



Bimeda® Exports
 Broomhill Road,
 Tallaght,
 Dublin 24, D24 E032,
 Ireland
 Tel. +353 (0) 1466 7900
 Fax. +353 (0) 1451 5803
 Email: exportsales@bimeda.com

CERTIFICATE OF ANALYSIS

PRODUCT: BIMECTIN PLUS
BATCH NUMBER: 5F050C
ITEM CODE: 1BIM157
DATE OF MANUFACTURE: JUN 2015
DATE OF EXPIRY: MAY 2018
UNIT SIZE: 250ml
MARKET: HUNGARY
SITE OF MANUFACTURE: BIMEDA MTC

TEST DESCRIPTION	METHOD	REPORT	
		SPECIFICATION	RESULT
	Ph Eur 2.2.2 Method 1 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}	10.0mg/ml 100% of LC 99% 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.Rf of the sample corresponds to the Rf 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	0.4%, 0.4%
	Total	NMT 5.0% Ivermectin B _{1a} + Ivermectin B _{1b} peak area	2.3%
CLORSULON Assay	RD-AM085	95.0-105.0 mg/ml 95 – 105% L.C.	98.5mg/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	Conforms
	RD-AM104	2.Rf of the sample corresponds to the Rf for the clorsulon standard	Conforms
RELATED SUBSTANCES (Provisional)	RD-AM085	Individual Impurity: NMT 0.5%	N.D
	RD-AM085	Total Impurities: NMT 2.0%	N.D
FILL CHECK	SOP 003-071	NLT claimed volume	261.75ml
STERILITY	SOP 004-072	Meets EP Spec for Sterility Testing	Conforms

CONCLUSION: *Conforms to Bimeda Products Release Specification*

Signed: *[Signature]*
 Qualified Person

Date: 24/2/16

Bimeda Exports is a business name of Cross Vetpharm Group Limited
 Directors: G A Doyle, P.D Brady (Company Secretary)
 Registered Address: 1B The Herbert Building, The Park, Carrickmines, Dublin 18, D18 K8Y4, Ireland
 Registered in Ireland: 8340