Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 39541 1: Authorisation Number

ASCOT LABORATORIES LIMITED 2: Name of authorisation holder

ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, WARWICK ROAD, BOREHAMWOOD, WD6 1UA, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, 4: Legally registered address of authorisation holder

WARWICK ROAD, BOREHAMWOOD, WD6 1UA, UNITED

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 15/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, WARWICK ROAD, BOREHAMWOOD, WD6 1UA, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Issue Date: 15 Apr 2025