

# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

### (MEDICINAL PRODUCTS FOR HUMAN USE)

- |  |   |
|--|---|
| 1. Authorisation Number  | UK WDA(H) 18716   |
| 2. Name of Authorisation Holder  | ETHIGEN LIMITED   |
| 3. Legally registered address of Authorisation Holder  | ETHIGEN LIMITED, ETHIGEN HOUSE, UNITS 10-16 COLVILLES PLACE, KELVIN INDUSTRIAL ESTATE, EAST KILBRIDE, GLASGOW, G75 0SN, UNITED KINGDOM<br><br>ETHIGEN LIMITED (NEWCASTLE), UNIT 2 CHAINBRIDGE INDUSTRIAL ESTATE, TUNDRY WAY, BLAYDON-ON-TYNE, NE21 5SJ, UNITED KINGDOM  |
| 4. Address(es) of Site(s)  | ETHIGEN LIMITED (BOLTON), UNIT 30 OAKHILL TRADING ESTATE, DEVONSHIRE ROAD, WORSLEY, MANCHESTER, M28 3PT, UNITED KINGDOM<br><br>ETHIGEN LIMITED, ETHIGEN HOUSE, UNITS 10-16 COLVILLES PLACE, KELVIN INDUSTRIAL ESTATE, EAST KILBRIDE, GLASGOW, G75 0SN, UNITED KINGDOM   |
| 5. Scope of authorisation (complete for each site under 4)   | ANNEX 1   |
| 6. Legal basis of authorisation  | Regulation 18 of the Human Medicines Regulations 2012   |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | Confidential  |
| 8. Date  | 09/12/2025  |
| 9. Annexes attached  | Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 Additional provisions |

#### ANNEX 1

#### SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

**ETHIGEN LIMITED (NEWCASTLE)**, UNIT 2 CHAINBRIDGE INDUSTRIAL ESTATE, TUNDRY WAY, BLAYDON-ON-TYNE, NE21 5SJ, UNITED KINGDOM

##### 1. MEDICINAL PRODUCTS

1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.2 Holding

2.3 Supply

**Any restrictions or clarifying remarks (for all users)**

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

**ETHIGEN LIMITED (BOLTON)**, UNIT 30 OAKHILL TRADING ESTATE, DEVONSHIRE ROAD, WORSLEY, MANCHESTER, M28 3PT, UNITED KINGDOM

**1. MEDICINAL PRODUCTS**

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.2 Holding

2.3 Supply

**3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

**Any restrictions or clarifying remarks (for all users)**

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

**ETHIGEN LIMITED**, ETHIGEN HOUSE, UNITS 10-16 COLVILLES PLACE, KELVIN INDUSTRIAL ESTATE, EAST KILBRIDE, GLASGOW, G75 0SN, UNITED KINGDOM

**1. MEDICINAL PRODUCTS**

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

## **2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

2.6b Products not certified under Article 51 of Directive 2001/83/EC

## **3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

### **Any restrictions or clarifying remarks (for all users)**

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics