



BAJAJ HEALTHCARE LTD. [UNIT-II]

Head Office: 6th Floor, Bhoomi Velocity Infotech Park, Above ICICI Bank,

Road No.: 23, Wagle Industrial Estate, Thane (W)- 400 604,

Tel: +91 22 66177400 Website: www.bajajhealth.com

Manufacturing Site: Block No. 588, Savli, Karachia Road,

At & Post: Gothada – 391 776. Tal. Savli, Dist: Vadodara, Gujarat, India.

☎ 02667 – 220100, Fax: +91 02667 619135 E-mail: bajajhealth@bajajhealth.com

FORMAT NO: QA030/F/06-05

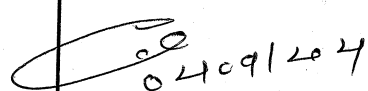
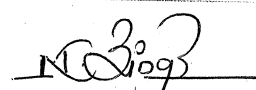
CERTIFICATE OF ANALYSIS

Product : Ivermectin EP
Batch No. : IVT-00020521
Mfg. Date : MAY-2021
Retest / Exp. Date : APR-2022

A.R. No. : FM/IVT/21/2498
Batch Size : 495 kg
Sampled on : 28/05/2021
Page No : 01 of 02

TEST	LIMITS	RESULT
Appearance	White or yellowish-white, crystalline powder. slightly hygroscopic.	White crystalline powder
Solubility	Practically insoluble in water freely soluble in methylene chloride, soluble in ethanol(96%).	Complies
Identification A. By IR	The IR spectrum of test sample should be concordant with IR spectrum obtained from Ivermectin WRS.	Complies
B. By HPLC	Examine the chromatograms obtained in the Assay.	Complies
Appearance of solution	The solution is clear and not more intensely coloured than reference solution BY ₇	Complies
Specific optical rotation	-20° to -17° (anhydrous substance)	-18.54°
Related substances by HPLC		
Impurity at RRT 1.3 to 1.5	Not more than 2.5 %	0.90 %
Any other Impurity	Not more than 1.0 %	0.73 %
Total impurities	Not more than 5.0 %	2.17 %
Alcohol and Formamide by GC		
Alcohol	Maximum 5.0 %	1.1 %
Formamide	Maximum 3.0 %	0.9 %

Conclusion: The sample Complies / Does not comply as per standard prescribed in specification as per EP-10.0.

Sign/Date			
	 04/09/2021	 02/09/2021	 02/09/2021
	Prepared by QC	Checked by QC	Approved by QA



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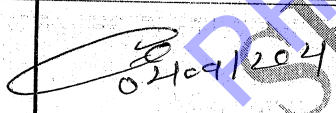
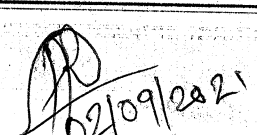
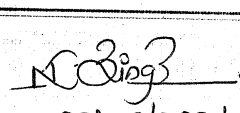
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Retest / Exp. Date:	APR-2022	Page No	: 02 of 02

TEST	LIMITS	RESULT
Sulfated ash	Maximum 0.1 %	0.02 %
Water content	Maximum 1.0 %	0.52 %
Assay (H ₂ B _{1a} + H ₂ B _{1b})	95.0% to 102.0% (anhydrous substance)	96.1 %
Ratio of H ₂ B _{1a} (H ₂ B _{1a} + H ₂ B _{1b})	Minimum 90.0%	98.8 %

Conclusion: The sample Complies / Does not comply as per standard prescribed in specification as per EP-10.0.

Sign/Date	 02/09/2021	 02/09/2021	 02/09/2021
	Prepared by QC	Checked by QC	Approved by QA