

GUIDELINE ON THE REGULATION OF MEDICINAL CANNABIS IN NEW ZEALAND

PART 3

Guidance for a New Medicinal Cannabis Product Application

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Section 1: Introduction

Part 1 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 sets the minimum quality standard requirements for medicinal cannabis products and ingredients. A medicinal cannabis product or ingredient that has been verified as meeting the minimum quality standard (the Quality Standard) can be lawfully supplied in New Zealand. A medicinal cannabis product or ingredient that has been verified as meeting the Quality Standard can be added to a Medicinal Cannabis Licence with a Supply activity, or to a licence issued under the Medicines Act 1981 (for cannabidiol (CBD) products). An application is required for new medicinal cannabis products and ingredients to provide evidence that satisfies the Medicinal Cannabis Agency (the Agency) that the product or ingredient meets the Quality Standard. If the Agency is satisfied that a product or ingredient meets the Quality Standard, it will then make a recommendation on whether the product or ingredient should be added to the applicant's Medicinal Cannabis Licence Supply activity or licence under the Medicines Act 1981 (for CBD products). An additional application to amend a Medicines Act 1981 licence is required in order to have a CBD product that meets the Quality Standard added to your licence.

This document is **Part 3: Guidance for a New Medicinal Cannabis Product Application** of the *Guideline on the Regulation of Medicinal Cannabis in New Zealand*. It outlines how to make an application for a new medicinal cannabis product.

Note: Applying for **provisional or full consent** for distribution under the Medicines Act 1981 is an option through the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) (the medicines application route). See the Medsafe website for more information on making [New Medicine Applications](#).

A medicinal cannabis product or ingredient that the Agency has verified as meeting the Quality Standard but that has not received provisional or full consent under the Medicines Act is an **unapproved medicine** under the Medicines Act 1981. See Part 1, Section 3.3 of the [Guideline on the Regulation of Therapeutic Products in New Zealand](#) for information on access to unapproved medicines.

1.1 Structure of this guideline

Section 1 (this section) provides the context for a New Medicinal Cannabis Product (NMCP) application and the types of application you can make. It includes regulatory references and additional information that will help you complete an application.

Section 2 is a guide to preparing an NMCP application for new starting material for export, a cannabis-based ingredient and/or a medicinal cannabis product (which may be a dried product or dosage product).

This section follows the same format as the NMCP application form. Its guidance covers the evidence you must include to show that the medicinal cannabis product or ingredient meets the

Quality Standard as well as the restrictions on the manufacture and type of product. For the application form, go to the [Agency's website](#).

[Section 3](#) outlines the supporting data that you must submit for each type of NMCP application.

1.2 Legislation relating to the Quality Standard requirements

The following legislation relates to the requirements of the Quality Standard:

- Misuse of Drugs (Medicinal Cannabis) Regulations 2019
- Misuse of Drugs Act 1975
- Misuse of Drugs Regulations 1977
- Medicines Act 1981
- Medicines Regulations 1984.

1.3 Other information relevant to this guideline

The following information will help you to conform to the Quality Standard:

- [European Pharmacopoeia \(Ph Eur\) 10th edition](#)
 - General monograph Pharmaceutical Preparations (2619)
- International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) quality guidelines:
 - [Q1A\(R2\) Stability Testing of New Drug Substances and Products](#)
 - [Q2\(R1\) Validation of Analytical Procedures: Text and Methodology](#)
- [New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods](#)
- [ISO/IEC 17025 Testing and Calibration Laboratories Accreditation](#)
- [World Health Organization \(WHO\) Model Certificate of Analysis](#).

1.4 Information on medicines regulated by Medsafe

For information on medicines that Medsafe regulates, see the [Guidelines on the Regulation of Therapeutic Products in New Zealand \(GRTPNZ\)](#).

1.5 Overview of the types of applications

The two broad types of applications related to medicinal cannabis that you can make are for a:

- new medicinal cannabis product (NMCP)
- changed medicinal cannabis product (CMCP).

1.5.1 New medicinal cannabis product

You must make and receive approval for an NMCP application before you can list a new medicinal cannabis product and/or ingredient on your Medicinal Cannabis Licence with Supply activity or licence issued under the Medicines Act 1981. Within this category are three types of NMCP applications:

- starting material for export
- cannabis-based ingredient
- medicinal cannabis product (dried product or dosage product).

For more information, see [Section 2](#) and [Section 3](#).

1.5.2 Changed medicinal cannabis product

You must make a CMCP application for any medicinal cannabis product or cannabis-based ingredient listed on a current Medicinal Cannabis Licence with Supply activity or licence issued under the Medicines Act 1981 that is affected by a change to any of the matters listed in regulation 47(1)(e). Specifically you must make a CMCP application when a product or ingredient has a change to:

- its trade name
- the label or description that will accompany it
- its composition, or its formulation (the quantity or proportion of each ingredient)
- its method of manufacture (including packing and testing)
- its container closure system
- the facilities for its manufacture (including packing and testing)
- the recommended method of administering, applying or using it
- its shelf life or storage conditions.

You must get approval for the CMCP before you distribute any batches affected by the change. In your application, you must include evidence to demonstrate that the product or ingredient will continue to meet the Quality Standard after the change. The Agency will publish further guidance on getting approval for a CMCP at a later date.

Note: The assessment of a starting material for export will always involve a NMCP application because each consignment of starting material for export must be assessed. The CMCP process does not apply to starting material for export.

Section 2: How to submit an application for a new medicinal cannabis product

2.1 Responsibilities of the licence holder

The Medicinal Cannabis Licence holder is legally responsible for all aspects of the medicinal cannabis product or ingredient in New Zealand, including any regulatory action relating to it. The Medicinal Cannabis Licence holder or Medicines Act 1981 licence holder is responsible for ensuring the accuracy of any information submitted to the Agency in support of any NMCP.

