

# Laboratory Report

LB Reference: Project 2821  
RCB reference: RC-025055

## Re: Iverguard-12 Ivermectin Tablets USP 12 mg

### Background

On Monday, 22 January 2024, Laboratories Branch (LB) Chemistry received the following sample from [s22](#) of the TGA Product Import Compliance Section (PICS) along with a Request for Analysis, dated Friday, 8 December 2023

- One, clear, plastic, tamper-evident, security bag bearing seal number 'A260346076'. The security bag contained a sealed plastic bag. This bag contained two, blister trays labelled as 'Iverguard-12, Ivermectin Tablets USP 12 mg'. Batch number and expiry details of 'TI-640011' and '06/2026' respectively, were also included on the blister tray.

The sample was assigned TGA sample number 2401000243 upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. It 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, photographed<sup>1</sup> and analysed. A 'Certificate of Analysis' for the sample ([D24-2002145](#) 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, convex bisect not flush tablets. Ten tablets were contained in a labelled blister tray. The average tablet weight (based on 10 tablets) was 110.8 mg.

Labelling details for the blister trays and carton included 'Fortune Health Care.' with address details.

<sup>1</sup> The photographs are located in TRIM container [E24-19959](#) TRIM records [D24-267473](#) & [D24-972634](#) (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 USP<sup>2</sup> monograph.

Ivermectin was identified in the sample. The average content in the sample was 88.4% of the labelled content, with the variation between the 10 tablets ranging from 81.8% to 94.3%.

Under the requirements of the USP, 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 'Iverguard-12 Ivermectin Tablets USP 12 mg' (TGA sample number **2401000243**). The content of ivermectin in the sample was 88.4 % of the labelled content.

Signed electronically by

s22

Authorised by:

s22

s22

23 May 2024

## Appendix 1: Photograph of the sample



<sup>2</sup> United States Pharmacopeia



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

## Certificate of Analysis

A sample of therapeutic goods, bearing TGA sample number 2401000243 has been examined and analysed

The sample was submitted by **s22** (PICS)

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:** Iverguard 12 Ivermectin Tablets USP 12mg  
**Sponsor:** NOT AVAILABLE  
**Batch Number:** TI-640011  
**Expiry Date:** 30-June-2026  
**Dosage Form:** Tablet

TEST	RESULT	REQUIREMENT
TGA Seal Number	A260346076	

### Sample Appearance

Twenty, white, Circular standard convex bisect not flush tablets. The average tablet weight (based on 10 tablets) was 110.8 mg. Two blister trays each contained 10 tablets, were in a sealed plastic bag. This plastic bag was received in a sealed 'Tamper Evident Security Bag' along with an opened post bag and a Australian Border Force 'Receipt for Goods' form.

Content of Ivermectin by UPLC (USP)	88.4 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Uniformity of dosage units - content uniformity (USP)	Acceptance Value (AV) = 19.1 (92.3, 85.1, 87.5, 88.6, 89.9, 94.3, 81.8, 84.7, 90.7, 89.4 %LC)	AV = 15.0 or less

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

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

Certificate: 2401000243

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