0 – 6.5 | 5.4 |
| | Related substances | Complies | Confirmed |
| | Loss on drying [%] | ≤ 0.5 | 0.0 |
| | Sulphated ash [%] | ≤ 0.1 | 0.03 |
| Assay [%] | | 99.0 – 101.0 | 100,7 |

Decision:

This batch of pharmaceutical raw material meets/does not meet the requirements of Ph. Eur. 11.0*

**Check
(Laboratory Manager):**

Z-ca Kierownika Laboratorium

mgr Grzegorz Piatek

**Accept
(Quality Manager):**

Kierownik Kontroli Jakości

mgr Inż. Katarzyna Mikrut

* cross out needless