

## Certificate of Analysis

**Productname:** Benzalkonii chloridum

**Inspection No:** J10535/0123/536  
**Batchnumber:** 22J11-T04-100060  
**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:** 149 x 10 g

**Batch no. of vendor:** BCCG4479

	Requirement	Result	Unit	Standard remark
<b>CHARACTERS</b>				
Appearance	(Yellowish)white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass.	Conform		
Solubility	Conform	Conform		
<b>IDENTIFICATION</b>				
Identification B	Conform	Conform		Chromatotograms
Identification E	Conform	Conform		Chlorides
<b>TESTS</b>				
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		
<b>ASSAY</b>				
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**

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<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521