Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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>.

Assurances to accompany an OTC new medicine N2 application

Please note

- Giving information that is false or misleading in a material particular is an offence under the *Therapeutic Goods Act 1989* (section 22A) and can give rise to civil penalties under the Act (section 22B).
- Under subsection 24(2) of the Act, an application for registration of an OTC lapses if:
  - it contains information that is inaccurate or misleading in a material particular
  - information that is inaccurate or misleading in a material particular is given to the TGA in connection with an OTC application, including information given for the purposes of section 31 of the Act.
- Following approval, medicines found not to comply with standard and specific conditions of registration could be subject to regulatory action.

Completing this form

Completing this form provides the assurances required to accompany an OTC New medicine N2 application. Ensure you:

- Enter the required administrative details in Section 1
- Select 'Yes' to provide the assurance or 'Not applicable' where appropriate (Do not select 'Not applicable' unless this option is available in the form).
- All assurances in this form must be provided. If you cannot provide all of the assurances, do not submit an OTC New medicine N2 application (as this is not the correct application level).
- Ensure this form is signed by a person authorised to conduct business on behalf of the applicant. This person must be listed on the TGA Business Services client database, and may be a company employee or an agent.
- Include the completed form within Module 1.5 of an OTC New Medicine N2 application.

Section 1: Administrative

Proposed trade name	
Active ingredients	
Dosage form	
Name of sponsor	
Name of Agent (if applicable)	

Section 2: Assurances

General

#	Assurance	Applies to this application
1.	The medicine that is the subject of this application complies with the: · relevant OTC medicine monograph · document Requirements for OTC New Medicine N2 applications	☐ Yes
2.	The sponsor holds a complete data set, in accordance with the *Australian Regulatory Guidelines for OTC Medicines (ARGOM)*, for the medicine that is the subject of this application. These data will be made available to the TGA in the required application format, within 30 calendar days of a request.	☐ Yes

Labelling

#	Assurance	Applies to this application
1.	Where claims are made that the medicine does not contain a particular excipient (e.g. gluten free, sugar free, alcohol free, lactose free), the statement is true and in accordance with any relevant ARGOM requirements.	☐ Yes ☐ Not applicable
2.	Where an internet address or QR code is included, the information about the medicine included on the website (including any direct links from that website) will be consistent with the information approved by the TGA for the medicine.	☐ Yes ☐ Not applicable

Active ingredients

#	Assurance	Applies to this application
1.	All active ingredients are controlled by the finished product manufacturer to the requirements of the relevant and current BP, Ph. Eur. or USP/NF, as specified in ARGOM Appendix 2.	☐ Yes
2.	The formulation includes the following **active** ingredient premixes (only if permitted by the relevant OTC Medicine Monograph; include proprietary name):	☐ Yes
3.	The individual components in the above premix(es) are controlled by the supplier to relevant and current BP, Ph. Eur. or USP/NF monographs. The finished product manufacturer's acceptance specifications for the active ingredient premix include testing as specified in the relevant specific OTC medicine monograph.	☐ Yes ☐ Not applicable

Formulation

#	Assurance	Applies to this application
1.	Any excipient-only premixes included in the formulation are restricted to colourings, flavours, fragrances, printing inks, film coatings and/or capsule shells.	☐ Yes ☐ Not applicable
2.	Any colourings, flavours, or fragrances do not exceed 2% w/w or w/v of the finished product.	☐ Yes ☐ Not applicable
3.	Only colourings permitted for use in medicines (as described in the document *Requirements for OTC New Medicine N2 applications*) are included in the formulation.	☐ Yes ☐ Not applicable

Manufacturing

#	Assurance	Applies to this application
1.	All sites involved in the manufacture, packaging, labelling, testing and release for supply of the finished product (including any active ingredient premix manufacturers) are specified in the application form.	☐ Yes
2.	The product is manufactured using standard processes (as defined in CPMP/QWP/2054/03 - *Annex II to Note for guidance on process validation CHMP/QWP/848/99 and EMEA/CVMP/598/99*.	☐ Yes
3.	Manufacturing process validation has been completed (or will be completed prior to supply in Australia) on a minimum of two commercial scale batches of product according to the Australian Code of Good Manufacturing Practice.	☐ Yes
4.	The manufacturer's validation report and related information will be available for review, on request by the TGA, within three months of release for supply of the first production batch.	☐ Yes

