

CERTIFICATE OF EU RELEASE

BE0090/15

PRODUCT : INSOL ® Trichophyton 100 ml
ARTICLE N° : 139310
COUNTRY : SI / HU
AMOUNT (number of units) : 2160
WDT BATCH N° : 560
COUNTRY SPECIFIC BATCH N° : 560
DATA TO THE EXPIRY DATE
1. Blending: 18.05.2015
2. End of the expiry time : 17.05.2018

It is hereby stated, that

1. following signed documents of the above mentioned product are available:
a) Manufacturing Batch Protocol
b) Manufacturers Release Document
c) Batch Release of the control authority (acc. Note for Guidance III/5372/93)
2. the temperature data during shipment from the manufacturer to the destination warehouse show no critical deviations from the specified limits.
3. samples of the finished product have been inspected and it has been verified, that this batch of product has been manufactured, included all packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be compliance with GMP.

The pharmaceutical product is released by a Qualified Person (2004/28/EC).

COMMENTS:

Date / Qualified Person ...2015-08-06.....

P. Heidekerf



Boehringer Ingelheim
Vetmedica GmbH
D - 55216 Ingelheim am Rhein

Aktenzeichen: 2.03.01.0357
Bearb.-Nr.: 3324/15
Eingang der Proben: 03.07.2015
Eingang des Antrages: 03.07.2015
Langen, den 14.07.2015

BESCHIED

Über das Ergebnis der staatlichen Chargenprüfung gemäß § 32 der Tierimpfstoff-Verordnung vom 24. Oktober 2006 (BGBl. I S. 2365)

Die im Folgenden genannte Charge wird freigegeben

Die Gebühren werden gesondert festgesetzt

Bezeichnung des Mittels	Insol Trichophyton		
Zulassungs-Nr.	277a/94		
Chargenbezeichnung	560	Verwendbar bis	17.05.2018
Anzahl der Behältnisse	4.168	Einzeldosen pro Behältnis	40
Behältnistyp	Glasflaschen		
Name und Adresse des Herstellers, wenn nicht identisch mit dem Antragsteller	Wirtschaftsgenossenschaft deutscher Tierärzte eG Serumwerk Memsen D-27318 Hoyerhagen		

Diese Charge wurde mit dokumentierten Verfahren geprüft, die Teil eines Qualitätsmanagementsystems sind.
Bemerkungen:

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden.
Der Widerspruch ist beim Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel,
Paul-Ehrlich-Str. 51-59, 63225 Langen, schriftlich oder zu Niederschrift einzulegen.

Im Auftrag

Dr. Karin Duchow



Das Paul-Ehrlich-Institut ist ein Bundesinstitut im Geschäftsbereich des
Bundesministeriums für Gesundheit / The Paul-Ehrlich-Institut is an Agency
of the German Federal Ministry of Health

Paul-Ehrlich-Str. 51-59 63225 Langen
Deutschland / Germany
E-Mail: info@pe.i-gv.de Telefon: +49 (0) 6103 12-0
Fax: +49 (0) 6103 12-1234
->> www.pe.i-gv.de

Boehringer Ingelheim
Vetmedica GmbH
D - 55216 Ingelheim am Rhein

Reference Number: 3324/15
Administrative Code: 2.03.01.0357
Date of Release of Certificate: 16.07.2015

**EU/EEA OFFICIAL BATCH PROTOCOL REVIEW
CERTIFICATE OF APPROVAL
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS**

Examined under Article 81 of Directive 2001/82/EC as amended by Directive 2004/28/EC

Trade name:	Insol Trichophyton
International non-proprietary name / Ph. Eur. name / common name:	-
Name and address of manufacturer responsible for batch release:	Wirtschaftsgenossenschaft deutscher Tierärzte eG Serumwerk Memsen 27318 Hoyerhagen
Marketing authorisation number (Member State / EC):	277a/94
Manufacturer's batch number(s): - final bulk no - final lot no - packaging lot no	- 560 -
Batch number of diluent (where appropriate):	-
Type of container:	glass vials
Total number of containers of this batch:	4,168
Number of doses/volume per container:	40
Date of start of period of validity:	18.05.2015
Expiry date:	17.05.2018

This batch has been examined using documented procedures that form part of a quality management system.

The signed manufacturer's release protocol for this batch has been examined in conformity with Article 81.

This batch is in compliance with all of the approved specifications laid down in the above noted marketing authorisation.

Fees are laid down separately.

