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White Label

What we offer

Valcon Medical offers supply of white label products to partners, who wish to sell and distribute medical cannabis oil under their own brand.

As your supplier, we will support you in the product approval process. This includes compilation of all regulatory documentation required for a smooth introduction of your white label products to the market.

Our promise is to deliver the highest quality of products while assuring consistent and scalable supply.

Starting material

The starting material – Cannabis Sativa L – used for extraction and manufacturing is cultivated in accordance with Good Agricultural and Collection Practice (GACP) for Starting Materials on Herbal Origin and required provisions of the EU GMP guideline. Starting material is cultivated in Denmark by Schroll Medical to meet the requirements of the European Pharmacopoeia and the Danish Cannabis Flower Monograph.

Compliance

White label products are manufactured under EU-GMP and tested in accordance with the German Monograph for cannabis extracts, DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur. We only apply well

established accredited laboratories performing the required range of analysis, including chemical, physical, and microbiological analysis of starting materials, intermediates and finished products. All according to validated analytical methods.

White label products are subject to stability according to ICH guidelines Q1A, Q1B, and EU -GMP guidelines.

Packaging

Valcon Medical offers a selection of primaryand secondary packaging solutions. Whether you require a lid with- or without child resistance, or encapsulation for a dosing syringe, we can manufacture accordingly. The product can be delivered labeled or unlabeled and packaged in outer carton with dosing syringe and leaflet.

GDP

Valcon Medical's supply chain complies with Good Distribution Practice (GDP). Qualified shipping solutions to customers include temperature monitoring according to individual product specifications.









Full-spectrum THC cannabis oil

- Full-spectrum CO₂ extracted
- 30 mL standardized oil solution
- THC: 25 mg/mL; CBD: <1 mg/mL
 (2.5% THC (w/w), <0.1% CBD (w/w))
- MCT carrier oil
- EU GACP/GMP cannabis floss input, origin Denmark

Select preferred potency

We offer THC cannabis oil in one formulation of 25 mg/mL according to the table below. Special formulations can be ordered under manufacturing service request.



Products are manufactured under EU-GMP and tested in accordance with the German Monograph for cannabis extracts, DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur. The product is composed of a soft extract from Cannabis Sativa L. 'White Widow' flower (floss) standardized with MCT (medium-chain triglycerides) oil to 25 mg/mL THC and <1 mg/mL CBD. Input: EU GACP/GMP cannabis floss, origin Denmark. The extraction solvent is carbon dioxide.

THC

Product Specification Table

Product name	To be determined by customer
Product description	Standardized full-spectrum cannabis oil
Product form	Oral fluid
Product composition	THC: 25 mg/mL; CBD <1 mg/mL (THC 2,5% w/w; CBD 0,1% w/w)
Input material	Cannabis Sativa L. (White Widow), Schroll Medical, Denmark
Storage conditions	2-8 °C or 15-25 °C
Primary Packaging	Amber glass bottle 30 mL, type III; Screw cap PP/HD-PE/LD-PE
Product ID	060518
Product monograph	DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur.
Application	For oral use
Carrier	MCT, CAS: 73398-61-5
Extraction	Carbon dioxide
Shelf life / Hold life	Stability according to ICH guidelines Q1A, Q1B, and EU-GMP
Dosing	To be determined by customer
Secondary packaging Optional:	 Label with branding, product information, expiry and batch number placed on the primary packaging. Dosing syringe/pipette separate or in outer carton. Outer carton with printed product information, expiry and batch number. Leaflet / preparation method information sheet placed in outer carton.



CBD Available Q1 2023



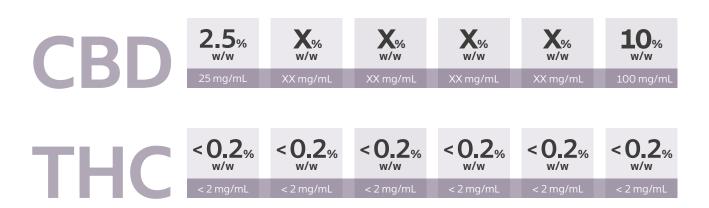


Full-spectrum mixed CBD cannabis oil

- Full-spectrum CO₂ extracted
- 30 or 50 mL standardized oil solution
- CBD: Formulation between of 2,5-10% w/w
 (25 to 100mg/mL); THC: less than 0,2% w/w (THC< 2 mg/mL)
- MCT carrier oil
- EU GACP/GMP cannabis floss input, origin Denmark

Select preferred potency

CBD cannabis oil is under development. Products can be formulated by request according to the range in the specification table below in a 30 or 50 mL bottle.



