MSD
Animal Health

Intervet International bv
P.O. Box 31
5830 AA Boxmeer
The Netherlands
T +31 485 58 7600
F +31 485 56 8111
msd-animal-health.com

Manufacturer's Batch Protocol

Product: Equilis Te szuszpenziós injekció lovaknak *Batch:A013A01*

MEMBER STATE SPECIFIC INFORMATION

Member state:	**Hungary**
Trade name:	**Equilis Te szuszpenziós injekció lovaknak**
Marketing authorisation number:	
Target species:	**Horse**
Total number of containers in this batch:	**72 005**
Number of containers the release is applied for:	**72 005**
Volume per container:	**1**
Number of samples for the competent authority:	**-**
Date of expiry:	**Sep-2016**
Name and address of Marketing Authorisation Holder:	**Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands, Represented by the local company**

16-Mar-2015/as
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Manufacturer's Batch Protocol

Product: Equilis Te szuszpenziós injekció lovaknak Batch:A013A01

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Equine tetanus vaccine (inactivated)**
Batch number of finished product:	**A013A01**
Batch number of final bulk:	**A013**
Pharmaceutical form of finished product:	**Suspension for injection**
Type of final container:	**Hydrolytical class type I glass vial**
Date of start of period of validity:	**10-Sep-2014**
Storage temperature:	**2-8 °C**
Name and address of manufacturer:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**
Name and address of the batch release site:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**

CERTIFICATION BY THE MANUFACTURER

I herewith certify that concerned batch was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended.

Name: S.T.M. Verstegen
Function: Qualified Person
Date: 20 MAR 2015
Signature: .....

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FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (FPC-02)
28-Aug-2014	11-Sep-2014	Tested according to Ph. Eur. 0062 / Ph. Eur. 2.6.1. Result: No growth Threshold: No growth Conclusion: Passed
		Potency using guinea pigs (FPC-03)
10-Sep-2014	22-Oct-2014	Tested according to Ph. Eur. 0697 Result: Conform Threshold: Conform Conclusion: Passed
		Potency Tetanus toxoid (FPC-03) Tested according to Ph. Eur. 0697 Result: 373.78 / 423.28 / 261.11 / 327.15 / 385.77 / 397.40 IU/ml Average: 361 IU/ml Threshold: >= 30 IU/ml Conclusion: Passed
		Identity Toxoid (FPC-03) Tested according to Ph. Eur. 0697 Result: Identity conform Threshold: Identity conform Conclusion: Passed
		Determination of pH (FPC-01)
19-Sep-2014	19-Sep-2014	Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 6.0 - 8.0 Conclusion: Passed
		Identity (Iscom-matrix adjuvant) (FPC-06)
07-Oct-2014	07-Oct-2014	Result: Iscoms present Threshold: Presence of iscoms Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Equilis Te szuszpenziós injekció lovaknak Batch:A013A01

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
12-Sep-2014	12-Sep-2014	**Saponin fraction C** Result: 479 µg/ml Threshold: 250 - 500 µg/ml Conclusion: Passed
25-Aug-2014	25-Aug-2014	**Appearance (FPC-05)** Result: Conform Threshold: Clear opalescent fluid Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Equilis Te szuszpenziós injekció lovaknak *Batch:A013A01*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
Tetanus toxoid	See composition table	Novartis/Chiron, Marburg, Germany
Bulk vaccin	See blending	Intervet, Boxmeer, the Netherlands
Filled product	See filling	Intervet, Boxmeer, the Netherlands

STARTING MATERIALS:

Virus seed lots:
Master seed material: **Tetanus toxoid**
MS-batch number: **E21**
Date of last testing: **18-JAN-1973**

Working seed material: **Tetanus toxoid**
WS-batch number: **E122**
Date of last testing: **25-Jan-2012**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF TETANUS TOXOID:

Production step	Start	End	Volume
Batch 0000305576			
Seed:	10-Jul-2013	04-Oct-2013	- mL
Harvest:	17-Jul-2013	10-Oct-2013	6600 kg
Inactivation:	17-Jul-2013	10-Oct-2013	250 kg
Purification:	18-Dec-2013	20-Dec-2013	17.2 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A013**
Start date: **14-Aug-2014**
End date: **14-Aug-2014**
Total volume: **90.0 kg**

COMPOSITION OF THE FINAL BULK

Component	Batch number	Total units
Tetanus toxoid	0000305576	847 g
Iscom matrix adjuvant	0000269777 0000269779	1419 g* 2157 g**
Buffer	0000229076 0000291116 0000186136 BMGM406821	To 85.53 kg

* containing 13.5 g Saponine fraction C
** containing 20.2 g Saponine fraction C

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Product: Equilis Te szuszpenziós injekció lovaknak *Batch:A013A01*

