

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 43252

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)

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

8: Authorisation Date 16/12/2024

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

[2.2.2] Non-sterile products