

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 51178
2: Name of authorisation holder	MILLICENT PHARMA (NI) LIMITED
3: Address(es) of manufacturing site(s)	MILLICENT PHARMA (NI) LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM
4: Legally registered address of authorisation holder	MILLICENT PHARMA (NI) LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	06/12/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MILLICENT PHARMA (NI) LIMITED, OLD BELFAST ROAD, MILLBROOK, LARNE, BT40 2SH, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.8] Other solid dosage forms [1.2.1.15] Other non-sterile medicinal products Vaginal Rings [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.8] Other solid dosage forms

[1.5.1.15] Other non-sterile medicinal products

Vaginal Rings

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[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