Australian Government
Department of Health
Office of Drug Control

Application - Medicinal Cannabis Permit - Manufacture

This application form seeks a permit from the Secretary of the Department of Health relating to the manufacture of one or more cannabis drugs, for one or more permitted supplies, in accordance with section 8P of the *Narcotic Drugs Act 1967* (Cth).

Once completed, email this form along with all relevant supporting documentation to the Office of Drug Control at mcs.application@health.gov.au.

Screening Questions (*circle yes/no*)

1. Is a licence currently held under the *Narcotic Drugs Act 1967* authorising the manufacture of a cannabis drug? YES / NO
2. Have any imposed licence conditions required to be met prior to submission of first permit application been met? YES / NO
3. Does the site/floor plan intended to be used for this activity match those on the licence? YES / NO

If 'Yes' to all the above, proceed to Part 1. If 'No' to any of the above, contact the Office of Drug Control for next steps by email at mcs.application@health.gov.au.

Part 1 - General details

1. Licence holder details						
Licence holder name						
Licence number						
Person(s) authorised to discuss this application with the Office of Drug Control, if different to approved contacts	Name		Phone		Email	
	Name		Phone		Email	

2. Details of the licenced premises at which authorised activities will be undertaken						
Address	Street					
	Town/ Suburb		State		Postcode	

Part 2 – Existing cannabis material at date of application (*for existing permit holders only*)

Existing permit number	
Expiry date	

Type of cannabis material	Estimated maximum quantity still in possession or control of the licence holder at the expiry date	Comments
Manufactured material – delta 9 THC extract (kg)		
Manufactured material – other THC extract (kg)		
Manufactured material – CBD extract (kg)		
Starting material – cannabis extract (kg)		
Starting material – Dried cannabis and resin (kg)		
Other (describe in comments)		

Part 3 – Overview of activities for manufacture purposes

Proposed permit start date	Click here to enter a date.	Permits will be granted for a standard 12 months from date of grant

1. Select which activity(s) the licence holder intends to undertake under this permit

☐ Solvent extraction (including CO2, supercritical fluid extraction) making an **extract** (including tinctures) from cannabis or from cannabis resin of the cannabis flowers, cannabis resin or cannabis plant.

☐ Isolation of cannabinoids from the extract of cannabis

☐ Refining the extract to obtain another drug, such as Tetrahydrocannabinol (THC) or Cannabidiol (CBD)

☐ Converting or transforming cannabinoids into another drug

☐ other – (provide details)

Provide details of the activities intended to be undertaken under the manufacture permit. If a permit has been previously held for this activity, please provide details of any changes or updates.

Note: *A medicinal cannabis licence that authorises manufacture does not cover the following activities if undertaken in isolation: dilution of an extract, mixing an extract with excipients, encapsulating or tableting, manufacturing quality, the manufacture of an active pharmaceutical ingredient (API), the manufacture of a preparation, production (processing, assembling, packaging, labelling, storage, sterilisation, testing release of supply), and Therapeutic Goods Order 93 (TGO93) requirements.*

SCHEDULE 1 State/Territory licences

Attach copies of relevant state/territory licences held by the licence holder

Relevant state/territory licences allow activities such as, but not limited to, carry on business as a manufacture chemist, possession, use and distribution of Schedule 4, Schedule 8, and Schedule 9 drugs in accordance with state/territory legislation.

Note: If the licence holder has been advised by the relevant state/territory agency that a state/territory licence is not required based on the proposed activities, attach evidence of this with the application.

Details of licence (File name, state/territory issued by, substances and activities included, substances and activities excluded)	**Quantities authorised under the licence**	**Licence No.**	**Expiry date**

If the licence holder has more than 2 state/territory licences, attach additional completed schedules as required.

SCHEDULE 2 Starting materials

Describe the supply arrangements for starting material. These details should include:

i. whether there is a standing order;
ii. who is supplying the starting material; and
iii. how frequently the material is being supplied.

Ref.	Supplier/producer	Source of stating material (Imported or domestic)	Source material type	THC Level	Amount required (kg)	Maximum amount held at any time (kg)
eg 1	*eg name of source*	*Imported*	*Dried cannabis (High CBD, Low THC)*	*10-15% CBD, 1-2% THC)*	*12*	*2*
eg 2	*eg name of source*	*Domestic*	*Cannabis resin (High THC)*	*15-20% THC, <1% CBD*	*2,500*	*500*
1						
2						
3						
4						

SCHEDULE 3 Proposed manufacture activities							
Ref. *Complete details for each activity with the corresponding reference number for the starting material from Schedule 2*	**Quantity of cannabis drug/s (kg) to be obtained from 1kg of starting material**	**Total quantity of cannabis drugs (kg) to be manufactured**	**Extracts to be manufactured**			**Maximum amount of cannabis drugs (kg) to be held at any one time**	**Will you, the licence holder, undertake further manufacture processes on this cannabis drug, to produce a cannabis drug in its final dosage form and pack type?**
			Delta-9 THC (kg)	**Other THC kg**	**CBD kg**		
eg 1	*0.5kg/kg*	*25kg*	*2.5kg*	*2.5kg*	*20kg*	*25kg*	*Tick box*
1							☐ **Yes** ☐ **No**
2							☐ **Yes** ☐ **No**
3							☐ **Yes** ☐ **No**
4							☐ **Yes** ☐ **No**

If the licence holder proposes to carry out more than 4 manufacture activities, provide separate sheets labelled appropriately.

