Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 18515 1: Authorisation Number

IBSA PHARMA LIMITED 2: Name of authorisation holder

IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS PARK, COLONIAL WAY, WATFORD, WD24 4PR, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS 4: Legally registered address of authorisation holder

PARK, COLONIAL WAY, WATFORD, WD24 4PR, 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)

Confidential

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

member state granting the manufacturing authorisation

8: Authorisation Date 05/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

IBSA PHARMA LIMITED, UNITS 4-6 COLONIAL BUSINESS PARK, COLONIAL WAY, WATFORD, WD24 4PR, 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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.8] Other biological medicinal products

Gonadotrophins

Issue Date: 05 Nov 2025