For this reason, an overseas company wishing to distribute a medicinal cannabis product or ingredient in New Zealand needs to have a New Zealand-based Medicinal Cannabis Licence holder or Medicines Act 1981 licence holder to act for them for that product or ingredient. The New Zealand licence holder is responsible for the product or ingredient, including the supply of the product or ingredient and any recall of the product from distribution.

It is the responsibility of the licence holder to fully understand and, if necessary, get appropriate advice (legal or otherwise) on their obligations, including under the Medicines Act 1981, the Misuse of Drugs Act 1975 and the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and associated regulations, before submitting an application for an NMCP and throughout the period they hold a licence.

2.2 Submitting an application

When submitting an application for an NMCP, you must include:

- a completed NMCP application form
- a signed declaration form
- additional data depending on the type of product you are applying to be assessed:
 - Type 1: Cannabis-based ingredient
 - Type 2: Medicinal cannabis product (dried or dosage product)
 - Type 3: Starting material for export.

For additional resources to help you compile an application, see Section 1.3. For a full summary of the application documents according to the type of product, see Appendix 1.

The NMCP application form is designed for you to complete electronically, following the guidance in this section. You must complete all fields of the form.

You must complete one copy of the application form for each unique product, ingredient or consignment of starting material for export.

A unique product is identified by its:

- trade name

- dose form
- active ingredient(s)
- strength.

For each product that has a different trade name, dose form, active ingredient(s) or strength, you will need to complete a separate form and application. Different sizes of the same product (eg, 10 ml and 20 ml) are considered to be one product so you can include them in one application for product assessment as long as the stability data supports the proposed shelf life and storage conditions for each product size.

When submitting several applications for similar products (eg, a product of varying strengths), you should state in the application for every additional version that the product is based on the named parent product.

2.3 Proposed product details

2.3.1 Type of application

The three types of NMCP are:

- Type 1: Cannabis-based ingredient
- Type 2: Medicinal cannabis product (dried or dosage product)
- Type 3: Starting material for export.

Choose the type that best describes your product or ingredient.

Type 1: Cannabis-based ingredient

The type 1 application is for the assessment of a cannabis-based ingredient that you intend to provide for further manufacture or incorporating into a dosage product. A cannabis-based ingredient can be a purified extract of cannabis (eg, delta-9-tetrahydrocannabinol (THC)) or a raw extract of cannabis that contains multiple constituents of cannabis (eg, a full spectrum extract). The cannabis-based ingredient can be assessed individually or alongside the corresponding dosage product.

Type 2: Medicinal cannabis product

The type 2 application is for the assessment of a medicinal cannabis product that you intend to provide for a medical practitioner to prescribe to a patient. The two types of medicinal cannabis product are:

- **dried product**, which is a medicinal cannabis product that is dried cannabis and must not contain any ingredient that is not dried cannabis
- **dosage product**, which is a medicinal cannabis product in a pharmaceutical dosage form (such as a tablet, a capsule or an oral liquid).

Choose the product that best describes your product or ingredient.

Type 3: Starting material for export

The type 3 application is for starting material (fresh or dried cannabis) that is intended to be exported from New Zealand for use in, or for, a medicinal cannabis product. The Agency must assess each consignment of starting material for export as complying with the Quality Standard before it issues a licence to export controlled drugs under the Misuse of Drugs Regulations 1977.

2.3.2 Proposed trade name

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

The proposed trade name is the proposed name under which your product will be distributed in New Zealand. The proposed label and all documentation should use that name consistently.

For cannabis-based ingredients and medicinal cannabis products (dried products and dosage products), the proposed trade name must:

- be unique (whether proprietary, non-proprietary, or a word or code)
- not be misleading about its therapeutic effects, safety or composition
- not cause confusion with another medicine in New Zealand.

There are no specific requirements for naming a starting material for export. You should enter a description that uniquely identifies the consignment. At a minimum, identifying information should include company name, material description, consignment weight, package size, country of origin, destination and date. This information is what will appear on your Medicinal Cannabis Licence and/or your licence to export controlled drugs.

2.3.3 Active ingredients

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 4](#)

You must state the full name of all active ingredients of the proposed product in your application. When the product contains a number of different active ingredients, separate the names by commas.

The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 define an [active ingredient](#) as:

- delta-9-tetrahydrocannabinol (THC)
- delta-9-tetrahydrocannabinolic acid (THCA)
- cannabidiol (CBD)
- cannabidiolic acid (CBDA)
- any other ingredient that is derived from cannabis and has a stated content of at least 1.0% by weight or volume of the ingredient or product.

Active ingredients cannot be synthetically derived. In any application for cannabis-based ingredients or medicinal cannabis products, you must demonstrate that all proposed active ingredients meet the requirements for identification, assay limits and labelling. See [Section 3](#) for more detailed guidance.

2.3.4 Strength of active ingredients

The strength and units you give in your application should be as stated on the product labelling. Units must include enough detail to accurately express the strength of the product. For example, giving the percentage on its own is not enough to express strength. When expressing strength as a percentage, you should include units that indicate whether the percentage has been calculated by weight or volume – for example, ‘%w/w’ or ‘%w/v’.

2.3.5 Dosage form

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 20](#)

Enter dosage form into the electronic application as named in the European Pharmacopoeia. Enter dried products as ‘herb dried’. Dosage products must be in a pharmaceutical dosage form for which the European Pharmacopoeia (10th edition) has a general dosage form monograph.

A dosage product should have properties that are consistent with the way it is intended to be taken or administered (ie, recommended method of administration). The general monographs set out characteristics and relevant tests for particular dosage forms (eg, an oral liquid, tablet or capsule). See Section 3.2.4 for dosage product requirements.

