



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Certificate of Analysis

A sample of therapeutic goods, bearing TGA sample number 2403001123 has been examined and analysed

The sample was submitted by RCB **s22**

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: N/A
Name: Iverheal-12 Ivermectin 12mg Tablets
Sponsor: NOT AVAILABLE
Batch Number: TI-490033
Expiry Date: 30-September-2026
Dosage Form: Tablet

TEST	RESULT	REQUIREMENT
TGA Seal Number	A340762807	
Sample Appearance		
Content of Ivermectin by UPLC (USP)	80.1 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Australian Border Force (ABF) Seal	D002424	
Uniformity of dosage units - content uniformity	Acceptance Value (AV) = 51.3 (89.1, 89.4, 87.6, 71.7, 85.7, 43.8, 84.1, 81.9, 83.0, 84.5 %LC)	AV = 15.0 or less

Abbreviations: ; USP = United States Pharmacopeia; UPLC = ultra performance liquid chromatography

This Certificate has been signed and issued electronically by the nominated analyst

Certificate: 2403001123

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Issued: 23-September-2024



Laboratory Report

LB Reference: Project 2853
 RCB reference: RC-027803

Re: *Iverheal 12, Ivermectin Tablets USP 12 mg*

Background

On Monday, 18 March 2024, Laboratories Branch (LB) Chemistry received a Request for Analysis form from **s22** of the TGA Product Import Compliance Section (PICS). On Tuesday, 2 April 2024 LB Chemistry received the following samples.

- One, clear, plastic, tamper-evident, security bag bearing seal number 'A340762807'. The security bag contained a sealed plastic bag bearing seal number 'D002424'. This bag contained two, blister trays labelled as '*Iverheal 12, Ivermectin Tablets USP 12 mg*'. Batch number 'TI-490033' and expiry date '09/2026' were included on the blister trays.

The sample was assigned TGA sample number **2403001123** upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. The sample is suspected to contain less than the labelled content of ivermectin.

PICS has requested LB Chemistry to check the amount of ivermectin in the sample.

Examination and Analysis

The sample was visually examined, photographed¹ and analysed. A '*Certificate of Analysis* for the sample ([D24-4063738](#) refers) is provided with this report. The results of the examination and analysis of the sample are reviewed below.

A photograph of the sample is provided in **Appendix 1** of this report.

(i) Visual examination

The sample consisted of twenty, round, white, flat faced bevel edge bisect, uncoated tablets. Ten tablets were contained in a labelled blister tray. The average tablet weight (based on 10 tablets) was 110.3 mg.

Labelling details for the blister trays included 'Manufactured By: *Healing Pharma.*' with address details.

¹ The photographs are located in TRIM container [E24-122666](#) TRIM records [D24-1202788](#) & [D24-3087623](#) (Web alert photo).

(ii) Testing

Analysis was conducted on 10 individual tablets, tested separately.

Confirmation of the presence of ivermectin and its content in the sample, was determined by analysing each tablet in accordance with the assay test outlined in the Ivermectin Tablets USP² monograph.

Ivermectin was identified in the sample. The average content in the sample was 80.1% of the labelled content, with the variation between the 10 tablets ranging from 43.8% to 89.4%.

This sample would not meet the requirements of the USP as the content is below 90.0% of the labelled amount.

Conclusions

Ivermectin was identified in the sample of '*Iverheal 12, Ivermectin Tablets USP 12 mg*' (TGA sample number **2403001123**). The content of ivermectin in the sample was 80.1 % of the labelled content.

Signed electronically by

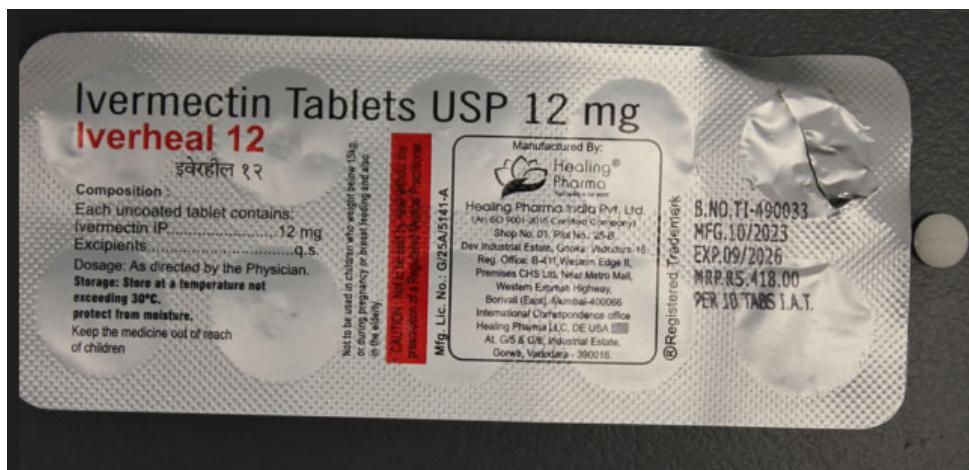
s22

Authorised by:

s22

23 September 2024

Appendix 1: Photograph of the sample



² United States Pharmacopeia