

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number	0842
2. Name of authorisation holder	UAB "Corpus Medica"
3. Address(es) of manufacturing site(s)	UAB "Corpus Medica", Sukilėlių pr. 61-2, Kauno m. sav., Kauno m., LT-49333, Lithuania
4. Legally registered address of authorisation holder	Sukilėlių pr. 61-2, Kauno m. sav., Kauno m., LT-49333, Lithuania
5. Scope of authorisation and dosage forms ²	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2012-09-14
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) ³

¹ The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : UAB "Corpus Medica", Sukilėlių pr. 61-2, Kauno m. sav.,
Kauno m., LT-49333, Lithuania

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.4 Other products or manufacturing activity

1.4.1 *Manufacture of*

1.4.1.4 Other: Holding of bulk products, holding of medicinal products until batch certification /(en)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 *Sterile products*

2.2.1.1 Aseptically prepared

2.2.2 *Non-sterile products*

2.3 Other importation activities

2.3.1 *Site of physical importation*

2.3.2 *Importation of intermediate which undergoes further processing*