

# 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 11717
2. Name or corporate name of registrant	SURFACHEM LIMITED
3. Permanent or legal address of registrant	SURFACHEM LIMITED, 2 THE EMBANKMENT, SOVEREIGN STREET, LEEDS, LS1 4BA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SURFACHEM LIMITED, 2 THE EMBANKMENT, SOVEREIGN STREET, LEEDS, LS1 4BA, UNITED KINGDOM SURFACHEM LIMITED, THE AINLEYS, HUDDERSFIELD ROAD, ELLAND, HX5 9JR, 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	16/04/2024

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

**SURFACHEM LIMITED**, 2 THE EMBANKMENT, SOVEREIGN STREET, LEEDS, LS1 4BA, UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

TOPIRAMATE (1000002932)

##### 3rd Country Manufacturer

**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

##### 3rd Country Distributor

EPINASTINE HYDROCHLORIDE (2000006570) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

AMILORIDE HYDROCHLORIDE (2000008529) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

BENZYDAMINE HYDROCHLORIDE (2000008364) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

BACLOFEN (1000009324) **MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA

CLOMIFENE CITRATE (4000007266) **BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

TORSEMIDE ANHYDROUS (3000020810) **MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA

MESALAMINE (3000003546) **BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA

GLICLAZIDE (1000001769) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

2,4-DICHLOROBENZYL ALCOHOL (3000009479) **BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

TOLTERODINE TARTRATE (2000013355) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

DAPSONE (1000003787) **MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA

PHENYLEPHRINE  
HYDROCHLORIDE (2000008067)

**DIVIS LABORATORIES LIMITED**, UNIT 2, CHIPPADA VILLAGE,  
ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM,  
ANDHRA PRADESH, IN-531 162, INDIA

HYDROQUINONE (1000008752)

**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I,  
INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH,  
IN-454 775, INDIA

TRANEXAMIC ACID  
(1000009308)

**HUNAN DONGTING PHARMACEUTICAL CO. LIMITED**, NO.16 DONGYANG  
ROAD, CHENJIAGANG COMMUNITY, DESHAN SUB-DISTRICT OFFICE,  
CHANGDE ECONOMIC AND TECHNICAL DEVELOPMENT ZONE,  
CHANGDE CITY, HUNAN PROVINCE, CN-415001, CHINA

CHLORHEXIDINE GLUCONATE  
SOLUTION (4000009485)

**BAJAJ HEALTHCARE LIMITED (UNIT-2)**, UNIT II, BLOCK NO 588, SAVLI-  
KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776,  
INDIA

ADAPALENE (1000002293)

**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA,  
ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

MESALAZINE (1000000859)

**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD  
DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA

BISOPROLOL FUMARATE  
(2000008290)

**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I,  
INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH,  
IN-454 775, INDIA

DEXTROMETHORPHAN  
HYDROBROMIDE (2000007835)

**DIVIS LABORATORIES LIMITED**, UNIT 1, LINGOJIGUDEM VILLAGE,  
CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT,  
TELANGANA, IN-508252, INDIA

GLUCOSAMINE SULFATE  
POTASSIUM CHLORIDE  
(4000011670)

**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263,  
VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT,  
ANDHRA PRADESH, IN 521110, INDIA

GLUCOSAMINE  
HYDROCHLORIDE (2000008777)

**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263,  
VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT,  
ANDHRA PRADESH, IN 521110, INDIA

KETOPROFEN (1000008346)

**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD  
DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA

GLUCOSAMINE SULPHATE  
SODIUM CHLORIDE  
(2000009013)

**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263,  
VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT,  
ANDHRA PRADESH, IN 521110, INDIA

AMYL METACRESOL  
(1000000573)

**BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL  
AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI,  
MAHARASHTRA, IN 421501, INDIA

METFORMIN HYDROCHLORIDE  
(2000008338)

**HARMAN FINOCHEM LIMITED**, PLOT NO. E-7, E-8, E-9, MIDC INDUSTRIAL  
AREA, CHIKALTHANA, AURANGABAD, MAHARASHTRA, IN-431006, INDIA

**HARMAN FINOCHEM LIMITED**, PLOT NO. A-100, A-100-1, A-100-2, D-1,  
MIDC INDUSTRIAL AREA, SHENDRA, AURANGABAD, MAHARASHTRA, IN-  
431007, INDIA

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

### B Distribution

TOPIRAMATE (1000002932)

EPINASTINE HYDROCHLORIDE (2000006570)

AMILORIDE HYDROCHLORIDE (2000008529)

BENZYLAMINE HYDROCHLORIDE (2000008364)

BACLOFEN (1000009324)

CLOMIFENE CITRATE (4000007266)

TORSEMIDE ANHYDROUS (3000020810)

MESALAMINE (3000003546)

GLICLAZIDE (1000001769)

2,4-DICHLOROBENZYL ALCOHOL (3000009479)

AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)

TOLTERODINE TARTRATE (2000013355)

DAPSONE (1000003787)

PHENYLEPHRINE HYDROCHLORIDE (2000008067)

HYDROQUINONE (1000008752)

TRANEXAMIC ACID (1000009308)

CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)