Products are manufactured under EU-GMP and tested in accordance with the German Monograph for cannabis extracts, DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur. The product is composed of a soft extract from Cannabis Sativa L. "Nightingale" flower (floss) standarzied with MCT oil (medium-chain triglycerides) to the required formulation. Input: EU GACP/GMP cannabis floss/origin Denmark. The extraction solvent is carbon dioxide.

CBD

Product Specification Table

Product name	To be determined by customer
Product description	Standardized full-spectrum cannabis oil
Product form	Oral fluid
Product composition	CBD: Formulation between of 2,5-10% w/w (25 to 100mg/mL); THC: less than 0,2% w/w (THC< 2 mg/mL)
Input material	Cannabis Sativa L. (Nightingale), Schroll Medical, Denmark
Storage conditions	2-8 °C or 15-25 °C
Primary Packaging	Amber glass bottle 30 mL, type III; Screw cap PP/HD-PE/LD-PE
Product ID	360118
Product monograph	DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur.
Application	For oral use
Carrier	MCT, CAS: 73398-61-5
Extraction	Carbon dioxide
Shelf life / Hold life	Stability according to ICH guidelines Q1A, Q1B, and EU-GMP
Dosing	To be determined by customer
Secondary packaging Optional:	 Label with branding, product information, expiry and batch number placed on the primary packaging. Dosing syringe/pipette separate or in outer carton. Outer carton with printed product information, expiry and batch number. Leaflet / preparation method information sheet placed in outer carton.



THC:CBD

Available Q4 2022





Full-spectrum mixed THC:CBD cannabis oil

- Full-spectrum CO₂ extracted
- 30 mL standardized oil solution
- THC: Formulation between of 1-3% w/w (10 to 30mg/mL);
 CBD: Formulated between 1-3% w/w (10 to 30mg/mL).
- MCT carrier oil
- EU GACP/GMP cannabis floss input, origin Denmark

Select preferred potency

THC:CBD cannabis oil can be formulated in 25 combinations as THC/CBD dominant or balanced in the preferred ratios. Potency options are listed in the specification table below.



Products are manufactured under EU-GMP and tested in accordance with the German Monograph for cannabis extracts, DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur. The product is composed of a soft extract from Cannabis Sativa L. "White Widow" & "Nightingale" flower (floss) standarzied with MCT oil (medium-chain triglycerides) to the required formulation. Input: EU GACP/GMP cannabis floss/origin Denmark. The extraction solvent is carbon dioxide.

THC:CBD

Product Specification Table

Product name	To be determined by customer
Product description	Standardized full-spectrum cannabis oil
Product form	Oral fluid
Product composition	THC: Formulation between of 1-3% w/w (10 to 30mg/mL); CBD: Formulated between 1-3% w/w (10 to 30mg/mL)
Input material	Cannabis Sativa L (White Widow & Nightingale), Schroll Medical, Denmark
Storage conditions	2-8 °C or 15-25 °C
Primary Packaging	Amber glass bottle 30 ml, type III; Screw cap PP/HD -PE/LD-PE
Product ID	060518/360118
Product monograph	DAB Eingestellter Cannabisextract, and the European Pharmacopoeia, Ph. Eur.
Application	For oral use
Carrier	MCT, CAS: 73398-61-5
Extraction	Carbon dioxide
Shelf life / Hold life	Stability according to ICH guidelines Q1A, Q1B, and EU-GMP
Dosing	To be determined by customer
Secondary packaging Optional:	 Label with branding, product information, expiry and batch number placed on the primary packaging. Dosing syringe/pipette separate or in outer carton. Outer carton with printed product information, expiry, and batch number. Leaflet / preparation method information sheet placed in outer carton.



Primary packaging

Amber glass bottle 30 ml, type III

Valcon Medical perform technical release of secondary packaging material compliant with all applicable laws and regulations and approved by costumer.





Lid 1 ID: PM-0089

Tamper evident

Child resistant

Screw cap
PP/HD-PE/LD-PE



Tamper evident

Child resistant

• Insert for dosing pipette

Screw cap
PP/HD-PE/LD-PE

Insert opening for dosing pipette Ø4,8mm





Lid 3: ID: PM-0113

- Tamper evident
- Insert for dosing pipette

Screw cap

PP/HD-PE/LD-PE

Insert opening for dosing pipette Ø4,8mm



Dosing pipette:

- 1 mL oral dosing syringe
- Fits opening Ø4,9mm.
- Individually packed

Usage: Dosage and administration of liquid medicine, intended for human use.

Type: Medical device, class I with measuring function according to EU Directive 93/42/CEE.

Body: PP/ Polypropylene, natural.

Plunger: Low-density Polyethylene, natural.

