

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

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| 1. Registration Number | UK API 2000 |
| 2. Name or corporate name of registrant | NORBROOK LABORATORIES LIMITED |
| 3. Permanent or legal address of registrant | NORBROOK LABORATORIES LIMITED, STATION WORKS,
CAMLOUGH ROAD, NEWRY, BT35 6JP, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | NORBROOK LABORATORIES LIMITED, STATION WORKS,
CAMLOUGH ROAD, NEWRY, BT35 6JP, UNITED KINGDOM

NORBROOK LABORATORIES LIMITED, 105 ARMAGH ROAD, NEWRY,
BT35 6PU, 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 | 09/10/2015 |

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

NORBROOK LABORATORIES LIMITED, STATION WORKS, CAMLOUGH ROAD, NEWRY, BT35 6JP, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

PROCAINE BENZYL PENICILLIN
(4000008224)

3rd Country Manufacturer

HEBEI HUARI PHARMACEUTICAL COMPANY LIMITED, NO 8
XINGYE STREET, HEBEI, CN-052165, CHINA

3rd Country Distributor

BENZYL PENICILLIN SODIUM
(2000006760)

HEBEI HUARI PHARMACEUTICAL COMPANY LIMITED, NO 8
XINGYE STREET, HEBEI, CN-052165, CHINA

PENICILLIN G SODIUM
(4000002689)

JIANGXI DONGFENG PHARMACEUTICAL COMPANY LIMITED, 15
DONGFENG ROAD, LEPING, CN-333300, CHINA

Name and address of the site

NORBROOK LABORATORIES LIMITED, 105 ARMAGH ROAD, NEWRY, BT35 6PU, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

OXYTETRACYCLINE HYDROCHLORIDE
2000012415

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Conversion of Oxytetracycline Dihydrate to Oxytetracycline Hydrochloride
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)
	F.4 Biological Testing

Active substance

OXYTETRACYCLINE DIHYDRATE
2000008150

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Purification of Oxytetracycline Dihydrate starting material
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)
	F.4 Biological Testing