



Certificate of Analysis

Productname: Benzalkonii chloridum

Inspection No: J07461/0622/536

Batchnumber: 22G18-T06-097994

Expiration date: 31.08.2024

Analysed according to: ČL 2017-Dopl.2021, Ph.Eur.10.4

Original Manuf. Date: 4.9.2021

Sample Unit: 1 x 5 g

Batch Size: 28 x 25 g

Identification of producer: V00363

Batch no. of vendor: BCCG4477

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Yellowish)white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification B	Conform	Conform		Chromatotograms	Contract Lab
Identification E	Conform	Conform		Chlorides	Contract Lab
TESTS					
Appearance of solution	Clear,<=Y6	Conform			Contract Lab
Acidity or alkalinity	Conform	Conform			Contract Lab
Aver.rel.mol.mass, rat. of alkyl.com.	Conform	Conform		HPLC	Contract Lab
C12 homologue	>=40	70	%		Contract Lab
C14 homologue	>=20	30	%		Contract Lab
sum of C12 and C14 homologues	>=70	100	%		Contract Lab
Impurities A, B and C	Conform	Conform		HPLC	Contract Lab
Impurity A	<=0,5	<0,5	%		Contract Lab
Impurity B	<=0,15	<0,15	%		Contract Lab
Impurity C	<=0,05	<0,05	%		Contract Lab
Amines and amine salts	Conform	Conform			Contract Lab
Water (Karl Fischer)	<=10	5	%		Contract Lab
Sulfated ash	<=0,1	0,1	%		Contract Lab
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
ASSAY					
Benzalkonium chloride	95,0 - 104,0	96,5	%	Anhydrous	Contract Lab

Quality: Excipient

Performed by: Ekocentrum

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QP

Date: 24.08.2022

Conclusion: **APPROVED**

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