Notes:

- Dosage form testing requirements do not apply to dried product.
- A medicinal cannabis product cannot be in a dosage form that is required to be sterile.

2.3.6 Recommended method of administration

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

You only need to provide information on recommended method of administration for medicinal cannabis products (dried product or dosage product).

Note: Smoking is not a permitted method of administration.

2.4 Overseas approval, declined approval or submission for approval

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

List the details of any overseas approvals, declined approvals or submissions for approval (if any) for each medicinal cannabis product included in your application. Include the country name and regulatory agency, along with the date of approval, declined approval or submission. Separate multiple entries by commas. If no approvals, declined approvals or submissions for approval exist for your product, enter ‘Not applicable’.

Note: If any overseas jurisdiction has approved your product, that does not mean it meets the Quality Standard in New Zealand. You are required to provide these details for information purposes only. The Agency undertakes an independent product assessment against the New Zealand Quality Standard.

2.5 Licence holder and contact person details

A contact person may be a licence holder, or be acting on behalf of a Medicinal Cannabis Licence holder or a Medicines Act 1981 licence holder, to submit an NMCP application to the Agency. The contact person is the person to whom the Agency will communicate on all matters (including the fee invoice) regarding this application for a New Medicinal Cannabis Product.

2.5.1 New Zealand licence holder

You must submit all requested details of the licence holder (the entity responsible for the product on the New Zealand market), including the type of licence held and the licence number. The licence holder is considered the applicant for the NMCP application.

2.5.2 Contact person

The contact person is the person to whom the Agency will communicate on all matters (including the fee invoice) regarding an NMCP application. The contact person is the individual responsible for submitting the application and for responding to all correspondence. A contact person may be a licence holder, a director/partner, or a responsible person for the licensed activity. Provide details of the contact person who is responsible for submitting the application and for responding to all correspondence. If applicable, include any letters of authorisation for a proposed contact person nominated to act on behalf of the licence holder, including details of the relationship between the contact person and the applicant.

2.6 Application fee and invoice details

The application fee is GST inclusive. The application form includes a space for comments relevant to invoicing.

The Agency's tax invoice for the NMCP fee will be sent to the licence holder as the entity legally responsible for the application.

The invoice can include a customer reference, if you require it.

2.7 Product formulation and composition

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 32

You must submit a full statement of the product formulation or composition in table format.

When listing amounts of active ingredients or excipients, express the amounts as concentration by weight or volume using standardised units of measurement – for example, ‘THC 2 mg/ml’.

When expressing active ingredients as a concentration, indicate whether the percentage has been calculated by weight or volume – for example, ‘%w/w’ or ‘%w/v’.

You must submit a table of the composition of a cannabis-based ingredient or dried product, or the formulation of a dosage product (meaning its ingredients and the quantity or proportion of each ingredient), with your application.

Give details about the composition or formulation as follows.

- **Type 1: Cannabis-based ingredient:** List the active ingredients and amounts present in the cannabis-based ingredient (CBI).
- **Type 2: Dried product:** List the active ingredients and amounts present in the dried product.
- **Type 2: Dosage product:** List the full formulation of the dosage product, including all active ingredients and excipients present in the dosage product, and the amounts present.

List each excipient as the ingredient name, amount present, and the quality standard (European Pharmacopoeia monograph number) – for example, ‘Sweet Orange Oil, excipient, 10 mg/ml, Ph. Eur. 1811’.

Express amounts of active ingredients and excipients as either:

- an amount per dosage unit – for example, ‘THC 2 mg per tablet’, or
- a concentration by weight or volume using standardised units of measurement – for example, ‘THC 2 mg/ml’.

Dosage products must have a named CBI that the Agency has assessed or has received a submission to assess in an NCMP application. Identify the CBI clearly in the formulation table by the unique trade name of the CBI (whether it is a proprietary name, or a word or code). List the type of ingredient as CBI, specifying the amount present. If the Agency has already assessed the CBI as meeting the Quality Standard, include the licence number of the CBI under the Quality Standard heading.

2.8 Product packaging and storage conditions

Primary packaging means the container or closure directly in contact with the medicinal cannabis product or ingredient. **Secondary packaging** means any box or other package surrounding the primary packaging, and includes any additional features such as wallets and pouches. Describe all packaging briefly.

List all pack sizes and container types proposed with the application.

Enter the applicable shelf life and storage conditions (including in-use storage conditions) for each proposed pack using only the options listed – for example, ‘six months, opened, at or below 25°C’. You must base the shelf life and storage conditions on the results of testing the medicinal cannabis product using ICH guideline [Q1A\(R2\) Stability Testing of New Drug Substances and Products](#). Submit the results of testing according to the ICH guideline to the Agency as part of your application (see Parts 3.1.5 and 3.2.8 for guidance).

There are no specific requirements for packaging a starting material for export. Include a description of the packaging. The packaging should be identifiable (see Section 2.3.2) and should protect the material during transport.

2.9 Good Manufacturing Practice certification

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

You must provide Good Manufacturing Practice (GMP) certification or other evidence of GMP compliance for the manufacturing, testing and packing site of each cannabis-based ingredient and medicinal cannabis product. The certification must:

1. relate to the product concerned
2. be issued by Medsafe, or a regulatory authority recognised by Medsafe as listed in the [Current Guidelines on the Regulation of Therapeutic Products in New Zealand \(GRTPNZ\) Part 4](#), and meet all of the other requirements in the [GRTPNZ Part 4](#)
3. not have expired by the time the product is likely to be added to the appropriate licence for distribution in New Zealand.

For further guidance on GMP, see **Part 2: Guidance for Manufacturers and Packers** of the [Guideline on the Regulation of Medicinal Cannabis in New Zealand](#).

