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(IMP) 142 ACCORD-UK LIMITED

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

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

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

Confidential

13/06/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal 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

[1.2.1.15] Other non-sterile medicinal products

Pessaries / hormonal activity - Progesterone

[1.2.2] Batch certification

Issue Date: 13 Jun 2025

[1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.12] Suppositories [1.5.1.13] Tablets Special Requirements Levothyroxine and Liothyronine [1.5.1.15] Other non-sterile medicinal products Pessaries and hormonal activity - Progesterone [1.5.2] Secondary packaging [1.6.3] Chemical/Physical