ADAPALENE (1000002293)

MESALAZINE (1000000859)

BISOPROLOL FUMARATE (2000008290)

DEXTROMETHORPHAN HYDROBROMIDE (2000007835)

GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)

GLUCOSAMINE HYDROCHLORIDE (2000008777)

KETOPROFEN (1000008346)

GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)

AMYL METACRESOL (1000000573)

Name and address of the site

**SURFACHEM LIMITED**, THE AINLEYS, HUDDERSFIELD ROAD, ELLAND, HX5 9JR, UNITED KINGDOM

**2. IMPORTATION AND DISTRIBUTION OPERATIONS**

**A Importation**

Active Substance	3rd Country Manufacturer	3rd Country Distributor
TRANEXAMIC ACID (1000009308)	<b>HUNAN DONGTING PHARMACEUTICAL CO. LIMITED</b> , NO.16 DONGYANG ROAD, CHENJIAGANG COMMUNITY, DESHAN SUB-DISTRICT OFFICE, CHANGDE ECONOMIC AND TECHNICAL DEVELOPMENT ZONE, CHANGDE CITY, HUNAN PROVINCE, CN-415001, CHINA	
BENZYLAMINE HYDROCHLORIDE (2000008364)	<b>BAL PHARMA LIMITED</b> , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA	
BACLOFEN (1000009324)	<b>MEDILUX LABORATORIES PVT. LIMITED.</b> , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA	
HYDROQUINONE (1000008752)	<b>MEDILUX LABORATORIES PVT. LIMITED.</b> , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA	
MESALAMINE (3000003546)	<b>BEC CHEMICALS PVT.LTD</b> , PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA	
GLUCOSAMINE HYDROCHLORIDE (2000008777)	<b>ANDHRA MEDIPHARMA INDIA PVT. LIMITED.</b> , SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA	
TOLTERODINE TARTRATE (2000013355)	<b>BAL PHARMA LIMITED</b> , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA	
DEXTROMETHORPHAN HYDROBROMIDE (2000007835)	<b>DIVIS LABORATORIES LIMITED</b> , UNIT 1, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, TELANGANA, IN-508252, INDIA	
CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)	<b>BAJAJ HEALTHCARE LIMITED (UNIT-2)</b> , UNIT II, BLOCK NO 588, SAVLI-KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776, INDIA	

ADAPALENE (1000002293) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

METFORMIN HYDROCHLORIDE (2000008338) **HARMAN FINOCHEM LIMITED**, PLOT NO. A-100, A-100-1, A-100-2, D-1, MIDC INDUSTRIAL AREA, SHENDRA, AURANGABAD, MAHARASHTRA, IN-431007, INDIA

KETOPROFEN (1000008346) **HARMAN FINOCHEM LIMITED**, PLOT NO. E-7, E-8, E-9, MIDC INDUSTRIAL AREA, CHIKALTHANA, AURANGABAD, MAHARASHTRA, IN-431006, INDIA

GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013) **BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA

CLOMIFENE CITRATE (4000007266) **ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA

2,4-DICHLOROBENZYL ALCOHOL (3000009479) **BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

PHENYLEPHRINE HYDROCHLORIDE (2000008067) **BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670) **DIVIS LABORATORIES LIMITED**, UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA

AMILORIDE HYDROCHLORIDE (2000008529) **ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA

GLICLAZIDE (1000001769) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

MESALAZINE (1000000859) **BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

MESALAZINE (1000000859) **BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA



TOPIRAMATE (1000002932)	<b>BAL PHARMA LIMITED</b> , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
EPINASTINE HYDROCHLORIDE (2000006570)	<b>BAL PHARMA LIMITED</b> , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
TORSEMIDE ANHYDROUS (3000020810)	<b>MEDILUX LABORATORIES PVT. LIMITED.</b> , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)	<b>BAL PHARMA LIMITED</b> , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
DAPSONE (1000003787)	<b>MEDILUX LABORATORIES PVT. LIMITED.</b> , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
BISOPROLOL FUMARATE (2000008290)	<b>MEDILUX LABORATORIES PVT. LIMITED.</b> , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
AMYL METACRESOL (1000000573)	<b>BIOXERA PHARMA PVT. LIMITED.</b> , PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	TRANEXAMIC ACID (1000009308)
	BENZYLAMINE HYDROCHLORIDE (2000008364)
	BACLOFEN (1000009324)
	HYDROQUINONE (1000008752)
	MESALAMINE (3000003546)
	GLUCOSAMINE HYDROCHLORIDE (2000008777)
	TOLTERODINE TARTRATE (2000013355)
	DEXTROMETHORPHAN HYDROBROMIDE (2000007835)
	CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)
	ADAPALENE (1000002293)
	METFORMIN HYDROCHLORIDE (2000008338)
	KETOPROFEN (1000008346)
	GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)
	CLOMIFENE CITRATE (4000007266)
	2,4-DICHLOROBENZYL ALCOHOL (3000009479)
	PHENYLEPHRINE HYDROCHLORIDE (2000008067)

GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)

AMILORIDE HYDROCHLORIDE (2000008529)

GLICLAZIDE (1000001769)

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