You do not need GMP certification for the laboratory or manufacturing site that is developing the medicinal cannabis product or ingredient. The medicinal cannabis product or ingredient must be developed before it can meet GMP. During product development, ISO/IEC 17025 Testing and Calibration Laboratories Accreditation is appropriate.

For general guidance on developing a pharmaceutical product, see ICH guideline [Q8\(R2\) Pharmaceutical Development](#). (Please be aware this guideline provides more detail than you need to include in an application to establish compliance with the Quality Standard.)

2.9.1 Manufacturing sites

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

Provide the address of the physical site that manufactures the medicinal cannabis product or ingredient (not the address of the company head office, unless it is the same).

If a manufacturing step does not apply to your application type, enter ‘Not applicable’ in the site name section.

2.9.2 Testing sites

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

Provide the address of the site that performs testing to the required Quality Standard for the medicinal cannabis product or ingredient (not the address of the company head office, unless it is the same).

Provide the manufacturer's address if the manufacturer is also the proposed testing site.

If multiple sites are performing testing, list which tests each site is carrying out – for example, microbial testing, physical testing or chemical testing.

If a testing step does not apply to your application type, enter 'Not applicable' in the site name section.

2.9.3 Packing sites

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

Provide the address of the site that packages the medicinal cannabis product or ingredient (not the address of the company head office, unless it is the same).

If the primary packing site is different to the secondary packing site, describe which packing step is carried out at each site – that is, primary packing or secondary packing.

If a packing step does not apply to your application type, enter 'Not applicable' in the site name section.

2.9.4 Site responsible for batch release

This information is about the site holding documentation for batches released onto the New Zealand market and is not necessarily the manufacturing, testing or packing site.

If the medicinal cannabis product or ingredient is manufactured and packed overseas, provide the name and address of the company that is importing the medicine into New Zealand. The site of this importing company is termed the 'New Zealand site of batch release' and is responsible for undertaking the duties described in section 42 of the Medicines Act 1981.

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

3.1 Additional data for Type 1: Cannabis-based ingredient

This section offers guidance on the additional data requirements for cannabis-based ingredients that you should submit along with the NMCP application form.

Provide the additional data in the same order as this section (3.1) follows.

3.1.1 CBD product

[Misuse of Drugs Act 1975, section 2A](#)

If your cannabis-based ingredient is claiming to be a cannabidiol (CBD) product (a ‘CBD product’ within the meaning of the Misuse of Drugs Act and therefore not a controlled drug), you must provide evidence that the product meets the definition set out in [section 2A](#) of the Misuse of Drugs Act 1975. To satisfy the requirement that a product meets the definition of a CBD product, you must provide evidence that the ratio of **specified substances** to CBD falls within the definition. At a minimum, include the amount of CBD, delta-9-tetrahydrocannabinol (Δ 9-THC), delta-9-tetrahydrocannabinolic acid (Δ 9-THCA) and cannabiol (CBN).

You must provide evidence for at least one pilot-scale batch of cannabis-based ingredient in the form of a Certificate of Analysis following the [WHO template](#). Express the results quantitatively with the limits of detection or limits of quantification for all tested substances. Any Certificates of Analysis you submit must have been signed.

3.1.2 Manufacturing description

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

You must submit details of the method of manufacturing (including packaging and testing) with your application.

The Agency expects that information you submit would include a description of:

- the manufacturing and packaging processes, including a diagrammatic representation (eg, a flow chart) of the manufacturing process
- the equipment used, and batch formulae and sizes (pilot and commercial)
- the in-process controls, crucial process parameters, test methods and acceptance limits at each step in the manufacturing and packaging processes should be defined.

3.1.3 Control of cannabis-based ingredient

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulations 7 and 8

You must submit with your application:

- specifications for the cannabis-based ingredient
- Certificates of Analysis for three pilot-scale batches of cannabis-based ingredient (see note below)
- method validation for all non-pharmacopoeial methods from all testing sites, including all supporting data.

The cannabis-based ingredient specifications that the manufacturer of the bulk cannabis-based ingredient applied must meet the Quality Standard. Table 1 sets out the tests that apply to a cannabis-based ingredient.

Laboratories and manufacturers must use the test methods published in the European Pharmacopoeia where applicable. Where the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 require a test method to be validated, that test method must have been validated in accordance with ICH guideline [Q2\(R1\) Validation of Analytical Procedures: Text and Methodology](#). Provide the test method validation data for non-pharmacopoeial tests that each testing site will undertake for routine quality control of cannabis-based ingredients.

Supply representative batch analytical data for at least three batches of cannabis-based ingredient at each of the proposed manufacturing sites. These batches must be at least pilot scale. You must include results for each specified test and all the reported test results must comply with the specifications.

Provide batch data in the form of a Certificate of Analysis following the [WHO template](#). Any Certificates of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as 'complies' or 'passes test'.

Note: A pilot-scale batch must be at least 10% of the size of a production-scale batch.

For example, if a full production-scale batch of extract is 200 litres, a pilot-scale batch is 20 litres. So you must get a representative sample of at least 20 litres of extract from each of three batches and test the samples to provide evidence that the cannabis-based ingredient meets the Quality Standard.

