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	16/04/2026

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	3rd Country Manufacturer	3rd Country Distributor
BISOPROLOL FUMARATE (2000008290)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA	

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GLICLAZIDE (1000001769)	**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
CLOMIFENE CITRATE (4000007266)	**BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421506, INDIA
BACLOFEN (1000009324)	**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
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 421506, INDIA
KETOPROFEN (1000008346)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA
AMYLMETACRESOL (1000000573)	**BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421506, INDIA
METFORMIN HYDROCHLORIDE (2000008338)	**HARMAN FINOCHEM LIMITED**, PLOT NUMBERS A-100, A-100/1, A-100/2, A-120 AND D-1, M.I.D.C. INDUSTRIAL AREA, SHENDRA, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431154, INDIA **HARMAN FINOCHEM LIMITED**, PLOT NUMBERS E-7, E-8, E-9 & E-53, M.I.D.C. INDUSTRIAL AREA, CHIKALTHANA, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431006, INDIA
HYDROQUINONE (1000008752)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, 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

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MESALAZINE (1000000859)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA
DAPSONE (1000003787)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
ADAPALENE (1000002293)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
PHENYLEPHRINE HYDROCHLORIDE (2000008067)	**DIVIS LABORATORIES LIMITED**, UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA
TOLTERODINE TARTRATE (2000013355)	**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
GLUCOSAMINE HYDROCHLORIDE (2000008777)	**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA
EPINASTINE HYDROCHLORIDE (2000006570)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, 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
CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)	**BAJAJ HEALTHCARE LIMITED (UNIT-2)**, UNIT II, BLOCK NO 588, SAVLI-KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776, INDIA
TOPIRAMATE (1000002932)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
MESALAMINE (3000003546)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA

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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
GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)	**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA
AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

BISOPROLOL FUMARATE (2000008290)

GLICLAZIDE (1000001769)

BENZYDAMINE HYDROCHLORIDE (2000008364)

CLOMIFENE CITRATE (4000007266)

BACLOFEN (1000009324)

DEXTROMETHORPHAN HYDROBROMIDE (2000007835)

2,4-DICHLOROBENZYL ALCOHOL (3000009479)

KETOPROFEN (1000008346)

AMYLMETACRESOL (1000000573)

METFORMIN HYDROCHLORIDE (2000008338)

HYDROQUINONE (1000008752)

GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)

MESALAZINE (1000000859)

DAPSONE (1000003787)

ADAPALENE (1000002293)

PHENYLEPHRINE HYDROCHLORIDE (2000008067)

TOLTERODINE TARTRATE (2000013355)

AMILORIDE HYDROCHLORIDE (2000008529)

GLUCOSAMINE HYDROCHLORIDE (2000008777)

EPINASTINE HYDROCHLORIDE (2000006570)

TORSEMIDE ANHYDROUS (3000020810)

CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)

TOPIRAMATE (1000002932)

MESALAMINE (3000003546)

TRANEXAMIC ACID (1000009308)

GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)

AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)

Name and address of the site

MHRA-GMDP MHRA

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
PHENYLEPHRINE HYDROCHLORIDE (2000008067)	**DIVIS LABORATORIES LIMITED**, UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA	
ADAPALENE (1000002293)	**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	
GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)	**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 421506, INDIA	
GLUCOSAMINE HYDROCHLORIDE (2000008777)	**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, 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	
MESALAMINE (3000003546)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA	
HYDROQUINONE (1000008752)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA	

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GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)	**ANDHRA MEDIPHARMA INDIA PVT. LIMITED.**, SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA
BACLOFEN (1000009324)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
AMYLMETACRESOL (1000000573)	**BIOXERA PHARMA PVT. LIMITED.**, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421506, INDIA
BENZYDAMINE HYDROCHLORIDE (2000008364)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
TOPIRAMATE (1000002932)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
KETOPROFEN (1000008346)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA
AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
METFORMIN HYDROCHLORIDE (2000008338)	**HARMAN FINOCHEM LIMITED**, PLOT NUMBERS A-100, A-100/1, A-100/2, A-120 AND D-1, M.I.D.C. INDUSTRIAL AREA, SHENDRA, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431154, INDIA **HARMAN FINOCHEM LIMITED**, PLOT NUMBERS E-7, E-8, E-9 & E-53, M.I.D.C. INDUSTRIAL AREA, CHIKALTHANA, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431006, 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
GLICLAZIDE (1000001769)	**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

MHRA-GMDP MHRA-GMDP MHRA MHRA

MESALAZINE (1000000859)	**BEC CHEMICALS PVT.LTD**, PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, 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 421506, INDIA
EPINASTINE HYDROCHLORIDE (2000006570)	**BAL PHARMA LIMITED**, UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, 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
DEXTROMETHORPHAN HYDROBROMIDE (2000007835)	**DIVIS LABORATORIES LIMITED**, UNIT 1, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, TELANGANA, IN-508252, INDIA
DAPSONE (1000003787)	**MEDILUX LABORATORIES PVT. LIMITED.**, PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

PHENYLEPHRINE HYDROCHLORIDE (2000008067)

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