

Certificate of Analysis

Productname: Benzalkonii chloridum

Inspection No: J10538/1222/536
Batchnumber: 22J11-T04-099549
Expiration date: 31.08.2024
Analysed according to: ČL 2017-Dopl.2021,Ph.Eur.10.4

Customer: FAGRON a.s.
Sample Unit: 1 x 5 g
Batch Size: 69 x 25 g

Batch no. of vendor: BCCG4479

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	(Yellowish)white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification B	Conform	Conform		Chromatotograms
Identification E	Conform	Conform		Chlorides
TESTS				
Appearance of solution	Clear,<=Y6	Conform		
Acidity or alkalinity	Conform	Conform		
Aver.rel.mol.mass,rat.of alkyl.com.	Conform	Conform		HPLC
C12 homologue	>=40	68	%	
C14 homologue	>=20	32	%	
sum of C12 and C14 homologues	>=70	100	%	
Impurities A, B and C	Conform	Conform		HPLC
Impurity A	<=0,5	<0,5	%	
Impurity B	<=0,15	<0,15	%	
Impurity C	<=0,05	<0,05	%	
Amines and amine salts	Conform	Conform		
Water (Karl Fischer)	<=10	5	%	
Sulfated ash	<=0,1	<0,1	%	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	CPMP/ICH/82 260/2006	Conform		
Metallic residues	ICH Q3D on elemental impurities	Conform		
ASSAY				
Benzalkonium chloride	95,0 - 104,0	100,2	%	Anhydrous

Quality: Excipient

Performed by: Ekocentrum
Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP
Date: 08.12.2022

Conclusion: **APPROVED**

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

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