**NEW RELATED PRODUCT APPLICATION FORM**

One copy of this form must be completed for each separate related product.

The Guide to completing a New Related Product Application Form (Application Guide) referred to in this form is available on the Medsafe website as a separate document. Please do not submit the Application Guide document to Medsafe.

The macro enabled form is no longer available for use.

1. **Proposed product details, required for all applications**

Type of application:

Proposed trade name:

Identifier (if the proposed trade name is the drug substance name):

Drug substance:

Dose form (refer to Application Guide):

Strength (include units):

New Zealand Classification (refer to Application Guide):

Route of administration (refer to Application Guide):

ATC classification (refer to Application Guide):

Proposed indications and/or label claims:

1. **Additional information, where applicable:**
* **All products**

The product is currently approved in the following countries:

The product is currently pending approval in the following countries:

* **Application based on a parent product**

If this application is a line extension for another product, provide the parent product details:

Parent product name:

Parent product dose form:

Parent product strength:

Additional application, submitted concurrently with the parent product: [ ]

Indicate the difference between the parent product and the new product (refer to Application Guide):

Parent product file number(s), if known: TT50-

Comments:

1. **Applicant and Sponsor details**

**New Zealand Sponsor**

Name and street address:

Postal address (eg. PO Box):

Contact phone number:

**Applicant**

All correspondence relating to the application (including the invoice) will be sent to this person.

Name and designation of the person submitting this application

Postal address:

Email address:

Contact phone number:

1. **Fees and Invoice details**

Tick those that apply

|  |  |  |
| --- | --- | --- |
| **Type of Application** | **Fee** |  |
| New related product  | 5,731 |  |
| Additional names, strengths, flavours and classifications notified at the same time as the parent application  | 0 |  |
| **Additional names and strengths – subsequent to the parent product**The following fees apply when the additional products are subsequent to approval of the parent product (ie, when additional product applications are submitted after approval of the parent product).[[1]](#footnote-1) |
| Additional name − Grade 1 | 865 |  |
| Additional name − Grade 2  | 1,730 |  |
| Additional strength  | 1,730 |  |
| Additional flavour or type of sweetening  | 1,730 |  |

**Calculated Fee:**

Comments:

All fees are GST inclusive.

Enter customer reference required on the invoice here (max 20 characters):

NB: All acknowledgement letters and invoices will be emailed but not sent in hard copy.

1. **Product formulation:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of ingredient** (For drug substance, identify amount equivalent to free base, if applicable) | **Type of ingredient** | **Quantity** (specify units) | **Quality standard**  |
| Component name (if applicable) |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |

Proprietary ingredients

* If the quantitative formulation of any proprietary ingredients has been previously provided to Medsafe, list the proprietary ingredient name and the associated reference number(s):
* If the quantitative formulation of any proprietary ingredients has not been previously provided to Medsafe, this information is presented in Module 3 on page:
* If the quantitative formulation of any proprietary ingredients has not been previously provided to Medsafe, but this information will be sent directly from the supplier, list the ingredient name, identifier, and supplier:
1. **Product packaging, patient information, and storage conditions:**

|  |  |
| --- | --- |
| Container closure system and administration device: | Primary container: Materials and description:      Closure:     Materials and description:       |
| Secondary container:      Materials and description:       |
| Administration device:      Materials and description:       |
| Pack size(s) to be registered: |       |
| A package insert is to be supplied with the product: |  |
| Proposed shelf life and storage conditions: | Protect from light | Protect from moisture | Do not refrigerate | Do not freeze |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |

1. **Production**

**Manufacturing of the drug substance**

|  |  |
| --- | --- |
| Name of drug substance |       |
| Name of manufacturer |       |
| Manufacturing site address |       |
| Regulatory authority which issued the GMP evidence |       |
| GMP evidence date of expiry |       |
| DMF number, if knownOr Certificate of Suitability number | TT60-     R -CEP     -   -Rev    |
| Letter of access provided | [ ]  |

**Manufacturing of the drug product**

|  |  |
| --- | --- |
| Name of manufacturer |       |
| Manufacturing site address |       |
| Regulatory authority which issued the GMP evidence |       |
| GMP evidence date of expiry |       |
| Manufacturing steps carried out at this site |  |

**Packing of the drug product**

|  |  |
| --- | --- |
| Name of packer |       |
| Site address |       |
| Regulatory authority which issued the GMP evidence |       |
| GMP evidence date of expiry |       |
| Packing steps carried out at this site |  |

**Testing of the drug product**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |
| Regulatory authority which issued the GMP evidence |  |
| GMP evidence date of expiry |  |
| Testing steps carried out at this site |  |

**New Zealand site of batch release**

|  |  |
| --- | --- |
| Name of release site |  |
| Street address of batch release site |  |

1. **Provided information**

|  |  |  |
| --- | --- | --- |
| **Documentation** (Please ensure ALL relevant sections in this table are completed) | **Section**  | **Volumes(s)** |
| **If available, electronic dossier (two copies, hyperlinked, and copy-enabled) should be provided.** |
| **Module 1** |  |       |
| * Detailed table of contents for the dossier
 |       |  |
| * Labels
 |       |  |
| * Data sheet
 |       |  |
| * Package Insert
 |       |  |
| * GMP documentation
 |       |  |
| * CEP with declaration of access
 |       |  |
| **CTD Module 2** Overviews and Summaries |  |       |
| **CTD Module 3** Chemical, pharmaceutical, and/or biological documentation  |  |       |
| * Drug product formulation/Batch formula
 |       |  |
| * Drug product release and expiry specifications
 |       |  |
| * Proprietary ingredients formulation
 |       |  |
| **CTD Module 4**Toxicological and pharmacological (pre-clinical) documentation |  |       |
| **CTD Module 5**Clinical Documentation  |  |       |
| * Bioequivalence study results
 |       |  |
| * Bridging study between the reference product used in the biostudy and the New Zealand reference product
 |       |  |
| * Bioanalytical method validation
 |       |  |
| **Drug Master File(s) or Plasma Master File(s)** |  |       |
| Letter(s) of access to the Drug Master File(s) or Plasma Master File(s) |       |  |
| **Total number of volumes submitted:** |  |       |

1. Fees for this category are cumulative. That is, an applicable fee is charged for each additional name, strength, etc. [↑](#footnote-ref-1)