

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 0909
2. Name of authorisation holder UAB "ABC Farma"
3. Address(es) of manufacturing site(s) UAB "ABC Farma", Ryternos g. 5, Kauno r. sav., Karmėlavos sen., Biruliškių k., LT-54469, Lithuania
4. Legally registered address of authorisation holder Ryternos g. 5, Kauno r. sav., Karmėlavos sen., Biruliškių k., LT-54469, Lithuania
5. Scope of authorisation and dosage forms² 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 2018-03-13
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 "ABC Farma", Ryternos g. 5, Kauno r. sav., Karmėlavos sen., Biruliškių k., LT-54469, Lithuania

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>