Dr. Karin Duchow



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Paul-Ehrlich-Strasse 61-69
63225 Langen
Deutschland | Germany

Telefon / Phone: +49 621 6103 20 0
Fax: +49 621 6103 12 34
e-mail: [pride](mailto:pride@pepi.de)

Manufacturers Release Document

Applicant/Manufacturer: Wirtschaftsgenossenschaft
deutscher Tierärzte eG
Serumwerk Memsen
27318 Hoyerhagen

for: Boehringer Ingelheim
Vetmedica GmbH
55216 Ingelheim/Rhein

Product: **Insol® Trichophyton**
trivalent, inactivated vaccine for cattle

Licensing numbers: Germany: 277a/94

Batch number: 560

Batch quantification:

1. total number of containers: 4228 x 100 ml

2. number of containers, the release is applied for: 4168 x 100 ml

3. number of doses per container: depending from age of animals
40 doses

4. type of container: glass vials, type II (EP)

Samples for the competent authority: 3 x 100 ml

data to the expiry time: 1. blending: 18.05.2015
2. end of the expiry time: 17.05.2018

Remarks:

After reviewing all manufacturing and testing data, I am satisfied that the product has been manufactured in accordance with Good Manufacturing Practice and is in conformity with the methods and standards described in the application dossier (as amended by variations). We as well apply and ask for a certificate of the result of batch release testing according to the Note for Guidance III/5372/93.

date: 02.07.2015



Dr. Silke Kräft
Qualified Person

Manufacturers Batch Protocol

Product name: Insol[®] Trichophyton
Batch number: 560
Member States and license number: Germany: 277a/94

Starting materials:

master seed materials

- *Trichophyton verrucosum* (strain no.: 410)
MS-batch number: M169Tver410
last testing: 30.03.2009

- *Trichophyton mentagrophytes* (strain no.: 1032)
MS-batch number: M171Tmen1032
last testing: 30.03.2009

- *Trichophyton sarkisovii* (strain no.: 551)
MS-batch number: M173Tsar551
last testing: 30.03.2009

working seed materials

- *Trichophyton verrucosum* (strain no.: 410)
WS-batch number: W110869Tver410
last testing: 30.03.2009

- *Trichophyton mentagrophytes* (strain no.: 1032)
WS-batch number: W100871Tmen1032
last testing: 30.03.2009

- *Trichophyton sarkisovii* (strain no.: 551)
WS-batch number: W100873Tsar551
last testing: 30.03.2009

Production:

	start:	end:	volume:
<i>Trichophyton verrucosum, batch no 34/14 I:</i>			
seed:	23.10.2014	23.10.2014	300 Roux bottles
harvest:	10.11.2014	11.11.2014	110 litres
inactivation:	11.11.2014	12.11.2014	110 litres
<i>Trichophyton verrucosum, batch no 34/14 II:</i>			
seed:	12.11.2014	12.11.2014	300 Roux bottles
harvest:	01.12.2014	02.12.2014	150 litres
inactivation:	02.12.2014	03.12.2014	150 litres
<i>Trichophyton mentagrophytes, batch no 45/14 I:</i>			
seed:	20.11.2014	20.11.2014	300 Roux bottles
harvest:	08.12.2014	10.12.2014	540 litres
inactivation:	09.12.2014	11.12.2014	540 litres
<i>Trichophyton sarkisovii, batch no 33/14 II:</i>			
seed:	06.11.2014	06.11.2014	300 Roux bottles
harvest:	24.11.2014	25.11.2014	180 litres
inactivation:	25.11.2014	26.11.2014	180 litres

Blending:

product batch no: 560 start: 18.05.2015 end: 18.05.2015 volume: 450 kg

out of 3 x 150 kg:

<i>Trichophyton verrucosum:</i>	34/14 I	100 kg
	34/14 II	50 kg

<i>Trichophyton mentagrophytes:</i>	45/14 I	150 kg
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<i>Trichophyton sarkisovii:</i>	33/14 II	150 kg
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Vaccine composition:

components:	final concentration:	target concentration:
<i>Trichophyton verrucosum:</i>	54 x 10 ⁶ /ml	50 - 60 x 10 ⁶ / ml
<i>Trichophyton mentagrophytes:</i>	54 x 10 ⁶ /ml	50 - 60 x 10 ⁶ / ml
<i>Trichophyton sarkisovii:</i>	55 x 10 ⁶ /ml	50 - 60 x 10 ⁶ / ml
Thiomersal:	39 µg/ml	38 - 44 µg/ml

Filling:

batch number: 560
filling date: 26.05.2015

volume filled: 4228 x 100 ml

In process controls:

A. Trichophyton verrucosum, batch no 34/14 I and 34/14 II

1. test for identity (during cultivation)

start: 23.10.2014 end: 24.11.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

2. test for cultural purity (after cultivation)

start: 11.11.2014 end: 15.12.2014 method: see: HV-No. Poli T-I.01/4.1
threshold: no bacterial growth
result: no bacterial growth

3. visual test for conglomerates (after homogenisation)

start: 10.11.2014 end: 02.12.2014 method: see: HV-No. Poli T-I.01/4.2
threshold: no visible conglomerates
result: no visible conglomerates

