BE 0051/14

CERTIFICATE OF RELEASE
Quality Control

Klocke Pharma-Service GmbH
Straßburger Str. 77
77767 Appenweier, Germany
Phone: +(49) 7805 / 401-0

A) BASIC DATA

PRODUCT:	**Vetmedin 5mg 100 Kapseln HU**
COUNTRY:	Hungary
PRODUCT CODE MANUFACTURER:	90001697
MANUFACTURING SPECIFICATION N°:	K 1322-05-01
BATCH N° (MANUFACTURER):	0267227
COUNTRY SPECIFIC BATCH N°:	0267227-3
MANUFACTURING DATE:	18. Februar 2014
EXPIRY DATE:	02 2017
QUANTITY:	720 pieces

B) RAW MATERIALS
We herewith certify that all raw materials have been tested and are in compliance with the requirements of the testing specifications.

C) MANUFACTURING / PACKAGING
The manufacturing and packaging documentation for the above mentioned product have been reviewed and it was determined that this lot number was manufactured and packaged according to the requirements of the manufacturing specifications and master production documents.

D) QUALITY ASSURANCE
All documentation has been found to be in compliance with the requirements of the above mentioned manufacturing specifications and master production documents. Explanations for deviations, if any are attached. This lot has been tested to the requirements of the above mentioned testing specification and the certificate of analysis is attached. All batch documentation is available upon request.

E) QUALITY ASSURANCE RELEASE
The product has been tested and complies with the requirements of the testing specifications and the relevant marketing authorisation. The product is released by a competent Quality Assurance Person.

COMMENTS:

Released by:

Qualified Person (QP): 24.03.14
Datum / Signum

KLOCKE

PHARMA-SERVICE GmbH, Straßburgerstr. 77, 77767 Appenweier

Certificate of Analysis

Product Name:	Vetmedin 5.0 mg HU	**No. of Analysis:**	14/001201
Batch / Lot No.:	0267227	**Date of Manufacture:**	February 18, 2014
Country specific		**Batch Size:**	592.000 kg
Batch No.:	0267227-3	**Quantity:**	-
Article No:	90001697	**Dosage Form:**	Capsules
Manufacturer:	Klocke Pharma-Service	**Printed on:**	March 21, 2014
Manufacturing site:	Appenweier-Urloffen	**Analysis Date:**	March 20, 2014
Testing Spec. No.:	101 5644 010 - 02	**Expiry Date:**	02/2017

TESTING - PARAMETER	SPECIFICATION		RESULTS
Description	Oblong hard gelatin capsules consisting of an orange opaque cap and a white opaque body and containing a white or slightly yellowish granulate.		corresponds
Odour	Almost imperceptible		corresponds
Dimensions	Length:	about 19.5 mm	19.3 mm
	Diameter of capsule cap:	about 6.9 mm	6.7 mm
Identification A) Liquid chromatography (HPLC)	The uncorrected retention time of the active ingredient in the test solution must be the same as the uncorrected retention time of the active ingredient in the standard solution.		corresponds
B) Thin-layer chromatography (TLC)	The Rf value of the active ingredient obtained with the test solution corresponds to that obtained with the standard solution.		corresponds
Water content	Specification:	≤ 2.0 %	1.0 %
Disintegration time	Specification:	≤ 30 minutes	3 minutes
Active ingredient decomposition Liquid chromatography	UD-CG 115 BS decomposed to UD-CG 134:	≤ 0.5 %	< 0.01 %
	UD-CG 115 BS decomposed to K 2006 a:	≤ 0.5 %	< 0.01 %
Assay Liquid chromatographic determination (HPLC)	UD-CG 115 BS:	4.75 - 5.25 mg/capsule	5.09 mg/capsule
Dissolution Paddle method on accordance with Ph. Eur./USP Liquid chromatographic determination (HPLC) UD-CG 115 BS (If the results for the first 5 production batches are within specification, at least 2 batches are tested per year, depending on the frequency of production.)	After 30 minutes Requirement 1 (n=6) Each individual value ≥ 75 Requirement 2 (n=12) Mean ≥ 70 Individual values ≥ 55 Requirement 3 (n=24) Mean ≥ 70 Not more than 2 values < 55 No value < 45 In accordance with USP	≥ 70 %	90 %
Content Uniformity Liquid chromatographic determination UD-CG 115 BS	In accordance with the requirements of Ph. Eur. / USP		corresponds 5.1 mg RSD: 3.7

KLOCKE

PHARMA-SERVICE GmbH, Straßburgerstr. 77, 77767 Appenweier

Certificate of Analysis

Product Name:	Vetmedin 5.0 mg HU	No. of Analysis:	14/001201
Batch / Lot No.:	0267227	Date of Manufacture:	February 18, 2014
Country specific		Batch Size:	592.000 kg
Batch No.:	0267227-3	Quantity:	-
Article No:	90001697	Dosage Form:	Capsules
Manufacturer:	Klocke Pharma-Service	Printed on:	March 21, 2014
Manufacturing site:	Appenweier-Urloffen	Analysis Date:	March 20, 2014
Testing Spec. No.:	101 5644 010 - 02	Expiry Date:	02/2017

TESTING - PARAMETER	SPECIFICATION		RESULTS
Microbial contamination Testing in accordance with Ph. Eur. (If the results for the first 5 production batches are within specification, at least 2 batches are tested per year, depending on the frequency of production.)	Total aerobic microbial count (TAMC):	≤ 10^3 CFU/g	< 100 CFU/g
	Total combined yeasts/ moulds count (TYMC):	≤ 10^2 CFU/g	< 100 CFU/g
	Escherichia coli/g:	absent	absent

The product was tested according to GMP requirements and the actual authorized testing procedure.
The product has the required quality.

Head of Quality Control — March 21, 2014 (Date) — Hans Werle