

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 49160
2: Name of authorisation holder	ERAMOL (UK) LTD
3: Address(es) of manufacturing site(s)	ERAMOL (UK) LTD, UNIT 9, NORTH DOWNS BUSINESS PARK, LIMEPIT LANE, DUNTON GREEN, SEVENOAKS, TN13 2TL, UNITED KINGDOM
4: Legally registered address of authorisation holder	ERAMOL (UK) LTD, UNIT 11, GATWICK METRO CENTRE, BALCOMBE ROAD, HORLEY, RH6 9GA, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ERAMOL (UK) LTD, UNIT 9, NORTH DOWNS BUSINESS PARK, LIMEPIT LANE, DUNTON GREEN, SEVENOAKS, TN13 2TL, UNITED KINGDOM
6: Legal Basis of authorisation	ANNEX 1 and/ or ANNEX 2
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
8: Authorisation Date	Confidential
9: Annexes attached	19/11/2024
	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ERAMOL (UK) LTD, UNIT 9, NORTH DOWNS BUSINESS PARK, LIMEPIT LANE, DUNTON GREEN, SEVENOAKS, TN13 2TL, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products

- [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
 - [1.2.1.1] Capsules, hard shell
 - [1.2.1.5] Liquids for external use
 - [1.2.1.6] Liquids for internal use
 - [1.2.1.13] Tablets
- [1.2.2] Batch certification

[1.3] Biological medicinal products

- [1.3.2] Batch certification
 - [1.3.2.5] Biotechnology products

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.2] Capsules, soft shell
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.13] Tablets
- [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

- [2.2.1] 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
 - [2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

- [2.3.1] Site of Physical Importation
- [2.3.2] Importation of Intermediate which undergoes further processing

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ERAMOL (UK) LTD, UNIT 11, GATWICK METRO CENTRE, BALCOMBE ROAD, HORLEY, RH6 9GA, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation