

**UNILAB CHEMICALS & PHARMACEUTICALS PVT. LTD.**

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NAME OF FINISHED PRODUCT	: BENZALKONIUM CHLORIDE BP		
MANUFACTURED BY	: UNILAB CHEMICALS & PHARMACEUTICALS PVT. LTD.		
BATCH NO.	: B/050/23	A.R. NO.	: BD/051/23
MANUFACTURING DATE	: April 2023	QTY. MFGD.	: 500 Kg
EXPIRY DATE	: March 2026	QTY. SAMPLED	: 100 g
DATE OF RECEIPT	: 15/04/23	SAMPLED BY	: Sarita

**CERTIFICATE OF ANALYSIS**

(THE DRUGS &amp; COSMETICS ACT 1940 &amp; THE RULES THERE UNDER)

TESTS	REQUIREMENTS	RESULT
Appearance	White or yellowish-white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass.	Yellowish-white gelatinous, hygroscopic. On heating it forms a clear molten mass.
Solubility	Very soluble in water and in ethanol (96%). An aqueous solution froths copiously when shaken.	Complies
Identification	To Comply the BP tests. B. HPLC test E. Chloride test	B. Positive E. Positive
Appearance of solution	1% w/v solution in CO <sub>2</sub> free water is clear and not more intensely coloured than reference solution Y6.	Complies
Acidity/alkalinity	Not more than 0.1 ml of 0.1M HCl or 0.1M NaOH is required to change the colour.	0.08 ml of 0.1M HCl
Average relative molecular mass and ratio of alkyl components	C <sub>12</sub> H <sub>25</sub> homologue: Minimu 40% C <sub>14</sub> H <sub>29</sub> homologue: Minimu 20% Sum of C <sub>12</sub> H <sub>25</sub> & C <sub>14</sub> H <sub>29</sub> homologue: Minimum 70%	C <sub>12</sub> H <sub>25</sub> homologue: 71.79% C <sub>14</sub> H <sub>29</sub> homologue: 28.21% Sum of C <sub>12</sub> H <sub>25</sub> & C <sub>14</sub> H <sub>29</sub> homologue: 99.99%
Impurity A (Benzyl alcohol)	Not more than 0.50%	0.014%
Impurity B (Benzaldehyde)	Not more than 0.15%	Not detected
Impurity C (Chloromethyl)Benzene	Not more than 0.05%	Not detected
Amines & amine salts	Not more than 5 ml of 0.1N tetrabutyl ammonium hydroxide added between two inflection points.	2.21 ml
Water	Not more than 10.0%, determined on 0.3 g	2.15%
Sulphated ash	Not more than 0.1%, determined on 1.0 g	0.04%
Assay	Not less than 95.0% and not more than 104.0% of alkylbenzyltrimethylammonium chlorides (anhydrous substance) calculated using the average relativemolecular mass	102.6%

**Remarks :** The material Complies with BP Specifications.

ANALYSED BY	:  Sarita (Q.C Chemist)	APPROVED BY	:  Ashvini (Q.C Manager)	AUTHORISED BY	:  Pradip Kumar (Q.A Manager)
DATE	: 25/04/23	DATE	: 25/04/23	DATE	: 25/04/23

