



Australian Government
Department of Health
Therapeutic Goods Administration

TGA Request for Samples – Guide for Sponsors

Introduction

The Therapeutic Goods Administration (TGA) is responsible for regulating the quality of therapeutic goods in Australia. Samples are tested in the Laboratories Branch in TGA for compliance with relevant standards or agreed specifications. As part of this surveillance, we ask you to provide samples of the products requested in the Sample Request Notice. You will be advised of the outcome of the laboratory testing following completion of the testing. In addition, outcomes of laboratory testing are published biannually in the TGA Database of Laboratory Testing Results <http://www.tga.gov.au/ws-labs-index>.

Which samples?

Samples should be taken from batches that are within shelf life as instructed on the accompanying correspondence.

Retention samples

In accordance with the Australian Code of GMP, we recommend that you retain an adequate quantity of the same batch.

How many and when to send?

Refer to the Sample Request Notice. The quantity of product we have requested is based on our testing requirements.

What do I do if I do not have all of the requested samples?

If you do not have all of the requested sample(s) or the number of batches requested, please send an email to s22@health.gov.au stating the reason why the product(s) is(are) unavailable. If you are awaiting the next production batch, please advise when you expect to receive product.

Transport of Sample

The Sponsor should dispatch the samples to the TGA. Do not arrange shipment directly to the TGA from overseas, unless otherwise agreed. Sponsors are responsible for arranging any AQIS permits and associated costs required for receiving samples from overseas.

Packaging

Samples must be packaged to prevent damage and deterioration during transport. The outer container should be clearly labeled 'SAMPLES' and have both the sender and recipient addresses.

Shipping temperature

Samples must be shipped at the approved storage condition. Samples requiring refrigeration or freezing should be sent in insulated containers with adequate refrigeration or dry ice.

Hazardous substances

If the container holds hazardous substances the outer container should be clearly labelled with any warnings or precautions.

Payment for Sample

If payment is required, please contact LB for more information, prior to shipping the sample.

Where to send the samples

The samples should be sent to the TGA preferably by an overnight courier. The delivery address is:

Attention: s22
TGA Laboratories Branch – Chemistry section
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Note:

All deliveries must be received at TGA Loading Dock 1 between the hours of 8am and 5pm. To ensure cold chain requirements are met for any samples requiring refrigeration or freezing we recommend delivery to TGA prior to 4pm (16:00) AEST.

Any questions?

If you have any questions regarding this request, please contact s22 by phone s22 or email s22@health.gov.au