Table 1: Tests and specifications for cannabis-based ingredients

Test	Test method	Specification	Test method validation
Microbial contamination	Ph Eur 2.6.12, 2.6.13 and 2.6.31	Limits specified in Ph Eur 5.1.4 and 5.1.8	Required
Heavy metals	Ph Eur 2.4.27	≤ 3.0 ppm arsenic ≤ 0.5 ppm cadmium ≤ 5.0 ppm lead ≤ 0.5 ppm mercury	Required
Pesticides (imported products)	Ph Eur 2.8.13	Limits specified in Ph Eur 2.8.13	Required

Test	Test method	Specification	Test method validation
Pesticides (non-imported products)	Ph Eur 2.8.13	≤ 0.020 ppm Abamectin ≤ 0.020 ppm Bifenazate ≤ 0.100 ppm Bifenthrin ≤ 0.010 ppm Chlormequat chloride ≤ 0.020 ppm Daminozide ≤ 0.020 ppm Etoxazole ≤ 0.020 ppm Fenoxycarb ≤ 0.010 ppm Imazalil ≤ 0.020 ppm Imidacloprid ≤ 0.020 ppm Myclobutanil ≤ 0.020 ppm Paclobutrazol ≤ 0.050 ppm Pyrethrins (I and II) ≤ 0.010 ppm Spinosad (Spinosyn A and D) ≤ 3.000 ppm Spiromesifen ≤ 0.020 ppm Spirotetramat ≤ 0.020 ppm Trifloxystrobin	Required
Absence of aflatoxins	Ph Eur 2.8.18	≤ 2 µg/kg Aflatoxin B1 ≤ 4 µg/kg sum of aflatoxins B ₁ , B ₂ , G ₁ and G ₂	Required
Ochratoxin A	Ph Eur 2.8.22	≤ 20 µg/kg	Required
Residual solvents	Ph Eur 2.4.24 and 5.4	Limits specified in Ph Eur 5.4	Required
Identification of active ingredient	Chromatographic and/or spectroscopic method	Positively identified	Required
Assay of active ingredient	Chromatographic and/or spectroscopic method	90–110% of its stated content	Required

3.1.4 Container closure system

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 15

Container material of a cannabis-based ingredient must comply with Chapters 3.1 and 3.2 of the European Pharmacopoeia. This means that these items must use only the container materials described in those chapters.

You must clearly define the packaging materials used (eg, polymers, types of glass), containers, seals, closures and any delivery device(s) supplied with the product. Provide specifications and schematic drawings of the proposed container system.

Laboratories and manufacturers (including packers) must use the test methods published in the European Pharmacopoeia for the applicable container material monograph. You must provide batch data for one batch in the form of a Certificate of Analysis following the [WHO template](#) and that data must demonstrate the batch conforms with the monograph of the relevant material from Chapters 3.1 and 3.2 of the European Pharmacopoeia.

Any Certificates of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as ‘complies’ or ‘passes test’.

3.1.5 Stability

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 10

The stability of the market formulations of the cannabis-based ingredient packaged as intended for storage and distribution must have been tested in accordance with the drug substance requirements in ICH guideline [Q1A\(R2\) Stability Testing of New Drug Substances and Products](#). This includes the ICH requirements for the number and sizes of batches used.

You must describe in detail the stability trial protocol, packaging, storage conditions and test procedures.

The testing schedule must have included all of the stability-indicating organoleptic, physical, chemical and microbiological quality parameters relevant to the dose form and type of packaging. Monitoring of all those parameters must have used appropriate, clearly defined, validated (in the testing laboratory used for the stability samples), stability-indicating test procedures. Stability studies must include the following specific tests and test methods listed in the Medicinal Cannabis Regulations as minimum testing requirements:

- microbiological contamination
- loss on drying
- assay limits for active ingredients.

If test procedures change during the stability trials, you must justify them and correlate the results.

Update the stability data before submitting it. Wherever relevant, express results quantitatively rather than as ‘complies’ or ‘passes test’.

The results must adequately support the proposed shelf life under the recommended storage conditions. Any extrapolation proposed must be in line with ICH guidelines.

3.2 Additional data for Type 2: Medicinal cannabis product

This section offers guidance on the additional data requirements for medicinal cannabis products (dried product and dosage product) that you should submit along with the NMCP application form.

Provide the additional data in the same order as this section (3.2) follows.

3.2.1 CBD product

If your medicinal cannabis product is claiming to be a cannabidiol (CBD) product (a ‘CBD product’ within the meaning of the Misuse of Drugs Act and therefore not a controlled drug), you must provide evidence that the product meets the definition set out in [section 2A](#) of the Misuse of

Drugs Act 1975. To satisfy the requirement that a product meets the definition of a CBD product, you must provide evidence that the ratio of specified substances to CBD falls within the definition. At a minimum, include the amount of CBD, delta-9-tetrahydrocannabinol (Δ 9-THC), delta-9-tetrahydrocannabinolic acid (Δ 9-THCA) and cannabiniol (CBN).

You must provide evidence for at least one pilot-scale batch of cannabis-based ingredient in the form of a Certificate of Analysis following the [WHO template](#). Express results quantitatively with the limits of detection or limits of quantification for all tested substances. Any Certificates of Analysis you submit must have been signed.

3.2.2 Labelling

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 19](#)

[Medicines Regulations 1984, Part 4](#)

You must submit colour artworks of labels. Artwork does not need to be actual size, but must be legible, be drawn to a specified scale and include a statement of the label dimensions.

Medicinal cannabis products (dried products and dosage products) must meet the same requirements for packaging and labelling as other medicines in New Zealand, according to Part 4 of the Medicines Regulations 1984. See [G RTPNZ Part 5: Labelling of medicines and related products](#).

Medicinal cannabis product label should not include directions for use and dosing instructions. However, requirements they must meet are that:

- the active ingredient definition in the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 applies to the Medicines Regulations 1984 for these products
- the directions for use and dosing instructions are not on the label
- the principal display panels of the product labelling must contain the words 'MEDICINAL CANNABIS PRODUCT'.

The Medicines Act 1981 defines the terms **container** and **package**. A medicine can have only one container. Bottles, tubes, ampoules, sachets and blisters are examples of containers. A container may be enclosed in a package, and it may include multiple layers of packaging. Cardboard boxes are a common form of package used for medicines.

