ÖSTERREICHISCHE
ICHTHYOL GESELLSCHAFT m.b.H.
nunmehr KG

CERTIFICATE OF ANALYSIS

ICHTHAMMOL® PH. EUR. (BP)

Description: **ICHTHAMMOL® PH. EUR. (including BP)**

Manufacture in accordance with the WHO-Guidelines for Good Manufacturing Practice (GMP), certificate available

complying with article 46f of Directive 2001/83/EC and 50f of Directive 2001/82/EC (amended by Directives 2004/27/EC and 2004/28/EC) according to Doc. Ref. EMEA/INS/GMP/15202/2005 for Good Manufacturing Practice of active substances for medicinal products for human and veterinary use

Manufacture in complete compliance with the European Pharmacopoeia

Certificate of Suitability (Certificate No. R1-CEP 2001-274-Rev 01)

Registration for application in veterinary medicine according to Council Regulation [EEC] 2377/90 (unrestricted application in all mammalian food producing species including milk according to EMEA Summary Report)

product free from Genetically Modified Organisms (GMO) and residual solvents
product not from animal origin

Order No: **6036320**
Barrel No.:
Batch size: **6.250 kg**
Batch No.: **3/11**
Gross Weight: **53 kg**
Net Weight: **50 kg**
Manuf. Date: **April 2011**
Release date: **04.04.11**
Expiry Date: **March 2017**
Manufacturer:

Lot: 030811

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1. Obligatory specifications

Check of identification

A. formation of a resinous precipitate..... corresponds
B. reaction of ammonium salts and salts of volatile bases..... corresponds
C. 'identification of sulphur'..... corresponds

Check of purity

test	specification	result
Acidity or alkalinity	requirement of hydrochloric acid or sodium hydroxide solution	corresponds
Relative Density*	1.040 - 1.085	1,056/20 °C
Sulphated ash	max. 0.3 %	< 0,3 %

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ICHTHAMMOL® PH. EUR. (BP) Batch No. 3/11

Obligatory specifications (continued)

Assay

Content	specification	result
Dry matter	50.0 - 56.0 %	52,4 %
Total ammonia**	4.5 - 7.0 %	5,3%
Organically combined sulphur**	min. 10.5 %	15,8 %
Sulphur in the form of sulphate***	max. 20.0 %	15,6 %

* determined on a mixture of equal volumes of the substance to be examined and water
** with reference to the dried substance, *** with reference to the total sulphur content

2. Non-obligatory characters

(according to Ph.Eur. 1.3 statements given under the side-heading characteristics (properties) are no analytical norm and not to be regarded as official requirements)

Consistency and colour	dense, blackish-brown liquid
Miscibility with water.....	in all proportions, partly colloidal
Miscibility with glycerol.....	miscible (observed for 24 hours)
Solubility in ethanol, ether, fatty oils and in liquid paraffin.....	slightly soluble
Mixtures with wool fat and soft paraffin.....	homogeneous

Test for residual Polycyclic Aromatic Hydrocarbons according to the European Directorate for the Quality of Medicines – Certificate No. R1-CEP 2001-274-Rev 01

benzo[a]pyrene	< 0.05 ppm	corresponds

Additional specifications (beyond Ph. Eur.)

pH	DGF standard methods (DGF Einheitsmethoden) Tenside (surfactants) H-III 1 (92); 1 g/100 ml** 6.0 – 7.5	6,5

Manufacturer's remarks concerning storage and handling

Storage: tightly closed. Long time storage not exceeding 25°C.

Remarks: Improper storage may result in separation of an oily phase.

The appearance of an oily phase on the surface of Ichthammol® has no negative effect on the product. It is recommended to stir the container before use.

Date: 29.06.2011

Quality Control