This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Module 1.2.1: Assessed listed medicine general application information form

This form is to be completed in conjunction with the Assessed listed medicines application form.

Complete the form as per the instructions in the guidance for completing the application form for an assessed listed medicine on the TGA website. Please include the form in module 1.2.1 of your application dossier.

The form is divided into two parts:

Part	
A – Formulation details	Complete one part A for each formulation in a medicine.
B – Manufacturer details	Complete one part B for each application

Please note:

- The information recorded should reflect the new ARTG record, not what is currently recorded in the Australian Register of Therapeutic Goods (ARTG) for the medicine

If there is insufficient room in any field/section on this application form:

- enter 'see attached' in the field
- attach a separate page with the full details

Include the completed information form (Parts A and B) in Module 1.2.1 of the CTD.

Part A Formulation details

Single active ingredient ☐ multi-active ingredient ☐

Is the application for a composite pack? ☐ Yes ☐ No

For each formulation in your composite pack, include the formulation details in a separate table.

Are all ingredients within the formulation included in the Therapeutic Goods (Permissible Ingredients) Determination? ☐ Yes ☐ No

Do all ingredients comply with the requirements for their use in listed medicines as specified in the Therapeutic Goods (Permissible Ingredients) Determination? ☐ Yes ☐ No

Active ingredients

Active ingredient(s) (and equivalents)	Category	Quantity	Units	Are there restrictions on the use of the ingredient?
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐

Note: Insert additional rows if there is insufficient room in the above table.

Excipient ingredients

Excipient ingredient(s)	Category	Quantity	Units	Are there restrictions on the use of the ingredient?
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐

Note: Insert additional rows if there is insufficient room in the above table.

Australian Herbal Name (AHN) ingredients details (if applicable)

AHN only			
Plant part			
Plant preparation			
Equivalent preparation			
Equivalent quantity		Final preparation ratio	
Remaining restricted solvent		Carrier	

Note: Provide a separate table for each AHN in your medicine.

Proprietary ingredients details (if applicable)

Proprietary ingredient			
Proprietary ingredient name			
Proprietary ingredient ID		Formulation type	
Ingredient role		Ingredient type	
Quantity		Units	
Equivalent			

Note: Provide a separate table for each proprietary ingredient in your medicine.

Ingredients of human or animal origin details (if applicable)

Does the formulation contain ingredients of human or animal origin? ☐ Yes ☐ No

If yes, you are required to submit the ingredient source details and (if applicable) pre-clearance code in the table below.

Source of material in product			
Name of ingredient (and pre-clearance code if applicable)	Animal species (e.g. bovine)	Animal part (e.g., hide)	Country of origin

Note: Insert additional rows if there is insufficient room in the above table.

Part B – Manufacturer details

All Australian manufacturers involved in the manufacture of the product have a current Good Manufacturing Practice (GMP) licence which is suitable for the product type, and dosage form and steps? ☐ Yes ☐ No

All overseas manufacturers involved in the manufacture of the product have current GMP clearance which is suitable for the product type, and dosage form and steps? ☐ Yes ☐ No

Note: All Australian manufacturers involved in the manufacture of the product should be entered.

Provide the approved Good Manufacturing Practice (GMP) clearance or licence tracking number for all manufacturing sites relevant to the application.

Product manufacturer details	
Manufacturer 1	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
GMP licence/clearance number	
Steps in manufacture	
Manufacturer 2	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
GMP licence/clearance number	
Steps in manufacture	
Manufacturer 3	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
GMP licence/clearance number	
Steps in manufacture	
Manufacturer 4	
Manufacturer's business name	
Manufacturer's site address	

Product manufacturer details	
Manufacturer’s Client ID (if known)	
GMP licence/clearance number	
Steps in manufacture	

Note: Insert additional rows if there is insufficient room in the above table.