Note: It is at the applicant's discretion as to whether a product label specifies the quantities of the active ingredients THC and THCA as 'total THC' and the active ingredients CBD and CBDA as 'total CBD', or specifies the quantities individually. If a total is specified, the label must state that the total includes both THCA and THC, or both CBD and CBDA. The label may state active ingredients as total THC or CBD content using a conversion factor of 0.877.

For example, Total content = Neutral cannabinoid + (Acidic cannabinoid \times 0.877)

Package insert

You may use a separate information sheet where it is impractical to include all the required information or extra safety information on the label because the container is too small.

Over-labelling

Over-labelling a product to comply with New Zealand legislation is permitted. New Zealand and overseas sites that carry out labelling (including over-labelling) must comply with Good Manufacturing Practice requirements. All labelling activities in New Zealand must occur at a site that both:

- is covered by either a Licence to Manufacture Medicines or a Licence to Pack Medicines
- holds a Medicinal Cannabis Licence with a possess for manufacture activity.

Warning statements

Regulation 22 of the Medicines Regulations allows the Agency to specify warning statements that medicinal cannabis product labelling must give. No warning statements for medicinal cannabis products are currently required.

If the Agency had a proposal to require warning statements, it would consult on that proposal and notify interested parties. If it decided to introduce the requirement, the Agency would also provide a reasonable transition period.

3.2.3 Manufacturing description

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulation 32](#)

You must submit details of the method of manufacturing (including packaging and testing) with your application.

The Agency expects that the information you submit would include a description of:

- the manufacturing and packaging processes, including a diagrammatic representation (eg, a flow chart) of the manufacturing process
- the equipment used, and batch formulae and sizes (pilot and commercial)
- the in-process controls, crucial process parameters, test methods and acceptance limits at each step in the manufacturing and packaging processes should be defined.

3.2.4 Dosage product requirements

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019: Regulation 20](#)

Dosage products must be in a pharmaceutical dosage form for which the European Pharmacopoeia has a monograph. A dosage product cannot be in a form that is required to be sterile. The dosage product must comply with the requirements of the monograph.

Laboratories and manufacturers must use the test methods published in the European Pharmacopoeia for the applicable dosage form monograph. All test methods must have been

validated in accordance with ICH guideline [Q2\(R1\) Validation of Analytical Procedures: Text and Methodology](#). Provide the test method validation data for non-pharmacopoeial tests that each testing site that will undertake routine quality control of the product.

Provide batch data for three pilot batches in the form of a Certificate of Analysis following the [WHO template](#). Any Certificates of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as 'complies' or 'passes test'.

3.2.5 Control of medicinal cannabis product

[Misuse of Drugs \(Medicinal Cannabis\) Regulations 2019, regulations 7 and 8](#)

You must submit with your application:

- specifications for the medicinal cannabis product
- Certificates of Analysis for three pilot-scale batches of medicinal cannabis product (see note below)
- method validation for all non-pharmacopoeial methods from all testing sites, including all supporting data.

The medicinal cannabis product specifications the manufacturer applies must be in line with the Quality Standard. See the following tables for the tests and specifications that apply to a **dried product** (Table 2) and to a **dosage product** (Table 3).

Laboratories and manufacturers must use the test methods specified in the Table 2 and Table 3 and, where applicable, the methods are published in the European Pharmacopoeia. Where the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 require a test method to be validated, that test method must have been validated in accordance with ICH guideline [Q2\(R1\) Validation of Analytical Procedures: Text and Methodology](#). Provide the test method validation data for non-pharmacopoeial tests that each testing site will undertake for routine quality control of the medicinal cannabis product.

You must supply representative batch analytical data for three pilot-scale batches of medicinal cannabis product at each of the proposed manufacturing sites. Include results for each specified test and all the reported test results must comply with the specifications.

Provide batch data in the form of a Certificate of Analysis following the [WHO template](#). Any Certificate of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as 'complies' or 'passes test'.

Note: A pilot-scale batch must be at least 10% of the size of a production-scale batch.

For example, if a full production-scale batch is 10,000 tablets, a pilot-scale batch is 1,000 tablets. So you must get a representative sample of at least 1,000 tablets from each of three pilot-scale batches and test the samples to provide evidence that the product meets the Quality Standard.

Table 2: Tests and specifications for dried products

Test	Test method	Specification	Test method validation
Microbial contamination	Ph Eur 2.6.12, 2.6.13 and 2.6.31	Limits specified in Ph Eur 5.1.4 and 5.1.8	Required
Heavy metals	Ph Eur 2.4.27	<p>≤ 3.0 ppm arsenic</p> <p>≤ 0.5 ppm cadmium</p> <p>≤ 5.0 ppm lead</p> <p>≤ 0.5 ppm mercury</p>	Required
Pesticides (imported products)	Ph Eur 2.8.13	Limits specified in Ph Eur 2.8.13	Required
Pesticides (non-imported products)	Ph Eur 2.8.13	<p>≤ 0.020 ppm Abamectin</p> <p>≤ 0.020 ppm Bifenazate</p> <p>≤ 0.100 ppm Bifenthrin</p> <p>≤ 0.010 ppm Chlormequat chloride</p> <p>≤ 0.020 ppm Daminozide</p> <p>≤ 0.020 ppm Etoxazole</p> <p>≤ 0.020 ppm Fenoxycarb</p> <p>≤ 0.010 ppm Imazalil</p> <p>≤ 0.020 ppm Imidacloprid</p> <p>≤ 0.020 ppm Myclobutanil</p> <p>≤ 0.020 ppm Paclobutrazol</p> <p>≤ 0.050 ppm Pyrethrins (I and II)</p> <p>≤ 0.010 ppm Spinosad (Spinosyn A and D)</p> <p>≤ 3.000 ppm Spiromesifen</p> <p>≤ 0.020 ppm Spirotetramat</p> <p>≤ 0.020 ppm Trifloxystrobin</p>	Required
Absence of aflatoxins	Ph Eur 2.8.18	<p>≤ 2 µg/kg Aflatoxin B1</p> <p>≤ 4 µg/kg sum of aflatoxins B₁, B₂, G₁ and G₂</p>	Required
Ochratoxin A	Ph Eur 2.8.22	≤ 20 µg/kg	Required
Foreign matter	Ph Eur 2.8.2	≤ 2%	Not required
Loss on drying	Ph Eur 2.2.32	≤ 10%	Not required
Total ash	Ph Eur 2.4.16	≤ 20%	Not required
Identification of cannabis	Macroscopic and microscopic examination	Positively identified	Not required
Assay of active ingredient	Chromatographic and/or spectroscopic method	80–120% of its stated content	Required

