

# National Authority Of Medicines And Health Products

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

1. Registration Number : 007/23/SA/2024/001
2. Name or corporate name of registrant : Somai Pharmaceuticals Unipessoal Lda. (ORG-100049214/LOC-100083375)
3. Permanent or legal address of registrant : Lugar De Casal Pinheiro, Urbanizacao Pinheiros Park II Bloco B, Rua 13 De Maio 52, Carregado, 2580-507, Portugal
4. Address(es) of site(s) where registered activities take place : Lugar De Casal Pinheiro, Urbanizacao Pinheiros Park II Bloco B, Rua 13 De Maio 52, Carregado, 2580-507, Portugal
5. National legal basis of registration : Art. 72.º A of Decree-law 176/2006, of 30th August
6. Name of responsible officer of the competent authority of the member state validating the registration : Maria Fernanda Ralha Henriques Matos
7. Signature :
8. Date : 2024-01-16

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.

**Name and address of the site:** Somai Pharmaceuticals Unipessoal Lda., (ORG-100049214/LOC-100083375), Lugar De Casal Pinheiro, Urbanizacao Pinheiros Park II Bloco B, Rua 13 De Maio 52, Carregado, 2580-507, Portugal

Human Active Substances

<b>1. MANUFACTURING OPERATIONS</b>	
Active Substance : CANNABIS SATIVA EXTRACT (211_INFARMED_PT)	
<b>B</b>	<b>Extraction of Active Substance from Natural Sources</b>
	<i>B.1 Extraction of substance from plant source</i> <i>B.5 Modification of extracted substance</i> <i>Plant</i> <i>B.6 Purification of extracted substance</i> <i>Plant</i> <i>B.7 Other</i> <i>Dilution</i>
<b>E</b>	<b>General Finishing Steps</b>
	<i>E.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <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)</i>
<b>F</b>	<b>Quality Control Testing</b>
	<i>F.1 Physical / Chemical testing</i> <i>F.3 Microbiological testing including sterility testing</i>