

**BENZALKONII CHLORIDUM 25 g**
**Lot No.: 24C27-APR24064**

|                        |  |                     |                |
|------------------------|--|---------------------|----------------|
| Autorisation :         | 1890R05662                               | Date Of Analysis :  | 20/09/2023     |
| Analytical Reference : | Ph. Eur. 10.8 [04/2009 :0372] Corr. 10.4 | Production Number : | 270324-GS23091 |
| CNK :                  | 3463-197                                 | Expiry Date :       | 03/2027        |

**ANALYTICAL TESTS**

| CHARACTERS | SPECIFICATION   | RESULT   |
|------------|---|----------|
| Appearance | White or yellowish-white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass. | Complies |

| IDENTIFICATION   | SPECIFICATION  | RESULT   |
|------------------|--|----------|
| Identification B | The principal peaks in the chromatogram obtained with the test solution are similar in retention time to the principal peaks in the chromatogram obtained with the reference solution. | Complies |

|                  |                                 |          |
|------------------|---------------------------------|----------|
| Identification E | Gives reaction (a) of chlorides | Complies |
|------------------|---------------------------------|----------|

| TESTS | SPECIFICATION | RESULT |
|-------|---------------|--------|
|-------|---------------|--------|

|                        |  |          |
|------------------------|--|----------|
| Appearance of solution | Clear and not more intensely coloured than reference solution Y <sub>6</sub> . | Complies |
|------------------------|--|----------|

|                       |                                     |          |
|-----------------------|-------------------------------------|----------|
| Acidity or alkalinity | ≤ 0.1 mL of 0.1 M HCl or 0.1 M NaOH | Complies |
|-----------------------|-------------------------------------|----------|

|   |  |  |
|---|--|--|
| Average relative molecular mass and ratio of alkyl components |  |  |
|---|--|--|

|                           |       |     |
|---------------------------|-------|-----|
| C <sub>12</sub> homologue | ≥ 40% | 71% |
|---------------------------|-------|-----|

|                           |       |     |
|---------------------------|-------|-----|
| C <sub>14</sub> homologue | ≥ 20% | 29% |
|---------------------------|-------|-----|

|   |       |      |
|---|-------|------|
| Sum of C <sub>12</sub> and C <sub>14</sub> homologues | ≥ 70% | 100% |
|---|-------|------|

|                       |  |  |
|-----------------------|--|--|
| Impurities A, B and C |  |  |
|-----------------------|--|--|

|            |        |        |
|------------|--------|--------|
| Impurity A | ≤ 0.5% | < 0.5% |
|------------|--------|--------|

|            |         |         |
|------------|---------|---------|
| Impurity B | ≤ 0.15% | < 0.15% |
|------------|---------|---------|

|            |         |         |
|------------|---------|---------|
| Impurity C | ≤ 0.05% | < 0.05% |
|------------|---------|---------|

|                        |   |          |
|------------------------|---|----------|
| Amines and amine salts | Potentiometric titration curve complies | Complies |
|------------------------|---|----------|

|       |       |      |
|-------|-------|------|
| Water | ≤ 10% | 1.3% |
|-------|-------|------|

|              |        |      |
|--------------|--------|------|
| Sulfated ash | ≤ 0.1% | 0.0% |
|--------------|--------|------|

| ASSAY | SPECIFICATION | RESULT |
|-------|---------------|--------|
|-------|---------------|--------|

|           |   |        |
|-----------|---|--------|
| Titration | 95.0% to 104.0% of alkylbenzyltrimethylammonium chlorides (anhydrous substance) | 101.0% |
|-----------|---|--------|

|  |  |  |
|--|--|--|
| Manufacturer identification code: S/GS/122 |  |  |
|--|--|--|

**CONCLUSION: COMPLIES**
**RESPONSIBLE PHARMACIST:**

Maxime Brits (Signature)  
2024.06.06 13:45:41  
+02'00'



DISTRIBUIDO POR  
METAPHARMACEUTICAL  
INDUSTRIAL SLU

01 OCT 2024



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