

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 36699

2: Name of authorisation holder INDIVIOR UK LIMITED

3: Address(es) of manufacturing site(s) INDIVIOR UK LIMITED, THE CHAPLEO BUILDING, PRIORY PARK, HENRY BOOT WAY, HULL, HU4 7DY, UNITED KINGDOM

4: Legally registered address of authorisation holder INDIVIOR UK LIMITED, THE CHAPLEO BUILDING, PRIORY PARK, HENRY BOOT WAY, HULL, HU4 7DY, 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 21/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

INDIVIOR UK LIMITED, THE CHAPLEO BUILDING, PRIORY PARK, HENRY BOOT WAY, HULL, HU4 7DY, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS
[1.2] Non-sterile investigational medicinal products
[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
 [1.2.1.1] Capsules, hard shell
 [1.2.1.8] Other solid dosage forms
 [1.2.1.13] Tablets
 [1.2.1.15] Other non-sterile medicinal products
 Powders
[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Powder in bottle

[1.6] Quality control testing

[1.6.3] Chemical/Physical