Table 3: Tests and specifications for dosage products

Test	Test method	Specification	Test method validation
Microbial contamination	Ph Eur 2.6.12, 2.6.13 and 2.6.31	Limits specified in Ph Eur 5.1.4 and 5.1.8	Required
Heavy metals	Ph Eur 2.4.27	≤ 3.0 ppm arsenic ≤ 0.5 ppm cadmium ≤ 5.0 ppm lead ≤ 0.5 ppm mercury	Required
Pesticides (imported products)	Ph Eur 2.8.13	Limits specified in Ph Eur 2.8.13	Required
Pesticides (non-imported products)	Ph Eur 2.8.13	≤ 0.020 ppm Abamectin ≤ 0.020 ppm Bifenazate ≤ 0.100 ppm Bifenthrin ≤ 0.010 ppm Chlormequat chloride ≤ 0.020 ppm Daminozide ≤ 0.020 ppm Etoxazole ≤ 0.020 ppm Fenoxycarb ≤ 0.010 ppm Imazalil ≤ 0.020 ppm Imidacloprid ≤ 0.020 ppm Myclobutanil ≤ 0.020 ppm Paclobutrazol ≤ 0.050 ppm Pyrethrins (I and II) ≤ 0.010 ppm Spinosad (Spinosyn A and D) ≤ 3.000 ppm Spiromesifen ≤ 0.020 ppm Spirotetramat ≤ 0.020 ppm Trifloxystrobin	Required
Absence of aflatoxins	Ph Eur 2.8.18	≤ 2 µg/kg Aflatoxin B1 ≤ 4 µg/kg sum of aflatoxins B ₁ , B ₂ , G ₁ and G ₂	Required
Ochratoxin A	Ph Eur 2.8.22	≤ 20 µg/kg	Required
Residual solvents	Ph Eur 2.4.24 and 5.4	Limits specified in Ph Eur 5.4	Required
Identification of active ingredient	Chromatographic and/or spectroscopic method	Positively identified	Required
Assay of active ingredient	Chromatographic and/or spectroscopic method	90–110% of its stated content	Required
Dosage form tests*	Refer to dosage form specific Ph Eur chapter	Refer to dosage form specific Ph Eur chapter	Required

* The European Pharmacopoeia sets out the dosage form tests, which are specific to each type of dosage form. For example, a tablet also requires disintegration testing and dissolution testing, which Chapter 0478 of the European Pharmacopoeia describes.

3.2.6 Container closure system

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 15

Container material of a medicinal cannabis product must comply with Chapters 3.1 and 3.2 of the European Pharmacopoeia. This means that you may use only the container materials in those chapters for these items.

You must clearly define the packaging materials used (eg, polymers, types of glass), containers, seals, closures and any delivery device(s) supplied with the product. Provide specifications and schematic drawings of the proposed container system.

Laboratories and manufacturers (including packers) must use the test methods published in the European Pharmacopoeia for the applicable container material monograph. You must provide batch data for one batch in the form of a Certificate of Analysis following the [WHO template](#) and that data must demonstrate the batch conforms with the monograph of the relevant material from Chapters 3.1 and 3.2 of the European Pharmacopoeia.

Any Certificate of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as ‘complies’ or ‘passes test’.

3.2.7 Control of excipients

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 21

Excipients are the non-active ingredients of a product. You can only use an excipient or another ingredient (including flavours and colourants) in a dosage product if a monograph for that excipient or other ingredient exists in the European Pharmacopoeia.

You must control the identity and quality of all excipients (including capsule shells) to the European Pharmacopoeia’s specifications. Laboratories and manufacturers must use the test methods published in the European Pharmacopoeia for the applicable excipient monograph.

You must take adequate measures to ensure that any ingredients of animal origin (eg, gelatin, magnesium or calcium stearate, and stearic acid) used in the product are free from transmissible spongiform encephalopathy (TSE) contamination. We recommend following European Commission and United States guidelines on TSE contamination.

Provide batch data for one batch in the form of a Certificate of Analysis following the [WHO template](#) and that data must demonstrate the batch conforms with the European Pharmacopoeia monograph of the applicable excipient. Wherever relevant, express results quantitatively rather than as ‘complies’ or ‘passes test’.

3.2.8 Stability

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulation 10

The stability of the medicinal cannabis product packaged as intended for supply must have been tested in accordance with ICH guideline [Q1A\(R2\) Stability Testing of New Drug Substances and Products](#) (including the ICH requirements for the number and sizes of batches used).

You must describe in detail the stability trial protocol, packaging, packaging orientation (if relevant), storage conditions and test procedures.

