

BrightGene Bio-Medical Technology Co., Ltd.
 Building C25-C28, No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, China
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Certificate of Analysis

Doramectin

BATCH NUMBER	<u>2110004</u>	TEST DATE	<u>2021-11-01</u>
BATCH SIZE	<u>109kg</u>	MANUFACTURE DATE	<u>2021-10-11</u>
QUANTITY	<u>109kg</u>	RETEST DATE	<u>2023-10-10</u>
Storage Condition:	<u>Store in an airtight container in a refrigerator (2-8°C).</u>		

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Appearance	White crystalline powder	<u>White crystalline powder</u>
Identification A: IR	The IR spectrum of the sample corresponds to the spectrum of reference standard.	<u>Conforms</u>
Identification B: HPLC	The retention time of major peak of test solution should correspond to that of standard solution.	<u>Conforms</u>
Appearance of Solution	The solution is clear and not more intensely colored than reference solution BY ₆ .	<u>Conforms</u>
Water	NMT 3.0%	<u>1.9%</u>
Heavy metals	NMT 20 ppm	<u>< 20ppm</u>
Sulfated ash	NMT 0.1%	<u>0.04%</u>
BHT	NMT 2000ppm	<u>1328ppm</u>
Related Substances		
Avermectin B1a	NMT 1.5%	<u>0.73%</u>
Avermectin B1b	NMT 1.0%	<u>0.26%</u>
Avermectin B1a and Avermectin B1b	NMT 2.0%	<u>0.99%</u>
Total impurities	NMT 5.0%	<u>2.9%</u>
Residual solvents		
Acetone	NMT 5000 ppm	<u>33ppm</u>
Ethanol	NMT 30000 ppm	<u>10ppm</u>
Ethyl acetate	NMT 5000 ppm	<u>Not detected</u>
Methanol	NMT 3000 ppm	<u>19ppm</u>
Assay	NLT 95.0% (on anhydrous and solvent free basis)	<u>96.6%</u>

Manufactured By: **Chongqing Daxin Pharmaceutical Co., Ltd.**

FINAL BATCH DISPOSITION: Approved ()

Analyst/Date:
蔡作波 2021.11.01

Checker/Date:
孙明 2021.11.01

By Date: 蔡作波 2021.11.01
 Supervisor/Date:
孙明 2021.11.01