

Information about TGA laboratory testing results

Important information on the Database of TGA Laboratory testing results.

Last updated:

11 June 2021

Safety alerts

When we identify serious safety or quality issues with therapeutic goods, information and recommendations are posted immediately on the <u>Safety information (https://www.tga.gov.au/node/287443)</u> pages of the TGA website.

This database does **NOT** provide timely alerts to healthcare professionals and consumers where a serious safety or quality issue has been identified.

About the TGA Laboratory testing results

Results of TGA Laboratory testing are released in May and November each year. There is a minimum delay of 6 months between the testing and publication of results. This delay in publication is necessary to allow the TGA to undertake any investigations and follow-up action in response to non-complying test results.

More information on laboratory testing of therapeutic goods is available at:

- TGA Laboratories (https://www.tga.gov.au/node/287127)
- TGA Laboratories: What we test and how to access the results (https://www.tga.gov.au/node/ 288012)
- Testing of therapeutic products (https://www.tga.gov.au/node/287128)
- TGA laboratory testing reports (https://www.tga.gov.au/node/287822)

Limitations of test results

TGA's laboratory testing targets the most appropriate quality and/or performance aspects relevant to the product being tested. As such, a PASS result indicates a sample has met those quality/performance requirements tested by us.

Sponsors

The sponsors identified in these testing results were the sponsor of the product at the time the samples were received by the TGA. This may no longer be the current sponsor for the product. The current sponsor of a therapeutic good can be found by searching the <u>Australian Register of Therapeutic Goods (ARTG) (https://www.tga.gov.au/node/287250)</u>.

Unregistered therapeutic goods

Many unregistered therapeutic goods tested by TGA Laboratories have no packaging, labels or distinguishable product name. In this situation the goods are identified within this database using a description of the goods followed by '(unlabelled)'. E.g. *Blue and White Pills (unlabelled)*.

More information on laboratory testing of unregistered therapeutic goods is available at: <u>Testing of therapeutic products (https://www.tga.gov.au/node/287128)</u>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the results and outcomes of TGA's laboratory testing, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the *Therapeutic Goods Act 1989*, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Topics:

Biological medicines (https://www.tga.gov.au/products/medicines/biological-medicines)

Over the counter (OTC) medicines (https://www.tga.gov.au/products/non-prescription-medicines/over-counter-otc-medicines)

Regulatory compliance (https://www.tga.gov.au/how-we-regulate/compliance-and-product-testing/regulatory-compliance)

Featured in:

<u>Australian Regulatory Guidelines for Prescription Medicines (ARGPM) (https://www.tga.gov.au/argpm)</u>