**Application Form**

|  |  |
| --- | --- |
| medicinal cannabisApplication for an assessment of a New Medicinal Cannabis ProductMisuse of Drugs (Medicinal Cannabis) Regulations 2019 | NP |

|  |
| --- |
| **Office use only** |
| Contact person name: |  |
| Licence holder: |  |
| Date application received: |  |
| Assigned to: |  |

INFORMATION FOR APPLICANTS

Use this application form to apply for an assessment of a New Medicinal Cannabis Product (NMCP). Before completing this application form, read **Part 3**: **Guidance for a New Medicinal Cannabis Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*. This NMCP application form follows the structure of **Part 3**.

A contact person may be a licence holder, a director/partner or a responsible person for the licensed activity.

For the application to be considered, you must complete all the relevant sections of the application form and provide the necessary information.

While this form provides space for you to provide the required information, you will also need to present the supporting information as clearly marked separate attachments.

During its assessment of the application, the Medicinal Cannabis Agency (the Agency) may request further information from you.

When the Agency receives your application, it will invoice you a fee of $345 (including GST) for an initial check of the application. This fee is non-refundable.

If the application appears to be in order, the Agency will invoice you for the full NMCP assessment fee.

The assessment of your NMCP will not start until you have paid the full assessment fee. The assessment fee is non-refundable.

|  |
| --- |
| **INSTRUCTIONS FOR COMPLETING THE APPLICATION** |
| * While this form includes space for you to provide the information required by Section 2 of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*, you may provide any additional information in clearly named attachments.
* Section 3 of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* and Section 3 of this form both outline the supporting information that you are required to submit with your application based on what type of application it is. Please attach all required documents and clearly name them in Section 3 of this form so that your application can proceed.
 |
| **APPLICATION FORM SUBMISSION** |
| * For electronic submission, scan the completed application form and supporting documents to the Medicinal Cannabis Agency (medicinalcannabis@health.govt.nz). You must ensure that the emailed form is legible and complete.
* If you are unable to scan and email the application form, you can post a copy to:

Medicinal Cannabis AgencyMinistry of HealthPO Box 5013Wellington 6145* Keep a copy of the completed application form for your records.
 |

# Application for assessment of a New Medicinal Cannabis Product

The sections of this form follow the structure and section names of **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*.

## Section 2.3: Proposed product details

|  |  |  |
| --- | --- | --- |
| S2.3.1 | Type of application: | Choose an item. |
|  |  |  |
| S2.3.2 | Proposed trade name: |  |
|  |  |  |
| S2.3.3 | Active ingredients: | Delta-9-tetrahydrocannabinol (THC)Delta-9-tetrahydrocannabinolic acid (THCA)Cannabidiol (CBD)Cannabidiolic acid (CBDA) |
|  |  |  |
|  | Other active ingredients: |  |
|  |  |  |
| S2.3.4 | Strength of active ingredients: |  |
|  | THC: |  |
|  |  |  |
|  | THCA: |  |
|  |  |  |
|  | CBD: |  |
|  |  |  |
|  | CBDA: |  |
|  |  |  |
|  | Strength of other active ingredients: |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| S2.3.5 | Dosage form: |  |
|  |  |  |
| S2.3.6 | Recommended method of administration: |  |

## Section 2.4: Overseas approval, declined approval or submission for approval

|  |  |
| --- | --- |
| The medicinal cannabis product has been: | Choose an item. |
|  |  |
| In the following country: |  |
|  |  |
| Regulatory agency: |  |
|  |  |
| Date of approval, declined approval or submission for approval: |  |
|  |  |
| Enter any additional information here: |  |

[Continue on additional sheets if necessary.]

## Section 2.5: Licence holder and contact person details

The contact person is the person with whom the Agency will communicate on all matters (including the fee invoice) to do with this application for an assessment of a New Medicinal Cannabis Product.

### S2.5.1 New Zealand licence holder

Tick the appropriate box below and complete the details underneath.

