Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'OFFICIAL'**.
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

These assurances confirm that the application meets the requirements for an N2 level application.

The importance of assurances

Making an N2 application for a new OTC medicine:

- reduces the amount of data that needs to be submitted to the TGA at the initial application stage, which reduces the evaluation time
- does not reduce the amount of data that the sponsor is required to hold.

Instead of providing full supporting data with the application, an applicant completes a list of assurances confirming that the product meets the specified requirements for an N2 level application.

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 medicine 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 medicine 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:

- **Provide all the assurances** in this form. If you cannot provide all of the **required** assurances, do not submit an OTC new medicine N2 application, because this is not the correct application level.
- Enter the required administrative details in Section 1.

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- Select 'Yes' to provide the assurance. 'Not applicable' is only an option where a 'Not applicable' check box has been provided.
- 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 1.5.7 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

No.	Assurance	
1	The medicine that is the subject of this application complies with the: • relevant OTC medicine monograph • requirements for OTC new medicine N2 applications	☐ Yes
2	The sponsor holds a complete data set for their product, as would be required for a higher level application. These data will be made available to the TGA in the required format within 20 working days of a request.	☐ Yes

Labelling

No.	Assurance	
1	Where claims are made that the medicine does not contain a particular excipient (e.g. gluten free, alcohol free, lactose free), the statement is true and in accordance with any relevant requirements in Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines (TGO 92).	☐ Yes ☐ Not applicable
2	Where an internet address or QR code is included, the information about the medicine 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

No.	Assurance	
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 described in ARGOM Appendix 2: Guidelines on quality aspects of OTC applications.	☐ Yes

No.	Assurance	
2	The formulation includes the following **active** ingredient premixes (include proprietary name) (only if permitted by the relevant OTC medicine monograph for N2 applications):	☐ Yes ☐ Not applicable (Move to next section)
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 for N2 applications.	☐ Yes

Formulation

No.	Assurance	
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 per the requirements for OTC new medicine N2 applications, described in Colourings used in medicines for topical and oral use) are included in the formulation.	☐ Yes ☐ Not applicable

Manufacturing

No.	Assurance	
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 the Guideline on process validation for finished products – information and data to be provided in regulatory submissions EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1.	☐ 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 Good Manufacturing Practice.	☐ Yes
4	The manufacturer's validation report and related information will be available for review, on request by the TGA, within 3 months of release for supply of the first production batch.	☐ Yes

Control of excipients

No.	Assurance	
1	Each excipient (excluding premixed flavours, fragrances, printing inks, film coatings, capsule shells and colourings) 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).	☐ 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 requirements for OTC new medicine N2 applications).	☐ Yes ☐ Not applicable

No.	Assurance	
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 (use the TGA PI number or proprietary name): a. b. c. d. The ingredients listed above are each controlled by the finished product manufacturer in accordance with the requirements for OTC new medicine N2 applications).	☐ Yes ☐ Not applicable
4	Any colourings used comply with the requirements for OTC new medicine N2 applications, as described in Colourings used in medicines for topical and oral use.	☐ Yes ☐ Not applicable
5	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

Number	Assurance	
1	The finished product specifications include all required tests and limits as described in the relevant OTC medicine monograph for N2 applications.	☐ Yes
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 (R8) on impurities: guideline for residual solvents (ICH Q3C (R8); EMA/CHMP/ICH/82260/2006 Corr.*)	☐ 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 are 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: Guidelines on quality aspects of OTC applications, *7.5.2 Subdivision of tablets*).	☐ Yes ☐ Not applicable

Container and/or measuring device

Number	Assurance	
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: Guidelines on quality aspects of OTC applications, *8 Finished Product Container*.	☐ Yes

Number	Assurance	
3	The proposed medicine complies with Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017 (TGO 95). Note 1: Sponsors are required to hold evidence of performance testing for reclosable closures. Note 2: Blister packaging is generally considered to be compliant with requirements for child-resistant packaging.	☐ 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 and Accuracy 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

Number	Assurance	
1	Stability data to support the nominated shelf life (including storage conditions) have been generated in accordance with ARGOM Appendix 2: Guidelines on quality aspects of OTC applications. I further declare that the nominated shelf life (including storage conditions) 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, section 9.6.6.	☐ Yes ☐ Not applicable
3	The stability batches used in the above stability studies: • are identical with respect to formulation and container type and container 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 Good Manufacturing Practice (GMP) requirements (PIC/S Guide to GMP for medicinal products, Part I chapter 6).	☐ Yes

Declaration

I declare that:

- The information and assurances I have provided above are true and correct. ☐ Yes
- I am authorised to act on behalf of the sponsor. ☐ Yes

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