

AMITRIPTYLINI HYDROCHLORIDUM 5 g

Lot No.: 24I09-F240125

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|-----------------------|------------------------|--------------------|----------------|
| Authorisation: | 1890R05756 | Date Of Analysis: | 26/07/2024 |
| Analytical Reference: | Ph.Eur. [01/2017:0464] | Production Number: | 230924-G240052 |
| CNK: | 3968-955 | Expiry Date: | 01/2029 |

ANALYTICAL TESTS

| CHARACTERS | SPECIFICATION | RESULT |
|------------------------|---|----------|
| Appearance | White or almost white powder or colourless crystals | Complies |
| IDENTIFICATION | SPECIFICATION | RESULT |
| Identification A | The spectrum complies with the spectrum obtained with amitriptyline hydrochloride CRS | Complies |
| Identification B | Reaction (a) of chlorides | Complies |
| TESTS | SPECIFICATION | RESULT |
| Appearance of solution | Clear and not more intensely coloured than reference solution B ₇ | Complies |
| Acidity or alkalinity | Solution should be yellow with NaOH and red with HCl | Complies |
| Related substances | | |
| Impurity B | ≤ 0.1% | < 0.05% |
| Impurity A | ≤ 0.05% | < 0.05% |
| Unspecified impurities | ≤ 0.10% | < 0.05% |
| Total | ≤ 0.3% | < 0.05% |
| Loss on drying | ≤ 0.5% | < 0.5% |
| Sulfated ash | ≤ 0.1% | < 0.1% |
| ASSAY | SPECIFICATION | RESULT |
| Titration | 99.0% to 101.0% | 100.9% |

Manufacturer identification code: S/GS/082

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: