



Sophix Natural

And Agro Products Ltd

RC-1615742

CERTIFICATE OF ANALYSIS

Product Name: Ichthammol Gel 10% w/w

CAS NUM.: 8029-68-3

Reference Standards: European Pharmacopoeia 11.0 (Ph. Eur. 11.0), ICH Q3D (Elemental Impurities)

1. Analysis of key physical and chemical indicators

Parameter	Specification	Result	Method	Compliance
Ichthammol Content	9.5-10.5% w/w	10.2%	HPLC-UV	Ph. Eur. 2.2.29
pH Value	4.0-5.5	4.8	Potentiometry	Ph. Eur. 2.2.3
Viscosity (25°C)	5000-8000 mPa·s	7200 mPa·s	Rotational Rheometer	ISO 2555
Water Content	≤5.0%	3.2%	Karl Fischer Titration	Ph. Eur. 2.5.12
Homogeneity	Uniform dispersion	Compliant	Visual & Microscopy	EU GMP Annex 1

2. Purity and impurity control

Impurity Type	Limit	Result	Method
Sulfated Ash	≤0.5%	0.18%	Ph. Eur. 2.4.14
Heavy Metals (Total)	≤10 ppm	<5 ppm	ICP-MS 6,8
Lead (Pb)	≤0.5 ppm	<0.1 ppm	ICH Q3D (Class 1)
Mercury (Hg)	≤0.1 ppm	<0.01 ppm	ICH Q3D (Class 1)
Residual Solvents	ICH Q3C Class 2 Limit	Not Detected	GC-FID 8

3. Microbiological safety and stability

Test	Acceptance Criteria	Result	Method
Total Aerobic Count	≤10 ² CFU/g	<10 CFU/g	Ph. Eur. 2.6.12
Yeast & Mould	≤10 ¹ CFU/g	<5 CFU/g	Ph. Eur. 2.6.13
E. coli / Salmonella	Absent in 1g	Absent	ISO 6579/21528
Stability (40°C/75% RH)	3 months: No degradation	Compliant	ICH Q1A(R2)

4. Declaration and Certification

Compliance Statement:

This batch of products complies with the following regulatory requirements:

EU Directive 2001/83/EC (Directive on Medicinal Products for Human Use)

EU GMP Annex 1: Sterile Products (Applicable provisions for non-sterile preparations)

ISO 22716:2007 (Cosmetic GMP, applicable to topical preparations)

ICH Q6A (Guidelines for the Development of Quality Standards)

Certification: Verified by Sophix Natural Agro & Products Ltd.