



## Manufacture & Extraction Licence

### Key Information

#### Overview

This licence allows businesses to turn raw cannabis plant material into products intended for medicinal use. It covers key activities such as:

- **Extraction** – separating cannabinoids from cannabis biomass or seeds. This often involves refining steps like filtration or removing unwanted substances (e.g. waxes).
- **Manufacture** – using extracted cannabinoids to create finished products. This may include advanced techniques like distillation, crystallisation, or encapsulation.
- **Formulation & Packaging** – preparing and packaging the final medicinal products.

If a business combines extraction and manufacturing processes, it may need both licence types.

This licence is essential for companies producing either final cannabis-based medicines or intermediate substances used in further manufacturing.

**Important to note:** The GSC Manufacture & Extraction Licence is issued by the Gambling Supervision Commission (GSC) and is distinct from any authorisations issued by the Department of Health and Social Care (DHSC).

If your operations involve repacking or reprocessing cannabis-derived substances into Schedule 2 controlled drugs, you may still require a DHSC-issued licence, even if you hold a GSC licence.

It's important to assess your activities carefully to ensure all necessary licences are in place.

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## Licence Scope

This licence is required for:

- Businesses converting raw cannabis into refined products
  - Organisations producing cannabis based medicines or ingredients
  - Entities preparing products for export or further formulation
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## Licence Types

### Class 6 – Extraction

Permits processing cannabis biomass and seeds in order to extract cannabinoids. Includes possession of biomass and extracted preparations, and supply of preparations.

#### **Allows:**

- Possession of cannabis biomass and preparations extracted from biomass
- Processing cannabis biomass and seeds to extract cannabinoids
- Refinement of extracted preparations to remove unwanted elements (e.g. waxes, chlorophyll and so forth)
- Supply and offer to supply extracted preparations
- No THC/CBN limits apply to materials during the extraction process

#### **Restrictions:**

- Cannot begin with untreated plant material for manufacturing purposes
- Activities that isolate specific cannabinoids or profiles (e.g. terpene blends) may require a Manufacture Licence
- Synthetic cannabinoids are not permitted under this licence
- Use of hazardous materials or machinery requires safety evidence and risk assessments
- Must comply with Isle of Man standards for fire safety and health and safety

### Class 9 – Manufacture

This licence permits commercial entities to manufacture cannabis-derived products (e.g. oils, tinctures, capsules). It also includes the authority to possess and supply cannabis-derived products.

## Permits:

- Possession and storage of preparations or cannabis-derived products.
- Manufacture of cannabis-derived products using substances other than raw biomass
- Supply and offer to supply cannabis-derived products

## Restrictions:

- Cannot begin with untreated cannabis biomass
- Any use of raw or semi-processed plant material must be justified and preapproved by the GSC
- Use of small quantities of plant material is allowed only if justified
- Activities typically go beyond simple uses of refrigeration, solvents, or filtration
- Activities must go beyond simple extraction (e.g. involve distillation, crystallisation, centrifugation)
- Synthetic cannabinoids are not permitted
- Re-packaging of products into Schedule 2 for clinical use is managed by the Department of Health and Social Care (DHSC) not the GSC

## Dual Licensing

A licensee may hold any number of licence classes to create vertical integration

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## Facility Requirements

Facilities must comply with Isle of Man standards for fire safety, health and safety, and security. This includes adherence to:

Any relevant regulations and guidance for fire evidence of equipment safety.

- A Standard Operating Procedures (SOPs) addressing safe operation and mitigation measures

Applicants must also consider applicable guidelines from the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#), including:

- **Good Manufacturing Practice (GMP)** – ensuring consistent, high-quality production standards
- **Good Distribution Practice (GDP)** – ensuring safe and compliant storage, handling, and transportation of active pharmaceutical ingredients and other ingredients used in the production of the medicines

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## Application Requirements

Please refer to the overview of the [application process](#) to ensure all requirements are met.

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## Licence Fees

<u>Licence Type</u>	<u>Year 1</u>	<u>Year 2+</u>
Extraction (Class 6)	£23,625	£18,375
Manufacturing (Class 9)	£23,625	£15,750
<u>Maximum Annual Cap</u>	£62,500	

Licences operate on a rolling 12-month basis. The cap is automatically applied when each fee is paid.

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## Contact & Application

Please refer to the Full Guidance Document.

If, after reviewing the guidance, you require further assistance, you may contact us by telephone or email. Contact details are provided in the footer of this page.