**New Medicine Application Form**

**Lower-Risk Medicines**

Notes on completing the form:

Complete one copy of this form for each separate Lower-Risk medicine (name + dose form + drug substance(s) + strength + classification + flavour, as applicable).

Use the New Medicine Application – Intermediate-Risk & Higher-Risk Medicines form for intermediate-risk and higher-risk products. Refer to the Guide to completing a New Medicine Application – Lower-Risk Medicines form (Application Guide) to select the correct category of application.

1. **Proposed product details**

|  |  |
| --- | --- |
| **Type of application**  (L1, L2, L3) |  |
| **Justification for selection** |  |
| **Proposed trade name** |  |
| **Identifier**  (Only applicable if the proposed trade name is the drug substance name) |  |
| **Drug substance and strength** |  |
| **Dose form** |  |
| **Route of administration** |  |
| **Classification**  (Refer to the Classification Database on the Medsafe website) |  |
| **ATC classification** |  |
| **Proposed indications and/or label claims:** |  |

**New Zealand Medicines Terminology:**

A New Zealand Medicines Terminology Listing Certificate should be provided as part of the Medsafe application process.

The New Zealand Medicines Terminology Listing Certification has been attached

Refer to [http://www.nzulm.org.nz](http://www.nzulm.org.nz/) or email [listings@nzmt.org.nz](mailto:listings@nzmt.org.nz) for further details on NZMT listings.

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 that includes clinical data and/or bioequivalence studies (if applicable):**

|  |  |  |
| --- | --- | --- |
| **Details of reference product (complete the row that applies)** | | |
|  | **New Zealand reference product and strength with which the biostudy was conducted:** |  |
|  | **Australian reference product and strength with which the biostudy was conducted:** |  |
|  | **Other reference product and strength with which the biostudy was conducted:** |  |

**Application based on a parent product**

|  |  |
| --- | --- |
| **Details of parent product** | |
| **Product name** |  |
| **Identifier** (if applicable) |  |
| **File reference number** (if applicable) | TT50- |
| **Drug substance and strength** |  |
| **Dose form** |  |
| **Route of administration** |  |
| **Classification** |  |
| **ATC classification** |  |
| **Differences between the parent product and the proposed product** |  |
| **Sponsor** |  |
| **Evidence is included that the sponsor of the parent product has granted full access rights to the product approval file(s) for the parent product** | Yes  N/A  Comments: |

1. **Applicant and Sponsor details**

|  |  |
| --- | --- |
| **Name, job title and address of person submitting the notification (the applicant)**  All correspondence about the application, including acknowledgement letter and invoice, will be sent to this person by email.  Note: Include a letter of authorisation from the sponsor if not provided previously |  |
| **Applicant email address**  This should be the company’s generic email address (if available) |  |
| **DMF holder email address** (if applicable) |  |
| **New Zealand sponsor name and street address** |  |

1. **Fees and Invoice details**

Select all application types that apply

All fees are GST inclusive

|  |  |  |
| --- | --- | --- |
| **Full applications** | Fee | Select |
| New lower-risk medicine | 10,649 |  |
| Additional dose form – lower-risk medicine – Grade 1 or 2 | 10,649 |  |
| New combination pack containing two or more currently approved products | 3,835 |  |

|  |  |  |
| --- | --- | --- |
| **Additional names and strengths – concurrent with parent product**  The following fees apply when the additional products are applied for at the same time as the parent product[[1]](#footnote-1) | Fee | Select |
| Additional name − Grade 1 | 432 |  |
| Additional name − Grade 2 | 865 |  |
| Additional classification (with/without new name) | 432 |  |
| Additional strength − Grade 1 | 1,298 |  |
| Additional strength − Grade 2 | 1,730 |  |
| Additional strength − Grade 3 | 3,460 |  |
| Additional flavour or type of sweetening | 865 |  |

|  |  |  |
| --- | --- | --- |
| **Additional names and strengths – subsequent to the approved 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). [[2]](#footnote-2) | Fee | Select |
| Additional name − Grade 1 | 865 |  |
| Additional name − Grade 2 | 1,730 |  |
| Additional classification (with/without new name) | 865 |  |
| Additional strength − Grade 1 | 2,595 |  |
| Additional strength − Grade 2 | 3,459 |  |
| Additional strength − Grade 3 | 6,919 |  |
| Additional flavour or type of sweetening | 1,730 |  |

|  |  |  |
| --- | --- | --- |
| **Provisional consent** | Fee | Select |
| Provisional consent to distribute a new medicine (stock shortage)  Low risk | 2,130 |  |
| Provisional conversion to full approval (stock shortage)  Lower risk | 8,176 |  |
| Application for renewal of provisional consent[[3]](#footnote-3) | 11,982 |  |

**Invoice details**

|  |  |
| --- | --- |
| **Calculated fee** | $ |
| **Comments** |  |
| **Customer reference code for invoice**  (Optional; maximum 20 characters): |  |

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**

For products that include one or more proprietary ingredient, select, and complete the option(s) that apply:

|  |  |  |
| --- | --- | --- |
|  | The quantitative formulation was previously provided to Medsafe | Name:  Supplier code: |
|  | The quantitative formulation hasnot previously been provided to Medsafe and is presented in Module 3 | Module 3 page: |
|  | The quantitative formulation has not previously been provided to Medsafe, and will be sent directly from the supplier with the Proprietary ingredient registration form <https://www.medsafe.govt.nz/regulatory/forms.asp> | Name:  Supplier code:  Supplier: |

1. **Product packaging, patient information, and storage conditions:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Notes:  Complete this table for each proposed container/closure/package type. Create a copy of the table for each additional container/closure/package type. | | | | | |
| Primary container description | |  | | | |
| materials of construction | |  | | | |
| Closure description | |  | | | |
| materials of construction | |  | | | |
| Secondary package description | |  | | | |
| materials of construction | |  | | | |
| Administration device description | |  | | | |
| materials of construction | |  | | | |
| Pack size(s) to be registered: | |  | | | |
| A package insert is to be supplied with the product: | | **Yes**  **No** | | | |
| 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 known  Or 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 carried out at this site |  |

**Biostudy/clinical site (if applicable)**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |

**Bioanalytical testing site (if applicable)**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |

**New Zealand site of batch release**

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

1. **Information included with the application**

|  |  |
| --- | --- |
| **Documentation** (Complete all relevant sections in this table) | **Section** |
| **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)** |  |
| Letter(s) of access to the Drug Master File(s) |  |
| **Total number of volumes submitted:** |  |

**The electronic dossier should be hyperlinked and copy-enabled**

1. Fees for this category are cumulative. That is, an applicable fee is charged for each additional name, strength, etc. [↑](#footnote-ref-1)
2. Fees for this category are cumulative. That is, an applicable fee is charged for each additional name, strength, etc. [↑](#footnote-ref-2)
3. [↑](#footnote-ref-3)