

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 36699
2. Name or corporate name of registrant INDIVIOR UK LIMITED
3. Permanent or legal address of registrant INDIVIOR UK LIMITED, THE CHAPLEO BUILDING, PRIORY PARK, HENRY BOOT WAY, HULL, HU4 7DY, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place INDIVIOR UK LIMITED, DANSOM LANE, HULL, HU8 7DS, 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 10/06/2024

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

INDIVIOR UK LIMITED, DANSOM LANE, HULL, HU8 7DS, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

BUPRENORPHINE HYDROCHLORIDE
2000008277

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) API is precipitated by formation of hydrochloride salt using hydrogen chloride gas
E	General Finishing Steps
	E.1 Physical Processing Steps Product is dried under nitrogen / vacuum and then sieved
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

BUPRENORPHINE

1000007171

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
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country Distributor

NALOXONE HYDROCHLORIDE
DIHYDRATE (4000006155)

SPECGX LLC, 3600 NORTH SECOND
STREET, ST LOUIS, 63147, UNITED
STATES

SPECGX LLC, 3600 NORTH SECOND
STREET, ST LOUIS, 63147, UNITED
STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

BUPRENORPHINE HYDROCHLORIDE (2000008277)
NALOXONE HYDROCHLORIDE DIHYDRATE (4000006155)
BUPRENORPHINE (1000007171)