

**CROSS VETPHARM GROUP LIMITED****CERTIFICATE OF ANALYSIS**

PRODUCT: BIMECTIN PLUS
BATCH NUMBER: 8A039A
PRODUCT CODE: 1BIM157
DATE OF MANUFACTURE: JAN 2018
DATE OF EXPIRY: DEC 2020
UNIT SIZE: 250ml
MARKET: HUNGARY
SITE OF MANUFACTURE: BIMEDA MTC

REPORT

TEST	METHOD	SPECIFICATION	RESULT
DESCRIPTION	Ph. Eur. 2.2.2 Method I Visual	Clear colourless to slightly yellow-coloured solution no darker in colour than EP reference solution Y ₁ No visible particulates	Complies
CONTAINER/CLOSURE	QCC-G046	Intact, no irregularities	Conforms
pH (as is)	SOP 014-012	5.0 – 7.0	5.2
MOISTURE	QCC-G021	Not more than 0.5%	0.2%
IVERMECTIN	Assay RD-AM084	9.5 to 10.5mg/ml 95.0 – 105.0% of LC Ivermectin B _{1a} is NLT 90% of B _{1a} Total Ivermectin B _{1a} + Ivermectin B _{1b}	10.1mg/ml 101% of LC 98% of total
	Identification RD-AM084	1. Retention times of the two Principle peaks (Ivermectin B _{1a} and Ivermectin B _{1b} .) in sample Chromatogram correspond to those of standard chromatogram 2. R _f of the sample corresponds to the R _f for the Ivermectin Standard	Conforms Conforms
Impurities:	Individual RT 1.3-1.5	NMT 2.5% of Ivermectin B _{1a} + Ivermectin B _{1b} peak area	1.5 %
	Any other individual	NMT 1.0% Ivermectin B _{1a} + Ivermectin B _{1b} peak area	0.3%
	Total	NMT 5.0% Ivermectin B _{1a} + Ivermectin B _{1b} peak area	1.8 %
CLORSULON Assay	RD-AM085	95.0-105.0 mg/ml 95 – 105% L.C.	98.5 mg/ml 99% of L.C
IDENTITY	RD-AM085	1. Retention time of the Clorsulon peak in the sample chromatogram corresponds to that of standard chromatogram 2. R _f of the sample corresponds to the R _f for the clorsulon standard	Conforms Conforms
	RD-AM104		
RELATED SUBSTANCES (Provisional)	RD-AM085 RD-AM085	Individual Impurity : NMT 0.5% Total Impurities : NMT 2.0%	N.D N.D
FILL CHECK	SOP 003-071	NLT claimed volume	262ml
STERILITY	SOP 004-072	Meets EP Spec for Sterility Testing	Conforms

CONCLUSION: *Conforms to Cross Vetpharm Group Ltd Products Release Specification***Signed:**_____
Qualified Person**Date:**

30/08/18

Business Address: Broomhill Road, Tallaght, Dublin 24, D24E032, Ireland
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Registered in Ireland: 8340

Docket No: 0154

SPECIAL IMPORT

Refer To Sop A5038

White Copy: To the QA Executive & the Head of Supply Chain.
Pink Copy: Retained by the Supply Chain Department.

MARKET REQUEST STOCK TRANSFER LOG BOOK

Section A Details Of Stock to be Transferred & Approval by QP and Registration.

Requested By: MAEVE KAUFON Reviewed By Supply Chain Dept.: [Signature] Sign & Date: 25/07/18

Item Code	PRODUCT NAME	Batch Number	QAD STATUS	STOCK LOCATION	QUANTITY REQUESTED	Proposed Market	Proposed Stock Location
1B1M157	BIMECTIN Plus 250mcL	8A039A	OK	FG81	200	50569911 - PANACEA HUNGARY	FG8E

Request Approved By: [Signature] Date: 27/07/18

Registration Approval. Request Approved By: [Signature] Date: / /

Section B Physical Transfer Details Completed by Warehouse

Details of Product to be moved

Item Code	Product Name	Batch Number	From: Original Location		To New Location	
			Qty. Of Stock To Move	Original Stock Warehouse Location	New Stock Warehouse Location	Qty of Stock Physically moved
1B1M157	BIMECTIN Plus 250mcL	8A339A	200	FG81	FG8E	200

Transferred By Warehouse: [Signature] Sign and Date: 30/07/18

Section C MRP Stock Transfer Details completed by the Supply Chain Dept.

Please Note: If any errors are noted that cannot be corrected at the time, the Head of Quality and Logistic Department Managers are notified

Details of Product to be moved

Item Code	Product Name	Batch Number	From: Original Location		To New Location & Qty. Transferred	
			Original QAD Status	Original Stock Location	New QAD Status	New QAD Stock Location
1B1M157	BIMECTIN Plus 250mcL	8A039A	OK	FG81	OK	FG8E 200

Transferred By Supply Chain Dept.: [Signature] Sign and Date: 03/08/18