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 8931
2. Name or corporate name of registrant	DR REDDY'S LABORATORIES (EU) LIMITED
3. Permanent or legal address of registrant	DR REDDY'S LABORATORIES (EU) LIMITED, STEANARD LANE, MIRFIELD, WF14 8HZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	DR REDDY'S LABORATORIES (EU) LIMITED, STEANARD LANE, MIRFIELD, WF14 8HZ, 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	14/04/2025

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

DR REDDY'S LABORATORIES (EU) LIMITED, STEANARD LANE, MIRFIELD, WF14 8HZ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
LUBIPROSTONE
1000012358

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance

	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
TREPROSTINIL
1000010532

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) chromatography, crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
PERMETHRIN MEDICAL GRADE VETERINARY CIS:TRANS 40:60
2000017046

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
E	General Finishing Steps

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
DELGOCITINIB
1000020359

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
TRAVOPROST
1000000660

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) chromatography, crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps desolvation (the API is a liquid)
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing

	F.1 Physical / Chemical testing

Active substance

PERMETHRIN MEDICAL GRADE CIS/TRANS ISOMERS 25/75

4000007597

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps desolvation (the API is a liquid)
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing