Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 54632
2. Name or corporate name of registrant	ENNOGEN HEALTHCARE INTERNATIONAL LIMITED
3. Permanent or legal address of registrant	ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G2-G4, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G4, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	05/06/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G4, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor

MHRA-GMDP

CLOBETASONE BUTYRATE (2000008013)	**AVIK PHARMACEUTICAL LTD**, A-1/7 AND A-1/8, PHASE-1, GUJARAT INDUSTRIAL DEVELOPMENT CORPORATION AREA, VALSAD DISTRICT, VAPI, GUJURAT, IN-396195, INDIA **SYMBIOTEC PHARMALAB PRIVATE LIMITED**, PLOT NO. 385/2 PIGDAMBER, NEAR HOTEL MASHAL, OFF A B ROAD, RAU, INDORE DISTRICT, MADHYA PRADESH, IN-453331, INDIA
ADENOSINE (1000009941)	**WOCKHARDT LIMITED**, PLOT NO. 138, GIDC ESTATE, ANKLESHWAR, DISTRICT BHARUCH, GUJARAT, IN 393002, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

CALCIUM OXYTETRACYCLINE (4000007436)

CLOBETASONE BUTYRATE (2000008013)

NYSTATIN (1000009661)

THEOPHYLLINE (1000009347)

AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)

ADENOSINE (1000009941)

MHRA-GMDP MHRA MHRA-GMDP MHRA