

CERTIFICATE OF ANALYSIS

(Form 39, Rule 150 E (F) THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER)

Product Name: Ivermectin Tablets USP 12 mg			
Generic Name: Ivermectin Tablets USP 12 mg			
Batch No.:	TPT24014	A.R. No.:	TPIL/FG/061
Mfg. Date:	08/2024	Date of Receipt:	16/08/2024
Exp. Date:	07/2027	Date of Analysis:	16/08/2024
Batch Size:	51,000 Tablets	Sample Qty.:	60 Tablets
Mfg. Lic. No.:	G/25/2700	Date of Release:	21/08/2024

Sr. No.	Test	Specifications	Observations
1.0	Description	Uncoated, White Coloured, Round, Std. convex shaped Tablet, Plain on both side.	Uncoated, White Coloured, Round, Std. convex shaped Tablet, Plain on both side.
2.0	Identification by		
2.1	HPLC	The Retention Time of the H ₂ B _{1a} and H ₂ B _{1b} peaks in the chromatogram of the assay preparation correspond to those in the chromatogram of the standard preparation as obtained in the assay.	Complies
3.0	Weight of 20 Tablets	3.6 gm \pm 7.5 % (3.33 gm to 3.85 gm)	3.611 gm
4.0	Average Wt. of Tablet	180 mg \pm 7.5 % (166.5 mg to 193.5 mg)	180.6 mg
5.0	Uniformity of Content	NLT 90 % and NMT 110 % of the labeled amount of Ivermectin.	95 %
6.0	Disintegration Time	Not more than 15 minutes	5 Minutes 38 Seconds
7.0	Friability	NMT: 1.0 %w/w	0.70 % w/w

	Analyzed by	Checked by	Approved by
Designation	QC Officer	QC Officer	Plant Head
Name	Dhruvi Machhi	Priyanka Thakare	Nilesh Desai
Signature	<i>D. Machhi</i>	<i>P. Thakare</i>	<i>N. Desai</i>
Date	21/08/2024	21/08/2024	21/08/2024

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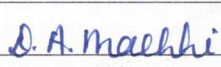
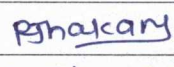
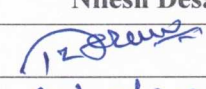
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8.0	Hardness	NLT: 3.0 kg/cm ²	4 kg/ cm ²	
9.0	Diameter	8 mm ± 0.2 mm	8.0 mm	
10.0	Thickness	4 mm ± 0.3 mm	4.13 mm	
11.0	Dissolution Test	NLT 80% of the stated amount of Ivermectin is dissolved in 45 minutes.	Average: 93.5 %	
12.0	Assay* Each Uncoated Tablet Contains: Ivermectin.....12 mg	NLT 90 % and NMT 110 % of the labeled amount of Ivermectin.	Found (mg/Tab)	%
			12.4 mg/Tab	103.3 %

Opinion: In the opinion of the undersigned. The sample referred to above is of STANDARD quality as defined in the Act and the Rules there under for the reasons given below. The Product Sample **Complies** with the prescribed Standard as per above **USP & IHS** Specification and Tests.

	Analyzed by	Checked by	Approved by
Designation	QC Officer	QC Officer	Plant Head
Name	Dhruvi Machhi	Priyanka Thakare	Nilesh Desai
Signature			
Date	21/08/2024	21/08/2024	21/08/2024

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