

Geldig van 27 DEC 2018
tot 27 DEC 2021

QUALITY CONTROL DEPARTMENT

HYOSCINI HYDROBROMIDUM
ANALYSIS REPORT: 21C10-APR21091

| | | | |
|-------------------|----------------|----------------------|------------------------------|
| AUTHORISATION | 1890R05988 | DATE OF ANALYSIS | 20/11/2020 |
| LOT NUMBER | 21C10-APR21091 | EXPIRY DATE | 05/2025 |
| PRODUCTION NUMBER | 300421-GS20119 | ANALYTICAL REFERENCE | PH. EUR. 10.0 [01/2008:0106] |

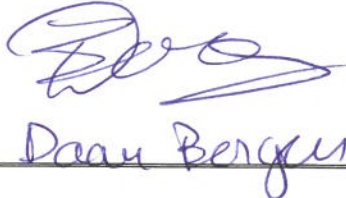
ANALYTICAL TESTS

| CHARACTERS | SPECIFICATION | RESULT |
|---------------------------|--|----------|
| Appearance | White or almost white, crystalline powder or colourless crystals, efflorescent | Complies |
| IDENTIFICATION | SPECIFICATION | RESULT |
| Identification B | The spectrum complies with the spectrum obtained with <i>hyoscine hydrobromide CRS</i> | Complies |
| Identification E | It gives reaction (a) of bromides | Complies |
| TESTS | SPECIFICATION | RESULT |
| pH | 4.0 to 5.5 | 5.0 |
| Specific optical rotation | - 24 to -27 | - 26 |
| Related substances | | |
| Impurity B | ≤ 0.5% | 0.1% |
| Impurity A | ≤ 0.1% | < 0.1% |
| Impurity C | ≤ 0.1% | < 0.1% |
| Impurity D | ≤ 0.1% | < 0.1% |
| Any other impurity | ≤ 0.1% | 0.0% |
| Total | ≤ 0.7% | 0.1% |
| Water | 10.0% to 13.0% | 12.1% |
| Sulfated ash | ≤ 0.1% | 0.1% |
| ASSAY | SPECIFICATION | RESULT |
| Potentiometric titration | 99.0% to 101.0% (anhydrous substance) | 100.1% |

CONCLUSION:

COMPLIES

RESPONSIBLE PHARMACIST:



Dean Bergem

DATE:

17/05/21