

# 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                                                                                                  | 09/12/2025                                                                       |
| 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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                    |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.5 ] Liquids for external use<br>[ 1.2.1.6 ] Liquids for internal use<br>[ 1.2.1.11 ] Semi-solids<br>[ 1.2.1.17 ] Other non-sterile medicinal products<br>Hormone Semi-Solid<br>[ 1.2.2 ] Batch certification<br><b>[ 1.5 ] Packaging</b> |

[ 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