

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 10592
2. Name or corporate name of registrant	SMITHKLINE BEECHAM LIMITED
3. Permanent or legal address of registrant	SMITHKLINE BEECHAM LIMITED, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, UNITED KINGDOM SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, 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	03/05/2024

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

SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

POTASSIUM CLAVULANATE DILUTED
4000012986

B	Extraction of Active Substance from Natural Sources
	B.7 Other classical fermentation
E	General Finishing Steps
	E.1 Physical Processing Steps Extraction, crystallisation, blending
	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

AMOXICILLIN
TRIHYDRATE
(4000006303)

3rd Country Manufacturer

CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED, TOANSA, BHAI MOHAN SINGH NAGAR, TOANSA, NAWANSHAHR, PUNJAB, IN-144 533, INDIA

BEECHAM PHARMACEUTICALS (PTE) LIMITED, 38 QUALITY ROAD, JURONG INDUSTRIAL ESTATE, Data Not Available, SGP- 618 809, SINGAPORE

3rd Country Distributor

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

AMOXICILLIN TRIHYDRATE (4000006303)

POTASSIUM CLAVULANATE DILUTED (4000012986)

Name and address of the site

SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

POTASSIUM
CLAVULANATE DILUTED
(4000012986)

3rd Country Manufacturer

CKD BIO CORPORATION, 454-486 MOKNAE-DONG, ANSAN-SI, KYUNGGI-DO, Data Not Available, SOUTH KOREA

3rd Country Distributor

BEECHAM PHARMACEUTICALS (PTE) LIMITED, 38 QUALITY ROAD,
JURONG INDUSTRIAL ESTATE, Data Not Available, SGP- 618 809,
SINGAPORE

AMOXICILLIN
TRIHYDRATE
(4000006303)

CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED, TOANSA, BHAI
MOHAN SINGH NAGAR, TOANSA, NAWANSHAHR, PUNJAB, IN-144 533, INDIA

SINOPHARM WEIQIDA PHARMACEUTICAL CO., LTD., HIGH-TECH
INDUSTRIAL ZONE, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT
ZONE, DATONG, SHANXI PROVINCE, CN-037304, CHINA

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