PCCA USA
9901 South Wilcrest Drive
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744 Baransway Drive
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Unit 1, 73 Beauchamp Road
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Tel: 02.9316.1500
Fax: 02.9316.7422

CERTIFICATE OF ANALYSIS

PRODUCT: IVERMECTIN USP (FOR HUMAN USE)
ITEM NUMBER: 30-5152
LOT NUMBER: C205122
MFG DATE: 03/27/2023
EXPIRATION: 03/26/2026

CAS: 70288-86-7
MW: N/A
FORMULA: C48H74O14:C47H72O14

Caution:For Prescription Compounding/Rx Only
Warning: Must be subjected to further processing during the preparation of injectable dosage forms to ensure acceptable levels of bacterial endotoxins.

MANUFACTURER TESTS

TEST	SPECIFICATIONS	RESULTS
ASSAY - ANHYDROUS/FREE	IVERMECTIN IS A MIXTURE OF AVERMECTIN A1A, 5-O-DEMETHYL-22,23-DIHYDRO- (COMPONENT H2B1A), AND AVERMECTIN A1A, 5-O-DEMETHYL-25-DE(1-METHYLPROPYL)- 22,23-DIHYDRO-25-(1-METHYLETHYL)-(COMPONENT H2B1B). IT CONTAINS NOT LESS THAN 95.0 PERCENT AND NOT MORE THAN 102.0 PERCENT FOR THE SUM OF COMPONENT H2B1A PLUS COMPONENT H2B1B, CALCULATED ON THE ANHYDROUS AND ALCOHOL- AND FORMAMIDE-FREE BASIS; AND THE RATIO (CALCULATED BY AREA PERCENTAGE) OF COMPONENT H2B1A/(H2B1A + H2B1B) IS NOT LESS THAN 90.0 PERCENT.	PASS
ASSAY - H2B1A	>=90.0 %	98.4 %
ASSAY - H2B1B	<=5.0 %	0.1 %
ASSAY -H2B1A+H2B1B	95.0-102.0 % ANHYDROUS AND ALCOHOL AND FORMAMMIDE FREE BASIS	98.5 %
DESCRIPTION	WHITE TO YELLOWISH-WHITE, CRYSTALLINE POWDER. SLIGHTLY HYGROSCOPIC.	WHITE CRYSTALLINE POWDER

Tested By: Rachel Buckner

Reviewed By: Gabrielle Williams

QC APPROVED: 2023.10.31
PRINT DATE: 2024.03.23

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MANUFACTURER TESTS

TEST	SPECIFICATIONS	RESULTS
IDENTIFICATION A	IR - IR SPECTRUM OF THE SAMPLE SHALL BE CONCORDANT WITH THAT OF STANDARD.	PASS
IDENTIFICATION B	HPLC-THE RETENTION TIMES OF THE COMPONENT H2B1A PEAK AND THE COMPONENT H2B1B PEAK IN THE CHROMATOGRAM OF THE ASSAY PREPARATION CORRESPOND TO THOSE IN THE CHROMATOGRAM OF THE STANDARD PREPARATION, AS OBTAINED IN THE ASSAY.	PASS
LIMIT OF ALCOHOL	<=5.0 %	4.4 %
LIMIT OF FORMAMIDE	<=3.0 %	2.3 %
RC - ANY OTHER IND. IMP.	<=0.5 %	0.29 %
RC - RRT ABOUT 0.5	<=0.7 % AVERMECTIN B1A	0.05 % <0.05%
RC - RRT ABOUT 0.7	<=1 % 8A-OXO-H2B1A AND AN IMPURITY WITH THE RELATIVE MOLECULAR MASS OF 891	0.05 % <0.05%
RC - RRT ABOUT 1.3-1.4	<=2.5 % H4B1A ISOMERS AND DELTA-2,3-H2B1A AND 24-ETHYL-IVERMECTIN B1A	1.13 %
RC - SUM OF ALL UNIDENT.	<=1 %	0.4 %

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MANUFACTURER TESTS

TEST	SPECIFICATIONS	RESULTS
RC - TOTAL IMPURITIES	<=4 %	1.9 %
RESIDUAL SOLVENTS	COMPLIES WITH USP/NF GENERAL CHAPTER <467>	PASS
RESIDUE ON IGNITION	<=0.1 %	0.0 %
SPECIFIC ROTATION	-20--17 ° CALCULATED ON THE WATER-, ALCOHOL-, AND FORMAMIDE-FREE BASIS.	-19 °
WATER DETERMINATION	<=1.0 %	0.1 %

PCCA TESTS

TEST	SPECIFICATIONS	RESULTS
DESCRIPTION	WHITE TO YELLOWISH-WHITE, CRYSTALLINE POWDER. SLIGHTLY HYGROSCOPIC.	WHITE
IDENTIFICATION A	IR - IR SPECTRUM OF THE SAMPLE SHALL BE CONCORDANT WITH THAT OF STANDARD.	PASS
SOLUBILITY	FREELY SOLUBLE IN METHANOL; SOLUBLE IN ACETONE; PRACTICALLY INSOLUBLE IN WATER.	PASS

End of Report

Tested By: Rachel Buckner

Reviewed By: Gabrielle Williams

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