1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

- Attached

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

1.1 Product Name

Generic Name or INN- CEFIXIME 200MG AND CLAVULANIC ACID 125MG TABLETS

Brand Name- CEFEXICLAV 325

1.2 Dosage Strength: CEFIXIME 200MG AND CLAVULANIC ACID 125MG TABLETS

1.3 Dosage Form: Solid Oral Dosage Form, Film coated Tablets

2. Quality and Quantitative Composition

Qualitative Declaration

Each Film Coated Tablet Contains:

Cefixime USP (As trihydrate)

Eq. to Anhydrous Cefixime……200 mg

Clavulanate Potassium USP

Eq. to anhydrous Clavulanic Acid ……125mg

Excipients……..q.s.

Color: Approved colors used

Quantitative Declaration

Qty of Cefixime Trihydrate is Approx. 223.840mg and Clavulanate Potassium with Avicel Base is Approx. 148.910mg equivalent to Cefixime 200mg and Clavulanic acid 125mg.

Composition: (For Batch size: 6000 Tablets)

Ingredients	Spec.	Label Claim	Qty. / Tablet (Mg)	Qty. /Batch (Tablets) (Kg)	Function
DRY MIXING					
Cefixime Trihydrate Compacted*	BP	200.00	223.840	1.343	API
Clavulanate Potassium with Avicel Base**	BP	125.00	148.910	0.893	API
Lactose Monohydrate $	BP	-	40.000	0.240	Diluent
Microcrystalline Cellulose 102 (Spray dried) $$	BP	-	301.250	1.807	Disintegrating agent
Croscarmellose Sodium	BP	-	25.000	0.150	Binder
Colloidal anhydrous silica (Aerosil)	BP	-	7.000	0.042	Disintegrating agent
Pregelatinized Starch	BP	-	70.000	0.420	Binder
Purified Talc	BP	-	15.000	0.090	Glidant
Total pre-lubricated weight			**831.000**	**4.986**	---
LUBRICATION					
Magnesium Stearate	BP	-	10.000	0.060	Lubricant
Compressed tablet weight			**841.000**	**5.046**	---
SEAL COATING					
Color coat MB4S-B (Clear)	IHS	-	10.000	0.060	Colouring Agent
Isopropyl Alcohol***	BP	-	60.000	0.360	Solvent

Dichloromethane ***	BP	-	90.000	0.540	Solvent
Seal Coated Tablet Weight			**851.000**	**5.106**	---
FILM COATING					
Color coat FC4S-I (White)	IHS	-	19.000	0.114	Coating Agent
Isopropyl Alcohol***	BP	-	100.000	0.600	Solvent
Dichloromethane ***	BP	-	150.000	0.900	Solvent
Coated Tablet Weight			**870.000**	**5.220**	**---**

Note:

- *Mentioned quantity is considering Assay (on as is basis) as 100%, Potency correction to be done while dispensing considering the actual assay on as is basis.
- $ Lactose Monohydrate to be compensate after potency correction of Cefixime Trihydrate Compacted.
- $$ Microcrystalline Cellulose – 102 (Spray dried) to be compensate after potency correction of Clavulanate Potassium with Avicel Base.
- *** Isopropyl Alcohol, Methylene Chloride will evaporate while coating.

BP- British pharmacopoeia

IHS- In House Specification

Calculation:

CEFIXIME TRIHYDRATE

Molecular weight of Cefixime trihydrate= 507.5 g/mol

Molecular weight of Cefixime = 453.45 g/mol

Dose for Cefixime = 200 mg

453.45 g/mol g/mol Cefixime trihydrate= 200mg

507.500 g/mol Cefixime trihydrate per bottle= $\frac{200 \text{ X } 507.5}{453.45}$ = 223.840 mg of Cefixime trihydrate required

POTASSIUM CLAVULANATE

Molecular weight of Clavulanate Potassium= 237.250 g/mol

Molecular weight of Clavulanic Acid = 199.160 g/mol

Dose for Clavulanate Potassium = 125 mg

199.160 g/mol g/mol Clavulanic Acid = 125mg

237.250 g/mol Cefixime trihydrate per bottle= $\frac{125 \text{ X } 237.250}{199.160}$ = 148.910 mg of Clavulanate Potassium required

3. Pharmaceutical Form:

White coloured, capsule shaped, biconvex, with one side break line and other side plain film coated tablets.

