

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 39930
2. Name or corporate name of registrant PEPCEUTICALS LIMITED
3. Permanent or legal address of registrant PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE, ENDERBY, LEICESTER, LE19 4JS, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE, ENDERBY, LEICESTER, LE19 4JS, 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 10/05/2024

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

PEPCEUTICALS LIMITED, 4 FELDSPAR CLOSE, ENDERBY, LEICESTER, LE19 4JS, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

ACTIVE SUBSTANCES FOR CLINICAL TRIALS
1000018046

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) Synthetically manufactured peptides are purified.
B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.6 Purification of Extracted Substance - PLANT
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing