

Certificate of Analysis

Productname: Ichthammolum

Inspection No: I01880/0321/536
Batchnumber: 20C23-T20-084771
Expiration date: 31.12.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.1.2020

Sample Unit: 1 x 10 g
Batch Size: 100 x 50 g

Identification of producer: V00662
Batch no. of vendor: 007012041501/20

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

Parameter correction

Performed by: Lucie Kubáňová DiS.

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

Date: 16.03.2021

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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