



Certificate of Analysis

Productname: Ichthammolum

Inspection No: K09966/0424/536
Batchnumber: 23J26-T02-110203
Expiration date: 02.01.2029
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 31.3.2023

Sample Unit: 1 x 10 g
Batch Size: 138 x 50 g

Identification of producer: V01339
Batch no. of vendor: 0/10323415O2/23

| | 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 | 1,051 | | 50% V/V | Fagron CZ |
| Sulfated ash | <=0,3 | 0,0 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 10 ³ | <10 | CFU/g | | Contract Lab |
| TYMC | <=2 x 10 ² | <10 | CFU/g | | Contract Lab |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | Data Producer |
| Residual solvents | ICH Q3C | Conform | | | Data Producer |
| Metallic residues | ICH Q3D | Conform | | | Data Producer |
| ASSAY | | | | | |
| dry matter | 50,0 - 56,0 | 52,2 | % | 105°C | Fagron CZ |
| total ammonia | 4,5 - 7,0 | 5,1 | % | Dried | Fagron CZ |
| organically combined sulfur | >=10,5 | 11,2 | % | Dried | Fagron CZ |
| sulfur in the form of sulfate | <=20,0 | 18,6 | % | | Fagron CZ |

Quality: API

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| 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 |

Performed by: Ing. Petra Drábková

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 19.01.2024

Conclusion: **APPROVED**

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