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 52731

DENDRON BRANDS LIMITED

DENDRON BRANDS LIMITED, 94 RICKMANSWORTH ROAD, WATFORD, WD18 7JJ, UNITED KINGDOM

DENDRON BRANDS LIMITED, 94 RICKMANSWORTH ROAD, WATFORD, WD18 7JJ, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

26/02/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

DENDRON BRANDS LIMITED, 94 RICKMANSWORTH ROAD, WATFORD, WD18 7JJ, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.11] Semi-solids

[1.2.1.17] Other non-sterile medicinal products

Hormone Semi-Solid

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

Issue Date: 26 Feb 2024

[1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.11] Semi-solids

[1.5.1.17] Other non-sterile medicinal products Hormone Semi-Solid

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