Control of excipients

#	Assurance	Applies to this application
1.	Each excipient (excluding premixed flavours, fragrances, printing inks, film coatings, capsule shells and colourings – see points 2-5 below) is the subject of a current BP, Ph. Eur. or USP/NF monograph and is controlled by the finished product manufacturer to the requirements of the relevant pharmacopoeial monograph). Where the USP is applicable, and there are both USP and NF monographs for the same substance, the USP monograph is applied.	☐ Yes
2.	The individual components of any active ingredient premixes, capsule shells or proprietary film coating mixtures are controlled by the supplier to a relevant and current BP, Ph. Eur. or USP/NF monograph (except that colourings within these must comply with requirements outlined in the document *Requirements for OTC New Medicine N2 applications*).	☐ Yes ☐ Not applicable
3.	Pharmacopoeial (BP, Ph. Eur. or USP/NF) monographs are not available for the following premixed flavours, fragrances, and/or film coating agents in the proposed product (include all as relevant, by TGA PI number or proprietary name): a. b. c. d.	
4.	The ingredients listed above are each controlled by the finished product manufacturer in accordance with requirements as specified in the document *Requirements for OTC New Medicine N2 applications*.	☐ Yes ☐ Not applicable
5.	Any colourings used comply with requirements outlined in the document *Requirements for OTC New Medicine N2 applications*.	☐ Yes ☐ Not applicable
6.	Any ruminant ingredients included in this product that are eligible for self-assessment have been assessed in accordance with the TGA document Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising the risk of exposure and data is held demonstrating compliance with those requirements.	☐ Yes ☐ Not applicable

Control of finished product

#	Assurance	Applies to this application
1.	The finished product specifications include all required tests and limits as described in the relevant OTC medicine monograph.	☐ Yes

#	Assurance	Applies to this application
2.	Any other necessary tests and limits are included in the finished product specifications in accordance with: · ICH Q6A guideline Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances (CPMP/ICH/367/96; e.g. limits on alcohol or preservative content are included, as applicable). · ICH Q3C guideline Note for Guidance on Impurities: Residual solvents (CPMP/ICH/283/95).	☐ Yes ☐ Not applicable ☐ Yes ☐ Not applicable
3.	Tests specified in the finished product specifications and used in the stability studies, for identification, assay, impurities and dissolution, use either the relevant pharmacopoeial method validated for specificity and accuracy or an alternative equivalent or superior method validated fully as described in the ICH/CPMP guideline, *Note for Guidance on Validation of Analytical Procedures: Text and Methodology* (CPMP/ICH/381/95).	☐ Yes ☐ Not applicable
4.	Tests for preservative content are validated as described in the ICH/CPMP guideline, *Note for Guidance on Validation of Analytical Procedures: Text and Methodology* (CPMP/ICH/381/95).	☐ Yes ☐ Not applicable
5.	Where the directions for use permit the subdivision of tablets (e.g. ½ tablet doses), the efficacy of the break-mark(s) has been assessed and the results ensure that the intended dose can be administered (see *ARGOM, Appendix 2, 7.5.2 Subdivision of tablets*).	☐ Yes ☐ Not applicable

Container / measuring device

#	Assurance	Applies to this application
1.	Packaging comprises conventional containers and material for the dosage form (e.g. oral liquids in bottles, tablets in bottles or blister packs).	☐ Yes
2.	Packaging materials, containers, seals and closures are suitable for the intended pharmaceutical use and are adequately controlled as described in *ARGOM, Appendix 2, 8 Finished Product Container*.	☐ Yes
3.	The container complies with Therapeutic Goods Order No. 80 - Child-Resistant Packaging Requirements for Medicines, as relevant.	☐ Yes ☐ Not applicable
4.	Where a measuring device is to be supplied with the medicine, the ability of the device to deliver the correct dose accurately and reproducibly has been ensured. The supplied measuring device complies with the test and requirement for *Uniformity of Weight (Mass) of Delivered Doses from Multidose Containers* (Ph. Eur. monograph 2.9.27) as specified in BP/Ph. Eur. *Appendix XII C. Consistency of Formulated Preparations*.	☐ Yes ☐ Not applicable

Stability

#	Assurance	Applies to this application
1.	Stability data to support the nominated shelf life have been generated in accordance with ARGOM Appendix 2: Guidelines on quality aspects of OTC applications. I further declare that the nominated shelf life has been determined in accordance with ARGOM Appendix 2: Guidelines on quality aspects of OTC applications.	☐ Yes
2.	Where the medicine is an aqueous multi-dose medicine, the applicant holds data demonstrating preservative efficacy in accordance with ARGOM Appendix 2: Guidelines on quality aspects of OTC applications 9.9.6.	☐ Yes ☐ Not applicable
3.	The stability batches used in the above stability studies: · are identical with respect to formulation and container type/material to the product to be marketed, **and** · were manufactured at pilot or production scale, using a process that simulates the final process intended for manufacture of the product to be marketed.	☐ Yes ☐ Yes
4.	Where a shelf life has been allocated on the basis of anything less than full-term data on two production batches, a stability testing program will be initiated on the first production batches of the goods (to a total of two), and any adverse results will be immediately reported to the TGA.	☐ Yes ☐ Not applicable
5.	An ongoing stability testing program will be carried out in accordance with GMP requirements (refer to details contained in the *Code of GMP* - *Chapter 6 Quality control*, or for additional advice contact the TGA).	☐ Yes

I declare that:

· The information and assurances I have provided above are true and correct. ☐

· I am authorised to act on behalf of the sponsor. ☐

Name			
Position (e.g. regulatory affairs officer, agent of the sponsor)			
Signature		Date	