

## Certificate of Analysis

**Product name:** **Benzalkonii chloridum**

**Batch number / Weight:** **20K23-B02-200991 / 10 G**

**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellowish-)white powder or gelatinous,	Conform		Dependent on temperature !
Identification E	White	Conform		Chloride
Appearance of solution	Clear / $\leq Y_6$	Conform		1% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Average rel. molecular mass and	C12 $\geq 40$	64,6	%	HPLC
Average rel. molecular mass and	C14 $\geq 20$	35,4	%	HPLC
Ratio of alkyl components	C12 + C14 $\geq 70$	100,0	%	
Impurity A	$\leq 0,5$	0,05	%	
Impurity B	$\leq 0,15$	0,011	%	
Impurity C	$\leq 0,05$	0,016	%	
Amines and amine salts	Conform	Conform		
Water (Karl Fischer)	$\leq 10$	4,95	%	
Sulphated ash	$\leq 0,1$	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Benzalkonium chloride	95,0 - 104,0	97,83	% <i>m/m</i>	Anhydrous
Total aerobic microbial count (TA)	$\leq 10$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 1$	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Remark	Use only as excipient!			

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

18-12-2020

Expiration: 31-08-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.