☐ This application is being made under a current Medicinal Cannabis Licence (with supply as a specified activity) or a licence issued under the Medicines Act 1981,[[1]](#footnote-1) as detailed below.

|  |  |
| --- | --- |
| Licence name: |  |
|  |  |
| Name of licence holder: |  |
|  |  |
| Current licence number: |  |

OR

☐ This application is being made at the same time as an application for a Medicinal Cannabis Licence (with supply as a specified activity) or a licence under the Medicines Act 1981,1 as detailed below.

|  |  |
| --- | --- |
| Licence name: |  |
|  |  |
| Name of applicant: |  |

### S2.5.2 Contact person

|  |  |
| --- | --- |
| Given name(s): |  |
|  |  |
| Surname: |  |
|  |  |
| Company name: |  |
|  |  |
| Job title / position held: |  |
|  |  |
| Relationship to licence holder: |  |
|  |  |
| Date of birth: |  |
|  |  |
| Physical address: |  |
| Street number and name: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Postal address: | ☐ Postal address same as physical address |
| PO Box: |  |
|  |  |
| Suburb: |  |
|  |  |
| Town/city: |  |
|  |  |
| Postcode: |  |
|  |  |
| Contact details: |  |
| Phone: |  |
|  |  |
| Email: |  |

## Section 2.7: Product formulation and composition

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of ingredient** | **Type of ingredient** | **Amount(specify units)** | **Quality standard(for excipients)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Section 2.8: Product packaging and storage conditions

### Primary packaging

|  |  |
| --- | --- |
| Container: |  |
|  |  |
| Materials and description: |  |
|  |  |
| Closure: |  |
|  |  |
| Materials and description: |  |

### Secondary packaging

|  |  |
| --- | --- |
| Materials and description: |  |

### Administrative device

|  |  |
| --- | --- |
| Materials and description: |  |

### Pack size(s) to be registered

A package insert is to be supplied with the product (if yes please provide the package insert as an attachment):

☐ Yes

☐ No

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Proposed shelf life** | **Proposed pack conditions** | **Proposed storage conditions** | **Protect from light** | **Protect from moisture** | **Do not refrigerate** | **Do not freeze** |
|  | Choose an item. | Choose an item. | ☐ | ☐ | ☐ | ☐ |
|  | Choose an item. | Choose an item. | ☐ | ☐ | ☐ | ☐ |
|  | Choose an item. | Choose an item. | ☐ | ☐ | ☐ | ☐ |
|  | Choose an item. | Choose an item. | ☐ | ☐ | ☐ | ☐ |

## Section 2.9: Good Manufacturing Practice certification

### S2.9.1 Manufacturing of the starting material

|  |  |
| --- | --- |
| Name of starting material: |  |
|  |  |
| Name of manufacturer: |  |
|  |  |
| Manufacturing site address: |  |

### S2.9.2 Testing of the starting material

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

### S2.9.1 Manufacturing of the cannabis-based ingredient

|  |  |
| --- | --- |
| Name of cannabis-based ingredient: |  |
|  |  |
| Name of manufacturer: |  |
|  |  |
| Manufacturing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: |  |
|  |  |
| GMP evidence date of expiry: |  |
|  |  |
| Manufacturing steps carried out at this site: |  |

### S2.9.2 Testing of the cannabis-based ingredient

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

### S2.9.1 Manufacturing of the dried cannabis product

|  |  |
| --- | --- |
| Name of dried cannabis product: |  |
|  |  |
| Name of manufacturer: |  |
|  |  |
| Manufacturing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: |  |
|  |  |
| GMP evidence date of expiry: |  |
|  |  |
| Manufacturing steps carried out at this site: |  |

### S2.9.2 Testing of the dried cannabis product

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

### S2.9.3 Packing of the dried cannabis product

|  |  |
| --- | --- |
| Name of packing site: |  |
|  |  |
| Packing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: |  |
|  |  |
| GMP evidence date of expiry: |  |
|  |  |
| Packing steps carried out at this site: |  |

### S2.9.1 Manufacturing of the dosage product

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

### S2.9.2 Testing of the dosage product

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

### S2.9.3 Packing of the dosage product

|  |  |
| --- | --- |
| Name of packing site: |  |
|  |  |
| Packing site address: |  |
|  |  |
| Regulatory authority that issued the GMP evidence: |  |
|  |  |
| GMP evidence date of expiry: |  |
|  |  |
| Packing steps carried out at this site: |  |

### S2.9.4 New Zealand site of batch release

|  |  |
| --- | --- |
| Name of release site: |  |
|  |  |
| Release site address: |  |