4. control of number of microconidia (before fermentation)

start: 10.11.2014 end: 02.12.2014 method: see: PV-No. Poli-II.13
threshold: 55 - 65 Mio. microconidia and SOP103
result: 56 - 63 x 10⁶ / ml

5. test for amount of germinated cells (during fermentation)

start: 11.11.2014 end: 03.12.2014 method: by microscope
threshold: > 50 % germinated cells
result: ≥ 80 %

6. test for identity (during fermentation)

start: 11.11.2014 end: 03.12.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

7. control of inactivation:

start: 11.12.2014 end: 02.02.2015 method: see: PV-No. Poli T-II.01/2.5
threshold: no growth and SOP104
results: no growth

8. test for sterility (after inactivation)

start: 11.12.2014 end: 19.01.2015 method: Ph. Eur. 2.6.1
threshold: has to be sterile
result: sterile

9. determination of OD_{560 nm}:

start: 12.05.2015 end: 12.05.2015 method: see: SOP360
threshold: 0,9 - 1,8 (blank: 0,03 - 0,09)
result: 1,5 (blank: 0,05 / 1st measurement: 1,5 / 2nd measurement: 1,5)

B. Trichophyton mentagrophytes, batch no 45/14 I

1. test for identity (during cultivation)

start: 20.11.2014 end: 02.12.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

2. test for cultural purity (after cultivation)

start: 09.12.2014 end: 22.12.2014 method: see: HV-No. Poli T-I.01/4.1
threshold: no bacterial growth
result: no bacterial growth

3. visual test for conglomerates (after homogenisation)

start: 08.12.2014 end: 10.12.2014 method: see: HV-No. Poli T-I.01/4.2
threshold: no visible conglomerates
result: no visible conglomerates

4. control of number of microconidia (before fermentation)

start: 08.12.2014 end: 10.12.2014 method: see: PV-No. Poli-II.13
threshold: 55 - 65 Mio. microconidia and SOP103
result: 56 - 64 x 10⁶ / ml

5. test for amount of germinated cells (during fermentation)

start: 09.12.2014 end: 11.12.2014 method: by microscope
threshold: > 50 % germinated cells
result: ≥ 80 %

6. test for identity (during fermentation)

start: 09.12.2014 end: 11.12.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

7. control of inactivation:

start: 12.01.2015 end: 12.02.2015 method: see: PV-No. Poli T-II.01/2.5
threshold: no growth and SOP104
results: no growth

8. test for sterility (after inactivation)

start: 12.01.2015 end: 29.01.2015 method: Ph. Eur. 2.6.1
threshold: has to be sterile
result: sterile

9. determination of OD_{560 nm}:

start: 12.05.2015 end: 12.05.2015 method: see: SOP360
threshold: 0,9 - 1,8 (blank: 0,03 - 0,09)
result: 1,1 (blank: 0,05 / 1st measurement: 1,1 / 2nd measurement: 1,1)

C. Trichophyton sarkisovii, batch no 33/14 II

1. test for identity (during cultivation)

start: 06.11.2014 end: 20.11.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

2. test for cultural purity (after cultivation)

start: 25.11.2014 end: 19.12.2014 method: see: HV-No. Poli T-I.01/4.1
threshold: no bacterial growth
result: no bacterial growth

3. visual test for conglomerates (after homogenisation)

start: 24.11.2014 end: 25.11.2014 method: see: HV-No. Poli T-I.01/4.2
threshold: no visible conglomerates
result: no visible conglomerates

4. control of number of microconidia (before fermentation)

start: 24.11.2014 end: 25.11.2014 method: see: PV-No. Poli-II.13
threshold: 55 - 65 Mio. microconidia and SOP103
result: 56 - 60 x 10⁶ / ml

5. test for amount of germinated cells (during fermentation)

start: 25.11.2014 end: 26.11.2014 method: by microscope
threshold: > 50 % germinated cells
result: ≥ 80 %

6. test for identity (during fermentation)

start: 25.11.2014 end: 26.11.2014 method: see: PV-No. Poli T-II.01/2.6
threshold: has to correspond with photographic documentation
result: corresponds

7. control of inactivation:

start: 19.12.2014 end: 19.01.2015 method: see: PV-No. Poli T-II.01/2.5
threshold: no growth and SOP104
results: no growth

8. test for sterility (after inactivation)

start: 19.12.2014 end: 05.01.2014 method: Ph. Eur. 2.6.1
threshold: has to be sterile
result: sterile

9. determination of OD_{560 nm}:

start: 12.05.2015 end: 12.05.2015 method: see: SOP360
threshold: 0,9 - 1,8 (blank: 0,03 - 0,09)
result: 1,4 (blank: 0,05 / 1st measurement: 1,4 / 2nd measurement: 1,4)