

Certificate of Analysis

Productname: Aqua conservata/Konserviertes Wasser DAC

Inspection No: I04315/0521/536
Batchnumber: 21B16-T07-086471
Expiration date: 31.05.2023
Analysed according to: DAC 2018

Sample Unit: 1 x 250 ml
Batch Size: 418 x 1 l

Identification of producer: V01454
Batch no. of vendor: 21B16-T07

	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	5,6			
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	0,024	%	HPLC	
Methyl 4-hydroxybenzoate	0,071 - 0,079	0,074	%	HPLC	

Performed by: Jitka Spáčilová

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


Date: 03.06.2021

Conclusion: APPROVED

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