

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 52731

2: Name of authorisation holder DENDRON BRANDS LIMITED

3: Address(es) of manufacturing site(s) DENDRON BRANDS LIMITED, 94 RICKMANSWORTH ROAD, WATFORD, WD18 7JJ, UNITED KINGDOM

4: Legally registered address of authorisation holder DENDRON BRANDS LIMITED, 94 RICKMANSWORTH ROAD, WATFORD, WD18 7JJ, 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 12/11/2024

9: Annexes attached 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) 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) [1.2.1.5] 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
 - [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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

- [2.1.2] Microbiological: non-sterility
- [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