The testing schedule must have included all of the stability-indicating organoleptic, physical, chemical and microbiological quality parameters relevant to the dose form and type of packaging. Monitoring of all those parameters must have used appropriate, clearly defined, validated (in the testing laboratory used for the stability samples), stability-indicating test procedures. Stability studies must include the following specific tests and test methods that the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 identify as minimum testing requirements:

- microbiological contamination
- loss on drying
- assay for active ingredients
- any test(s) listed in the European Pharmacopoeia general monograph for the relevant dosage form.

If test procedures change during the stability trials, you must justify them and correlate the results. At least six months' data for storage under the recommended storage conditions must be available and you must submit it with your application.

Update the stability data before submitting it. Wherever relevant, express results quantitatively rather than as 'complies' or 'passes test'.

The results (and allowing for extrapolation within reasonable limits) must adequately support the proposed shelf life under the recommended storage conditions. (If you do not have these results, the Agency may grant a shorter shelf life until you can provide adequate stability data to support the proposed shelf life.)

If relevant, you must have investigated the stability of the product after first opening and shown that it is adequate for the intended use of the product.

If relevant, state adequate storage instructions and time limits for using the product after first opening on the draft product label.

3.3 Additional data for Type 3: Starting material for export

3.3.1 Control of starting material for export

Misuse of Drugs (Medicinal Cannabis) Regulations 2019, regulations 7 and 8

You must submit with your application:

- specifications for the starting material for export
- a Certificate of Analysis for the consignment of starting material
- method validation for all non-pharmacopoeial methods from all testing sites, including all supporting data.

The starting material specifications that the manufacturer of the starting material applies must meet the Quality Standard. Table 4 sets out the tests and specifications that apply to a starting material for export.

Laboratories and manufacturers must use the test methods published in the European Pharmacopoeia. All test methods must have been validated in accordance with ICH guideline [Q2\(R1\) Validation of Analytical Procedures: Text and Methodology](#). Provide the non-pharmacopoeial test method validation data for each testing site that will undertake routine quality control of starting material for export.

Perform tests on a representative sample of each consignment of starting material for export. A licence to export controlled drugs is issued on a per-consignment basis under the Misuse of Drugs Regulations 1977. This means that every time you want to export starting material, you must test the consignment and provide evidence to the Medicinal Cannabis Agency that the consignment meets the minimum Quality Standard.

You must supply satisfactory representative analytical data for each consignment of starting material for export at each of the proposed manufacturing or packing sites. Include results for each specified test and all the reported test results must comply with the specifications.

You must provide consignment analytical data in the form of a Certificate of Analysis following the [WHO template](#). Any Certificate of Analysis you submit must have been signed. Wherever relevant, express results quantitatively rather than as ‘complies’ or ‘passes test’.

Table 4: Tests and specifications for starting materials for export

Test	Test method	Specification	Test method validation
Microbial contamination	Ph Eur 2.6.12, 2.6.13 and 2.6.31	Limits specified in Ph Eur 5.1.4 and 5.1.8	Required
Heavy metals	Ph Eur 2.4.27	≤ 3.0 ppm arsenic ≤ 0.5 ppm cadmium ≤ 5.0 ppm lead ≤ 0.5 ppm mercury	Required

Test	Test method	Specification	Test method validation
Pesticides (non-imported products)	Ph Eur 2.8.13	≤ 0.020 ppm Abamectin ≤ 0.020 ppm Bifenazate ≤ 0.100 ppm Bifenthrin ≤ 0.010 ppm Chlormequat chloride ≤ 0.020 ppm Daminozide ≤ 0.020 ppm Etoxazole ≤ 0.020 ppm Fenoxycarb ≤ 0.010 ppm Imazalil ≤ 0.020 ppm Imidacloprid ≤ 0.020 ppm Myclobutanil ≤ 0.020 ppm Paclobutrazol ≤ 0.050 ppm Pyrethrins (I & II) ≤ 0.010 ppm Spinosad (Spinosyn A and D) ≤ 3.000 ppm Spiromesifen ≤ 0.020 ppm Spirotetramat ≤ 0.020 ppm Trifloxystrobin	Required
Absence of aflatoxins	Ph Eur 2.8.18	≤ 2 µg/kg Aflatoxin B1 ≤ 4 µg/kg sum of aflatoxins B ₁ , B ₂ , G ₁ and G ₂	Required
Ochratoxin A	Ph Eur 2.8.22	≤ 20 µg/kg	Required
Foreign matter	Ph Eur 2.8.2	≤ 2%	Not required
Loss on drying	Ph Eur 2.2.32	≤ 10%	Not required
Total ash	Ph Eur 2.4.16	≤ 20%	Not required
Identification of cannabis	Macroscopic and microscopic examination	Positively identified	Not required

Appendix 1: Application documents

Table 5 summarises the documents you must include for each type of application.

Note:

- **A** indicates a document is mandatory – you must submit it with your application.
- **B** indicates a document may be relevant – you must submit it with your application if it is.
- **NA** indicates a document is not relevant – you should not submit it with your application.

Table 5: Documents required for each application type

	Cannabis-based ingredient	Dried product	Dosage product	Starting material for export
NMCP application form	A	A	A	A
Good Manufacturing Practice certification	A	A	A	A (testing site)
CBD products (Certificate of Analysis)	B	NA	B	NA
Manufacture description	A	A	A	NA
Specifications	A	A	A	A
Test results (Certificates of Analysis)	A	A	A	A
Non-pharmacopoeial test method validation	A	A	A	A
Container closure description	A	A	A	NA
Container closure (Certificates of Analysis)	A	A	A	NA
Stability protocol	A	A	A	NA
Stability data	A	A	A	NA
Colour artwork of labels	NA	A	A	NA
Dosage product requirements (Certificates of Analysis)	NA	NA	A	NA
Excipients (Certificates of Analysis)	NA	NA	A	NA
Letter of authorisation for contact person from licence holder	B	B	B	B
Package insert	NA	B	B	NA