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 15020
2. Name or corporate name of registrant	HIGH FORCE RESEARCH LIMITED
3. Permanent or legal address of registrant	HIGH FORCE RESEARCH LIMITED, BOWBURN NORTH INDUSTRIAL ESTATE, BOWBURN, DURHAM, DH6 5PF, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	HIGH FORCE RESEARCH LIMITED, BOWBURN NORTH INDUSTRIAL ESTATE, BOWBURN, DURHAM, DH6 5PF, 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	16/12/2024

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

HIGH FORCE RESEARCH LIMITED, BOWBURN NORTH INDUSTRIAL ESTATE, BOWBURN, DURHAM, DH6 5PF, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
EP0042 FUMARATE
2000019379

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) The multistep synthesis of EP0042 included recrystallisation of the free base and formation of the fumarate salt
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

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) Purifcation by recrystallisation and salt formation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

EDV2209

3000024079

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) Purification by recrystallisation
F	Quality Control Testing
	F.1 Physical / Chemical testing