

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 45676
2. Name or corporate name of registrant
PUROGENIX LIMITED
3. Permanent or legal address of registrant
PUROGENIX LIMITED, B281, OLD BAY HOUSE, RIVER ROAD,
DISCOVERY PARK, SANDWICH, CT13 9FN, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place
PUROGENIX LIMITED, B281, OLD BAY HOUSE, RIVER ROAD,
DISCOVERY PARK, SANDWICH, CT13 9FN, 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
06/02/2017

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

PUROGENIX LIMITED, B281, OLD BAY HOUSE, RIVER ROAD, DISCOVERY PARK, SANDWICH, CT13 9FN, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

AMOXICILLIN TRIHYDRATE
4000006303

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates Special Requirements B-lactam Antibiotics

	A.2 Manufacture of Crude Active Substance Special Requirements B-lactam Antibiotics
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Purification: Crude Amoxicillin is dissolved in acidic medium then precipitate with strong base to g Special Requirements B-lactam Antibiotics
E	General Finishing Steps
	E.1 Physical Processing Steps Compaction, Granulation, Blending, Sieving, Micronization and Milling Special Requirements B-lactam Antibiotics
	E.2 Primary Packaging Special Requirements B-lactam Antibiotics
	E.3 Secondary Packaging Special Requirements B-lactam Antibiotics
F	Quality Control Testing
	F.1 Physical / Chemical testing Special Requirements B-lactam Antibiotics
	F.2 Microbiological testing (excluding sterility testing) Special Requirements B-lactam Antibiotics

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
AMOXICILLIN TRIHYDRATE (4000006303)