

## Certificate of Analysis

**Productname:** Aqua conservata/Konserviertes Wasser DAC  
**Inspection No:** H08209/0720/536 **Sample Unit:** 1 x 250 ml  
**Batchnumber:** 20C19-T15-077818 **Batch Size:** 20 x 5 l  
**Expiration date:** 30.06.2022  
**Analysed according to:** DAC 2018

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear and colourless liquid.	Conform			
Odour (2.3.4)	Odour of Alkyl-4-hydroxybenzoates.	Conform			
IDENTIFICATION					
B.Chrom.of Alkyl-4-hydroxybenzoates	Conform	Conform		HPLC	
TESTS					
Appearance (2.2.1), (2.2.2)	Clear, colourless	Conform			
pH (2.2.3)	5,0 - 6,5	5,3			
4-hydroxybenzoic acid (2.2.29)	Conform	Conform		HPLC	
Microbiology	Conform	Conform			
TAMC	$\leq 2 \times 10^2$	Conform	CFU/g		
TYMC	$\leq 2 \times 10^1$	Conform	CFU/g		
Pseudomonas aeruginosa	negative/1g	Conform			
Staphylococcus aureus	negative/1g	Conform			
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/2006	Conform			
ASSAY					
Propyl 4-hydroxybenzoate	0,024 - 0,026	0,025	%	HPLC	
Methyl 4-hydroxybenzoate	0,071 - 0,079	0,076	%	HPLC	

**Performed by:** Mgr. Zdeňka Šinclová  
**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
 PharmDr. Ivana Urbánková, QA



**Date:** 03.09.2020

**Conclusion:** APPROVED

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