FILLING

Batch number of final bulk:	**A013**
Final batch number:	**A013A**
Start date:	**18-Aug-2014**
End date:	**18-Aug-2014**
Filled containers:	**72 005**
Volume filled:	**1 ml**

IN PROCESS CONTROLS

In process controls Tetanus toxoid:

Test	Start	End	Result	Thresholds	Conclusion
Batch 0000305576					
Sterility (122/1)	09-Jan-2014	23-Jan-2014	No growth	No growth	Passed
pH value (122/2)	23-Dec-2013	23-Dec-2013	7.3	7.0 – 7.8	Passed
Sulphate determination (122/3)	13-Jan-2014	13-Jan-2014	2 mg/l	≤ 200 mg/l	Passed
Formaldehyde determ. (122/4)	08-Jan-2014	08-Jan-2014	14 mg/l	≤ 200 mg/l	Passed
Sodium Chloride determ. (122/5)	08-Jan-2014	08-Jan-2014	8 mg/ml	8 - 9 mg/ml	Passed
LF content (122/6)	02-Jan-2014	02-Jan-2014	4250 Lf/ml	≥ 2500 Lf/ml	Passed
Nitrogen determination (122/7)	02-Jan-2014	02-Jan-2014	2.568 mg/ml	n.a.	Passed
Purity (122/8)	02-Jan-2014	02-Jan-2014	1655 Lf/mg	≥ 1000 Lf/mg	Passed
Specific toxicity/ Irreversibility of Toxoiding (122/9-10)	02-Jan-2014	13-Feb-2014	*	*	Passed

* No animal shows signs or dies from tetanus, at least 80% surviving animals

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume (IPC-05)	18-Aug-2014	18-Aug-2014	1.17 ml	1.08-1.32 ml	Passed

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Model for manufacturers of a MARKETING INFORMATION FORM

Notification of the intention to market a batch of an immunological veterinary medicinal product, which has a marketing authorisation in the following EC/EEA Member State Hungary and has received an EC Batch release certificate after OBPR or OCABR in another Member State in accordance with Article 81 or Article 82 of EC Directive2004/28/EC and in view of mutual recognition.

Trade name in the above mentioned Member State:	Equilis Te szuszpenziós injekció lovaknak
International non-proprietary name / Ph. Eur. name / common name:	Equine tetanus vaccine (inactivated)
Name and address of Marketing Authorisation Holder (MAH) for the above mentioned Member State:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Respresented by the local company
Market authorisation number in the above mentioned Member State:	EU/2/05/055/001-002
Identification numbers associated with the lot to be marketed in the above mentioned Member State;	
Bulk number (final formulated bulk):	**A013**
Final lot number:	**A013A**
Packaging lot number (if different from final lot n°):	**A013A01**
Batch number of diluent: (where appropriate)	-
Type of Container:	Hydrolytical class type I glass vial
Number of doses/volume of container:	1
Total number of containers to be marketed in the above noted Member State:	2 390
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Sep-2016

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	OBPR
Official batch release certificate number:	8328/14

I hereby declare that:
- this batch is in compliance with the above marketing authorisation and the relevant European Pharmacopoeia monographs;
- this batch is the batch referred to in the accompanying batch release certificate;
- a copy of the batch release certificate (in the case of OCABR with the annexed test results) and the manufacturer's protocol are attached.

S.J.M. Verstegen
Qualified Person
20 MAR 2015

Signature of qualified person (MAH):	
Name of qualified person (MAH):	
Date of issue:	

Use of the following section is optional

For completion by the CA/OMCL after submission:

Date received:	
Signature of qualified authority (CA/OMCL):	
Name of qualified authority (CA/OMCL):	
Decision and Date:	

20-Mar-2015/sl

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach D-63207 Langen

Intervet International B.V.
Wim de Körverstraat 35
NL - 5830 AA Boxmeer

Reference Number: 8328/14
Administrative Code: 4/1:2.04.01.0026
Date of Release of Certificate: 08.12.2014

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:	Equilis Te
International non-proprietary name / Ph. Eur. name / common name:	-
Name and address of manufacturer responsible for batch release:	Intervet International B.V. Wim de Körverstraat 35 NL - 5830 AA Boxmeer
Marketing authorisation number (Member State / EC):	EU/2/05/055/001
Manufacturer's batch number(s): - final bulk no - final lot no - packaging lot no	A013 A013A A013A01-10
Batch number of diluent (where appropriate):	-
Type of container:	glass vial
Total number of containers of this batch:	72,005
Number of doses/volume per container:	1
Date of start of period of validity:	10.09.2014
Expiry date:	08.2016

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. Birgit Kegel