Hovione

CERTIFICATE OF ANALYSIS

Product : Ivermectin

Batch no.: 05KB21.HM00163

Retest Date : July 2022 **Manufacturing Date :** July 2020

TEST	REF.	SPECIFICATION	RESULT
Description:	AATG018_001	White to yellowish white powder	Conforms
Crystallinity:	USP, Monograph	The product is crystalline	Conforms
Identification (by IR):	EP, Monograph	Conforms to the spectrum of the European Pharmacopeia Chemical Reference Substance	Conforms
Identification (by HPLC):	CRLC177_001	In the chromatogram obtained with the sample solution, the principal peaks should have the same RTs as those of the principal peaks in the chromatogram obtained with the reference standard	Conforms
Appearance of solution:	EP, Monograph	A 2% w/v solution in toluene (1g/50mL) is clear and not more intensely coloured than the reference solution BY7.	Conforms
Water:	AA001835_002	Not more than 1.0 % w/w (2g)	0.2 % w/w
Residue on ignition:	USP, Monograph	Not more than 0.1 % w/w (1 g; 600°C; constant weight)	0.0 % w/w
Specific optical rotation:	AA001833_003	Not less than -20 ° and not more than -17 ° , calculated with reference to the anhydrous and solvent-free substance (c=2.5; methanol; t=20° C; 589.3nm)	-19 °
Ratio (by HPLC): Iv. B1a / (Iv. B1 a + B1b):	CRLC177_003	Not less than 90.0 %	98.4 %
Related substances (by HPLC):			
EP Impurity A	CRLC177_025	Not more than 1.0 % w/w	0.4 % w/w
EP Impurity H	CRLC177_026	Not more than 1.0 % w/w	0.3 % w/w
EP Impurity D	CRLC177_027	Not more than 1.0 % w/w	Less than 0.05 % w/w
EP Impurity E	CRLC177_036	Not more than 1.0 % w/w	0.3 % w/w
Impurity with RRT 0.87 (Impurity 1)	CRLC177_028	Not more than 0.2 % w/w	0.1 % w/w
Impurity with RRT 0.55	CRLC177_011	Not more than 0.4 % w/w	0.2 % w/w
Impurity with RRT 0.77	CRLC177_012	Not more than 0.4 % w/w	0.1 % w/w
Impurity with RRT 0.59	CRLC177_038	Not more than 0.5 % w/w	Less than 0.05 % w/w
Any unspecified impurity	CRLC177_034	Not more than 0.1 % w/w	0.1 % w/w
Sum of Impurities between RRT 1.3 -1.5 (Impurity K)	CRLC177_035	Not more than 2.5 % w/w	1.4 % w/w
Total impurities	CRLC177_018	Not more than 5 % w/w	3 % w/w
Residual solvents (by GC):			
Formamide	CRGC098_008	Not more than 3.0 % w/w	2.3 % w/w
Ethanol	CRGC098_009	Not more than 5.0 % w/w	4.1 % w/w
Methanol	CRGC175_001	Not more than 0.3 % w/w	0.0 % w/w
Assay (by HPLC):	CRLC177_002	Not less than 95.0 % w/w and not more than 102.0 % w/w , calculated with reference to the anhydrous and solvent-free substance	97.3 % w/w

The batch number 05KB21.HM00163 of Ivermectin has been tested as above and conforms to the latest EP and Hovione specifications.

Approved by:

Michael Cheang **17.Jul.2020 16:24:23**

Quality Control

Storage conditions : Protected from the incident of sunlight and/ or artificial light; store below 25 °C and 65% RH

The batch was manufactured according to Good Manufacturing Practices.

Released by:

Bruna Nunes **17.Jul.2020 17:24:10**

Quality Assurance

Reference: 177523, 177423 GQSP1314.8 E_NORMAL

This document has been signed electronically in compliance with 21CFR Part 11.

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