

## State Institute for Drug Control

### Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number : sukls336513/2019
2. Name or corporate name of registrant : CB21 Pharma s.r.o.
3. Permanent or legal address of registrant : Biology Park Brno, Studentská 812/6, Bohunice, Brno, 62500, Czechia
4. Address(es) of site(s) where registered activities take place : Vědeckotechnický park TITC, Purkyňova 648/125, Brno, 612 00, Czechia  
Biology Park Brno, Studentská 812/6, Bohunice, Brno, 62500, Czechia
5. National legal basis of registration : §69a odst. 2 zákona č. 378/2007 Sb., ve znění pozdějších předpisů
6. Name of responsible officer of the competent authority of the member state validating the registration : Confidential
7. Signature :
8. Date : 2022-01-20

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

## SCOPE OF REGISTRATION

**Name and address of the site:** CB21 Pharma s.r.o., Vědeckotechnický park TITC, Purkyňova 648/125, Brno, 612 00, Czechia

### 1. MANUFACTURING OPERATIONS

Active Substance : (-)-CANNABIDIOL, CAS 13956-29-1 (5419687215)

<b>A</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	<i>A.3 Salt formation / Purification steps crystallisation krystalizace</i>
<b>E</b>	<b>General Finishing Steps</b>
	<i>E.1 Physical processing steps drying sušení E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.4 Other storage of incoming materials and finished products</i>
<b>F</b>	<b>Quality Control Testing</b>
	<i>F.1 Physical / Chemical testing</i>

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

<b>B</b>	<b>Distribution</b>
	(-)-CANNABIDIOL, CAS 13956-29-1 (5419687215)

**Name and address of the site:** CB21 Pharma s.r.o., Biology Park Brno, Studentská 812/6, Bohunice, Brno, 62500, Czechia

### 1. MANUFACTURING OPERATIONS

Active Substance : (-)-CANNABIDIOL, CAS 13956-29-1 (817691)

<b>E</b>	<b>General Finishing Steps</b>
	<i>E.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) E.4 Other storage of incoming materials and finished</i>
<b>F</b>	<b>Quality Control Testing</b>
	<i>F.1 Physical / Chemical testing</i>

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<b>2. IMPORTATION AND DISTRIBUTION OPERATIONS</b>
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<b>B</b>	<b>Distribution</b>
	(-)-CANNABIDIOL, CAS 13956-29-1 (817691)

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