# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder ATNAHS PHARMA UK LIMITED

3: Address(es) of manufacturing site(s)

ATNAHS PHARMA UK LIMITED, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

4: Legally registered address of authorisation holder

ATNAHS PHARMA UK LIMITED, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

5: Scope of authorisation and dosage forms

ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

**UK MIA 43252** 

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Confidential

8: Authorisation Date

30/01/2024

9: Annexes attached

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

ATNAHS PHARMA UK LIMITED, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

**Human Medicinal Products** 

**Authorised Operations** 

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

# Part 1 - MANUFACTURING OPERATIONS

[ 1.1 ] Sterile Products

[1.1.3] Batch certification

[ 1.2 ] Non-sterile products

[1.2.2] Batch certification

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

[2.2.1.2] Terminally sterilised

Issue Date: 30 Jan 2024

