

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 12557

**2: Name of authorisation holder** BCM LIMITED

**3: Address(es) of manufacturing site(s)** BCM LIMITED, THANE ROAD, BEESTON, NOTTINGHAM, NG90 2PR, UNITED KINGDOM

**4: Legally registered address of authorisation holder** BCM LIMITED, 1 THANE ROAD WEST, NOTTINGHAM, NG2 3AA, 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** 20/12/2023

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BCM LIMITED**, THANE ROAD, BEESTON, NOTTINGHAM, NG90 2PR, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 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 <b>Special Requirements</b> Potent / Synthetic Hormone Ketoconazole [ 1.2.1.11 ] Semi-solids <b>Special Requirements</b> Potent / Hydrocortisone

[ 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

[ 1.5.2 ] 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