

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 | 15/04/2025 |

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

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
AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)	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
MESALAZINE (1000000859)	BEC CHEMICALS PVT.LTD , PLOT NO 24, MIDC DHATAV ROHA, RAIGAD DISTRICT, RAIGAD, MAHARASHTRA, IN-402 116, INDIA
EPINASTINE HYDROCHLORIDE (2000006570)	BAL PHARMA LIMITED , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
GLICLAZIDE (1000001769)	BAL PHARMA LIMITED , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA
ADAPALENE (1000002293)	BAL PHARMA LIMITED , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, 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
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
DAPSONE (1000003787)	MEDILUX LABORATORIES PVT. LIMITED. , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, 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

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

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

DEXTROMETHORPHAN
HYDROBROMIDE (2000007835)

DIVIS LABORATORIES LIMITED, UNIT 1, LINGOJIGUDEM VILLAGE,
CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT,
TELANGANA, IN-508252, 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 421506, INDIA

MESALAMINE (3000003546)

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

KETOPROFEN (1000008346)

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

PHENYLEPHRINE
HYDROCHLORIDE (2000008067)

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

AMILORIDE HYDROCHLORIDE
(2000008529)

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
TOLTERODINE TARTRATE (2000013355)	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
CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)	BAJAJ HEALTHCARE LIMITED (UNIT-2) , UNIT II, BLOCK NO 588, SAVLI- KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776, INDIA
BENZYDAMINE HYDROCHLORIDE (2000008364)	BAL PHARMA LIMITED , UNIT II, 61-B BOMMASANDRA INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-560099, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

METFORMIN HYDROCHLORIDE (2000008338)
 AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)
 GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)
 MESALAZINE (1000000859)
 EPINASTINE HYDROCHLORIDE (2000006570)
 GLICLAZIDE (1000001769)
 ADAPALENE (1000002293)
 BISOPROLOL FUMARATE (2000008290)
 HYDROQUINONE (1000008752)
 GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)
 DAPSONE (1000003787)
 TORSEMIDE ANHYDROUS (3000020810)
 TRANEXAMIC ACID (1000009308)
 2,4-DICHLOROBENZYL ALCOHOL (3000009479)
 GLUCOSAMINE HYDROCHLORIDE (2000008777)
 DEXTROMETHORPHAN HYDROBROMIDE (2000007835)
 AMYLMETACRESOL (1000000573)
 MESALAMINE (3000003546)
 KETOPROFEN (1000008346)
 CLOMIFENE CITRATE (4000007266)
 PHENYLEPHRINE HYDROCHLORIDE (2000008067)
 AMILORIDE HYDROCHLORIDE (2000008529)
 BACLOFEN (1000009324)

TOLTERODINE TARTRATE (2000013355)
TOPIRAMATE (1000002932)
CHLORHEXIDINE GLUCONATE SOLUTION (4000009485)
BENZYDAMINE HYDROCHLORIDE (2000008364)

Name and address of the site

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

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A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
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METFORMIN HYDROCHLORIDE (2000008338)	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 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	
DAPSONE (1000003787)	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	
GLUCOSAMINE SULPHATE SODIUM CHLORIDE (2000009013)	ANDHRA MEDIPHARMA INDIA PVT. LIMITED. , SURVEY NO. 263, VEERAVALLI VILLAGE, BAPULAPADU MANDAL, KRISHNA DISTRICT, ANDHRA PRADESH, IN 521110, INDIA	
MESALAZINE (1000000859)	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	
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	

TORSEMIDE ANHYDROUS
(3000020810)

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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

AMILORIDE HYDROCHLORIDE
(2000008529)

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
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HYDROBROMIDE (2000007835)

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TOPIRAMATE (1000002932)

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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

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

CHLORHEXIDINE GLUCONATE
SOLUTION (4000009485)

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

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B

Distribution

TOLTERODINE TARTRATE (2000013355)

METFORMIN HYDROCHLORIDE (2000008338)

DAPSONE (1000003787)

GLUCOSAMINE SULFATE POTASSIUM CHLORIDE (4000011670)

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