Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 25
2: Name of authorisation holder	ORGANON PHARMA (UK) LIMITED
3: Address(es) of manufacturing site(s)	ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, CRAMLINGTON, NE23 3JU, UNITED KINGDOM
4: Legally registered address of authorisation holder	ORGANON PHARMA (UK) LIMITED, THE HEWETT BUILDING, 14 HEWETT STREET, LONDON, EC2A 3NP, 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	17/06/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, CRAMLINGTON, NE23 3JU, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.8] Other solid dosage forms

Special Requirements

Bulk Granules and bulk blend for oral solution.

[1.2.1.13] Tablets

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.8] Other solid dosage forms

Special Requirements

Bulk Granules and bulk blend for oral solution.

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical