Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member

state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 142

ACCORD-UK LIMITED

ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE, EX32 8NS, UNITED KINGDOM

ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE, EX32 8NS, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations

2012 (SI 2012/1916)

Confidential

13/06/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE, EX32 8NS, 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

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.12] Suppositories

[1.2.1.13] Tablets

Special Requirements

Hormonal activity - Levothyroxine

[1.2.1.17] Other non-sterile medicinal products

Pessaries / hormonal activity - Progesterone

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[1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.12] Suppositories [1.5.1.13] Tablets [1.5.1.17] Other non-sterile medicinal products Pessaries and hormonal activity - Progesterone [1.5.2] Secondary packaging [1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[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



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