SCHEDULE 4 Proposed supply pathway		
Ref. *Complete details for all cannabis drugs with the corresponding reference number from Schedule 3 page 4.* *eg 1&2*	**Supply pathway** *Tick the box/s that the licence holder intends on supplying only*	**Provide a description of how the licence holder intends to supply under each supply pathway selected in the space provided below:** • **Clinical trial** – CTN/CTA number • **Research –** Details of research project • **Export –** The overseas importing country and *Customs Prohibited Export Regulations1956* Export licence number (if currently available) • **Supply to *Therapeutic Goods Act 1989* licenced manufacturer -** Name of licence holder • **Registered Goods** – ARTG number • **Public hospital pharmacist –** name of hospital pharmacy • **Supply to *Narcotic Drugs Act 1967* licenced manufacturer –** Name of licence holder • **Supply for use as a reference standard for medical or scientific testing purposes** – name of recipient • **Supply under the *Therapeutic Goods Act 1989* -** How will the licence holder ensure that supply is in accordance with an approval or authority under the TG Act?
	☐ Clinical trial ☐ Registered product ☐ Research ☐ Supply under the *Therapeutic Goods Act 1989* ☐ Supply to a public hospital pharmacist ☐ Reference standard ☐ Export ☐ Supply to the holder of a manufacture licence under the *Narcotic Drugs Act 1967* ☐ Supply to the holder of a licence under part 3-3 of the *Therapeutic Goods Act 1989*	

If the licence holder proposes to manufacture more than one cannabis drug, attach separate sheets labelled appropriately.

Part 4- Attachments

To support your application, please provide the following documents:

Document:	**Name of document** (and page number if applicable)
a. Details of how access will be provided to the premises for the purpose of inspecting such premises	
b. Other relevant supporting documentation	

Part 5- Additional requirements for an initial permit

If this application is for the first permit for this activity relating to this location as authorised by the licence, the following documents must also be provided:

Document:	**Name of document** (and page number if applicable)
a. Risk management plan detailing management of risks associated with the activities authorised by the licence, including risks posed to the health and safety of people and risks posed to the environment	
Standard operating procedures and/or policies that deal with the following matters:	
b. how persons entering the location will be controlled	
c. how unauthorised access at the location will be prevented, monitored, detected and recorded;	
d. the physical security being used to prevent, monitor and detect the loss of cannabis plants, cannabis drugs and starting materials relating to such drugs	
e. the loss and theft of cannabis plants, cannabis drugs and starting materials relating to such drugs	
f. the disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs	
g. the supply, delivery and transportation of cannabis plants, cannabis drugs and starting materials relating to such drugs	
h. the arrangements with emergency services (including a police service or relevant local government authority) to deal with loss, theft, spoilage, disposal and destruction of cannabis plants, cannabis drugs and starting materials relating to such drugs	
i. the retention of records	
j. the engagement and retention of suitable staff	

Part 6- Privacy

The Office of Drug Control is part of the Australian Government Department of Health. The Office of Drug Control collects a variety of personal information in the course of performing its functions. Personal information is defined in the *Privacy Act 1988* (Cth) (Privacy Act). The licence holder's personal information is

protected by law under the Privacy Act, which contains the Australian Privacy Principles. The Privacy Policy for this Department is available at www.health.gov.au.

Part 9 - Declaration

Declaration
• I am authorised by [INSERT COMPANY NAME] to act on its behalf in providing the information contained in this form to the Secretary of the Department of Health. • I declare that, to the best of my knowledge, this form is complete and all relevant information has been provided. • I have read guidance document '*Guidance: Applying for a Medicinal Cannabis Permit for Medicinal or Scientific Purposes – Manufacture activities'* in addition to completing this application; • I hold the appropriate authorisations under the licence to undertake activities in association with this permit, and the activities proposed in this application form are consistent with those proposed and accepted in the relevant licence application or variation. • I acknowledge that providing incomplete or out of date information may result in delays for the processing of this permit application. *Note: Providing false or misleading information may also constitute an offence (see Div 137 of the Criminal Code).*

Signature:	**Name**
	Date:
	Email:

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