Manufacturer/Importer Authorisation [1] , [2]

1. Authorisation Number	aM-61/2024
2. Name of authorisation holder	Advaxia Biologics S.r.l. In Forma Abbreviata Advaxia S.r.l. (ORG-100022033 / LOC-100030741)
3. Address(es) of manufacturing site(s)	Advaxia Biologics S.r.l. In Forma Abbreviata Advaxia S.r.l. (ORG-100022033 / LOC-100030741), Via Pontina Vecchia Km 30600, Pomezia, 00071, Italy
4. Legally registered address of authorisation holder	Via Pontina Vecchia Km 30600, Pomezia, 00071, Italy
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 Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2024-04-30
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 as amended and Article 88(1) of Regulation (EU) 2019/6, 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 Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3] *The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Advaxia Biologics S.r.l. In Forma Abbreviata Advaxia S.r.l., Via Pontina Vecchia Km 30600, Pomezia, 00071, Italy

Additional Details:

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS(according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

1.6.4 Biological: test "in vitro" - LAL test.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Advaxia Biologics S.r.l. In Forma Abbreviata Advaxia S.r.l., Via Pontina Vecchia Km 30600, Pomezia, 00071, Italy

Additional Details:

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.4 Gene therapy products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.4 Gene therapy products
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

1.1.1.4 Small volume liquids: only Immunological Products and Gene therapy products; 1.3.1.2 Immunological products: DNA vaccine (recombinant adenoviral vectors against infective agents); 1.3.1.4 Gene therapy products: Recombinant adenoviral vectors against tumour antigens; 1.3.2.2 Immunological products: aseptically prepared small volume liquids; 1.3.2.4 Genetherapy products: aseptically prepared small volume liquids; 1.6.4 Biological: "in vitro" testing, LAL test.