

CENTURION REMEDIES PVT. LTD.

G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016 REG.OFF.: G-5,INDUSTRIAL ESTATE,GORWA,VADODARA-390016

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A/C OF HEALING PHARMA INDIA PVT LTD QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THEREUNDER

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name Packing

: IVERHEAL-12 : 10x10 TAB

Generic Name

: IVERMECTIN TABLETS USP 12 MG

Product Code Batch No. **Actual Batch Size** : TI-49HEAL

: TI-490010 : 1005000 TAB

Mfg. Lic No. ; G/25A/5141-A

Sample Size Released Qtv

Remarks: Pass

: 50.000 TAB

: 1005000.000 TAB (10050 CAR)

Exp. Dt.

Mfg. Dt.

: 08/2021 : 07/2024

Test Packing: 10X10 TAB

Test As Per: USP

Specification Dt.: 15-02-2021 STP No.

T.R. Slip Dt.

Analysis Date

21 : STP/49-HEAL/AS PER

Specification No.: CRFS/TI-49HEAL/20-

USP

Location Make

A.R. No.

Rel. Dt. T.R. Slip No.

> : GORWA01 : HEALING

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: F/2156-A/21-22

: 04-09-2021

: 04-09-2021

: 04-09-2021

: CHPAP10112

Sr. Test Result Specification 1 DESCRIPTION A white coloured, round shaped, biconvex, uncoated A white coloured, round shaped, biconvex. tablet, breakline on one side, plain on other sides. uncoated tablet, breakline on one side, plain on other sides. **IDENTIFICATION** Must Complies as per USP BY HPLC in the chromatogram of the Assay preparation in the chromatogram of the Assay preparation correspond to those in the chromatogram of the correspond to those in the chromatogram of the Standard preparation, as obtained in the Assay Standard preparation, as obtaine in the Assay 3 AVERAGE WEIGHT OF TABLETS 110.4 mg 110.00 mg ± 5.0% of avg.weight UNIFORMITY OF WEIGHT 4 H.L.: + 2.71 % Within ± 7.5% of avg.weight. L.L.: - 2.55 % DIAMETER 6.02 mm $6.00 \text{ mm} \pm 0.2 \text{ mm}$ **THICKNESS** 6 3.37 mm $3.40 \text{ mm} \pm 0.3 \text{ mm}$ HARDNESS 4 Kg/cm2 NLT 3 Kg/cm2 8 FRIABILITY 0.41 % NMT 1.0 % 9 DISINTEGRATION TIME 06 Minute 53 Seconds in water; Medium at 37°c NMT 15 minutes in water medium at 37°c 10 DISSOLUTION 100.97% NLT 80.0 % (Q) UNIFORMITY OF DOSAGE UNITS 11 Min :99.62% 85.0 % TO 115.0 % Max: 101.60% Avg :100.97% 12 ASSAY Each uncoated tablets contains; 100.09% Ivermectin IP 12 ma [Limit; 90.0% To 110.0%]

Conclusion: The above sample complies as per USP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Prepared By Checked By Approved By PARTHSAPARA PINALPATEL **PUSHPENDRA QC CHEMIST** Q.C IN CHARGE **QA HEAD**

TRUPTI 08-09-21 12:17 PM

FGANLCERTQA