

# 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,<br>TW8 9GS, UNITED KINGDOM   |
| 4. Address(es) of site(s) where registered activities<br>take place   | SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM<br>PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, UNITED<br>KINGDOM<br><br>SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM<br>PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED<br>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<br>authority of the member state validating the<br>registration | Confidential   |
| 7. Date   | 25/05/2023   |

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

**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

#### 3rd Country Manufacturer

#### 3rd Country Distributor

AMOXICILLIN TRIHYDRATE (4000006303)	<b>BEECHAM PHARMACEUTICALS (PTE) LIMITED</b> , 38 QUALITY ROAD, JURONG INDUSTRIAL ESTATE, Data Not Available, SGP- 618 809, SINGAPORE
	<b>CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED, TOANSA</b> , BHAI MOHAN SINGH NAGAR, TOANSA, NAWANSHAHR, PUNJAB, IN-144 533, INDIA
POTASSIUM CLAVULANATE DILUTED (4000012986)	<b>CKD BIO CORPORATION</b> , 454-486 MOKNAE-DONG, ANSAN-SI, KYUNGGI-DO, Data Not Available, SOUTH KOREA