

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 1811 |
| 2. Name or corporate name of registrant | BARD PHARMACEUTICALS LIMITED |
| 3. Permanent or legal address of registrant | BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, 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 | 12/06/2023 |

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

BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

TRAMADOL
HYDROCHLORIDE
(2000008034)

3rd Country Manufacturer

WAVELENGTH PHARMACEUTICALS LIMITED,
NEOT HOVAV ECO INDUSTRIAL PARK, P.O.BOX
3593, BEER SHEVA, IL-8413502, ISRAEL

3rd Country Distributor

OXYCODONE
HYDROCHLORIDE
(2000006722)

NORAMCO INCORPORATED, 500 SWEDES
LANDING ROAD, WILMINGTON, 19801-4417,
UNITED STATES

HYDROMORPHONE
HYDROCHLORIDE
(2000007868)

NORAMCO INCORPORATED, 500 SWEDES
LANDING ROAD, WILMINGTON, 19801-4417,
UNITED STATES

NALOXONE
HYDROCHLORIDE
(2000008238)

NORAMCO INCORPORATED, 500 SWEDES
LANDING ROAD, WILMINGTON, 19801-4417,
UNITED STATES

NORAMCO INCORPORATED, 500
SWEDES LANDING ROAD,
WILMINGTON, 19801-4417, UNITED
STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

OXYCODONE HYDROCHLORIDE (2000006722)