# Section 3: Additional data required in an application for a medicinal cannabis product or ingredient

See Appendix 1 in **Part 3** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand* for a list of the documents you must submit for each type of application.

|  |  |
| --- | --- |
|  | **Name of attached document(s)** |
| GMP certification |  |
| CBD product (Certificate of Analysis) |  |
| Manufacture description |  |
| Specifications |  |
| Test results (Certificates of Analysis) |  |
| Non-pharmacopoeial test method validation |  |
| Container closure description |  |
| Container closure (Certificates of Analysis) |  |
| Stability protocol |  |
| Stability data |  |
| Labelling |  |
| Dosage product requirements (Certificates of Analysis) |  |
| Excipient (Certificates of Analysis) |  |
| Letter of authorisation for contact person from licence holder |  |
| Package insert |  |

# Statutory declaration

An NMCP application for assessment may be submitted to the Agency by a person acting on behalf of a Medicinal Cannabis Licence holder or applicant or on behalf of a Medicines Act 1981 licence holder or applicant. Include any letters of authorisation for all proposed contact persons nominated to act on behalf of the licence holder or applicant.

|  |  |
| --- | --- |
| I, *[full name]* |  |
| of *[place]* |  | *[occupation]* |  |
| solemnly and sincerely declare that I am authorised to complete this application on behalf of |
|  |
| *[name of applicant or entity]* |

**and I confirm that the ingredient, or product and all ingredients of the product:**

1. contain no adulterants

2. contain no prescription medicines or controlled drugs other than cannabis or cannabis-based ingredients

3. have been tested using methods that have been validated according to [ICH guideline Q2 (R1) Validation of analytical procedure: text and methodology](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-2-r1-validation-analytical-procedures-text-methodology-step-5_en.pdf), where test method validation is required

4. have not been subject to any decontamination treatment that adversely affects the quality, including the use of ethylene oxide

**and I confirm that** all active ingredients and cannabinoids present in the product are derived from *Cannabis sativa* only

**and I commit that:**

5. at least one commercial-scale batch of each strength, pack size and pack type will be placed on stability trial (with bracketing as appropriate) under real-time conditions for the duration of the proposed shelf life per year of production. The batches will be identical in every respect to those destined for distribution and the Medicinal Cannabis Agency will be informed of any out-of-specification results or data indicating that batches may be out of specification before the shelf life is reached.

If stability studies have not been conducted on the maximum proposed commercial batch size:
the first three commercial-scale product batches of each strength, pack size and pack type will be placed on stability trials (with bracketing as appropriate) under real-time (long-term) conditions for the duration of the shelf life, and accelerated conditions for at least six months. The batches will be identical in every respect to those destined for the New Zealand market and the Medicinal Cannabis Agency will be informed of any out-of-specification results or data indicating that batches may be out of specification before the shelf life is reached

**and I:**

6. agree that the information provided in this application may be shared with other agencies, including the New Zealand Police and the Ministry for Primary Industries

7. declare that the information I have supplied in this application is, to the best of my knowledge and belief, true and correct in every particular, and I make this declaration in the knowledge that a person making a false declaration is liable to prosecution under section 15 of the Misuse of Drugs Act 1975 (False statements) and regulation 78 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature |  | Date |

|  |  |
| --- | --- |
| Declared at*(place – for example, name of town or city):* |  |

|  |  |
| --- | --- |
| Before me*(name of official witness):*[[2]](#footnote-2) |  |

|  |  |
| --- | --- |
| Signature of official witness: |  |

1. Appropriate licences are a Licence to Manufacture Medicines, a Licence to Pack Medicines, a Licence to Sell Medicines by Wholesale and a Licence to Operate Pharmacy. You must make a separate application to amend an existing Medicines Act 1981 licence. [↑](#footnote-ref-1)
2. Authorised witnesses include (see [section 9 of the Oaths and Declarations Act 1957](http://www.legislation.govt.nz/act/public/1957/0088/latest/DLM314584.html) for complete list):

	* a justice of the peace (JP)
	* a solicitor or notary public – you may have to pay for their services
	* a Registrar or Deputy Registrar of the District Court or the High Court
	* authorised staff in some government agencies. [↑](#footnote-ref-2)