

Certificate of Analysis

Productname: Ichthammolum

Inspection No: I01732/0321/536
Batchnumber: 20C23-T20-085055
Expiration date: 31.12.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 10.4.2019

Sample Unit: 1 x 50 g
Batch Size: 60 x 50 g

Identification of producer: V00662
Batch no. of vendor: 0070120415Ö1/20

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Dense, blackish-brown liquid.	Conform			
Solubility	Conform	Conform			
IDENTIFICATION					
Identification A	Conform	Conform		Precipitate	
Identification B	Conform	Conform		Ammonium salts	
Identification C	Conform	Conform		Sulfate	
TESTS					
Acidity or alkalinity	Conform	Conform			
Relative density	1,040 - 1,085	1,055		50% V/V	
Sulfated ash	≤0,3	0	%		
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			
ASSAY					
Dry matter	50,0 - 56,0	52,5	%	105°C	
Total ammonia	4,5 - 7,0	5,7	%	Dried	
Organically combined sulfur	≥10,5	15,0	%	Dried	
Sulfur in the form of sulfate	≤20,0	14,8	%		

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
 PharmDr. Ivana Urbánková, QA

Date: 29.03.2021

Conclusion: APPROVED

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