

## Certificate of Analysis

**Productname:** Benzalkonii chloridum

**Inspection No:** I05414/0721/536  
**Batchnumber:** 20K23-B02-089504  
**Expiration date:** 31.08.2023  
**Analysed according to:** Ph.Eur.10.4  
**Original Manuf. Date:** 5.9.2020

**Sample Unit:** 1 x 5 g  
**Batch Size:** 86 x 10 g

**Identification of producer:** V00499  
**Batch no. of vendor:** BCCD6537

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	(Yellowish)white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
Identification B	Conform	Conform		Chromatotograms	Contract Lab
Identification E	Conform	Conform		Chlorides	Fagron CZ
<b>TESTS</b>					
Appearance of solution	Clear, <=Y6	Conform			Fagron CZ
Acidity or alkalinity	Conform	Conform			Fagron CZ
Aver.rel.mol.mass, rat. of alkyl. com.	Conform	Conform		HPLC	Contract Lab
C12 homologue	>=40	78	%		Contract Lab
C14 homologue	>=20	22	%		Contract Lab
sum of C12 and C14 homologues	>=70	100	%		Contract Lab
Impurities A, B and C	Conform	Conform		HPLC	Fagron PL
Impurity A	<=0,5	0,05	%		Fagron PL
Impurity B	<=0,15	0,011	%		Fagron PL
Impurity C	<=0,05	0,016	%		Fagron PL
Amines and amine salts	Conform	Conform			Fagron CZ
Water (Karl Fischer)	<=10	5,5	%		Fagron CZ
Sulfated ash	<=0,1	0	%		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
<b>ASSAY</b>					
Benzalkonium chloride	95,0 - 104,0	97,8	%	Anhydrous	Fagron PL

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

**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Pavel Mišák, QC  
PharmDr. Ivana Urbánková, QA  
**Date:** 11.08.2021  
**Conclusion:** **APPROVED**

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