4. Clinical Particulars

4.1 Therapeutic indications

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefixime and other antibacterial drugs, cefixime should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

When culture and susceptibility information are available, they should be considered in selecting or

modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CEFIXIME 200MG AND CLAVULANIC ACID 125MG TABLETS are indicated in the treatment of adults and paediatric patients, 6 months of age or older, with the following infections when caused by susceptible isolates of the designated bacteria:

- Uncomplicated urinary tract infections (e.g. cystitis, cystourethritis, uncomplicated pyelonephritis) caused by Escherichia coli and Proteus mirabilis.
- Otitis media caused by Haemophilus influenzae, Moraxella catarrhalis, and Streptococcus pyogenes.

Note: For patients with otitis media caused by Streptococcus pneumoniae, overall response was approximately 10% lower for cefixime than for the comparator.

- Pharyngitis and tonsillitis caused by Streptococcus pyogenes.

Note: Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes infections. Cefixime is generally effective in the eradication of Streptococcus pyogenes from the nasopharynx; however, data establishing the efficacy of cefixime in the subsequent prevention of rheumatic fever is not available.

- Acute exacerbations of chronic bronchitis caused by Streptococcus pneumoniae and Haemophilus influenzae.
- Uncomplicated gonorrhoea (cervical/urethral) caused by Neisseria gonorrhoeae (penicillinase- and non-penicillinase-producing isolates).
- For the treatment of enteric (typhoid) fever.

4.2 Posology and Method of Administration

Adults and Children over 10 Years of Age

One tablet twice daily.

The usual course of treatment is 7 days. This may be continued for up to 14 days if required

Geriatric Patients

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed, and dosage should be adjusted in severe renal impairment.

Patients with Renal Impairment

Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20 mL/min or greater. In patients whose creatinine clearance is less than 20 mL/min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis (CAPD) or haemodialysis should follow the same recommendation as that for patients with creatinine clearances of less than 20 mL/min.

4.3 Contraindications

Cefixime is contraindicated in patients with a known allergy to cefixime or other cephalosporins or any of the other components of the product.

4.4 Special Warnings and Precautions for Use

Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. There is some evidence of partial cross-allergenicity between the penicillins and cephalosporins. Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefixime occurs, discontinue the drug.

Clostridium difficile-associated Diarrhoea

Clostridium difficile-associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including cefixime, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile.

C. difficile produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing isolates of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhoea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

Dose Adjustment in Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing CAPD and haemodialysis. Patients on dialysis should be monitored carefully.

Coagulation Effects

Cephalosporins, including cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilised on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Encephalopathy

Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs.

Haemolytic Anaemia

Drug-induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after re-administration of cephalosporins in a patient with a history of cephalosporin (including cefixime)-associated haemolytic anaemia has also been reported.

Acute Renal Failure

As with other cephalosporins, cefixime may cause acute renal failure, including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Development of Drug-resistant Bacteria

Prescribing cefixime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

4.5 Interaction with Other Drugs, Other Forms of Interactions

Anticoagulants

Carbamazepine

Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants

In common with other cephalosporins, increases in prothrombin times with or without clinical bleeding have been noted in a few patients. Care should, therefore, be taken in patients receiving anticoagulation therapy.

Effects on Laboratory Tests

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.

A false-positive direct Coomb's test has been reported during treatment with other cephalosporins; therefore, it should be recognised that a positive Coomb's test may be due to the drug.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Pregnancy Category B

There are no adequate and well-controlled studies in pregnant women. Cefixime should, therefore, not be used in pregnancy or in nursing mothers unless considered essential by the physician.

Lactating Women

It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Paediatric Patients

Safety and effectiveness of cefixime in children aged less than 6 months old have not been established.

The incidence of gastrointestinal adverse reactions, including diarrhoea and loose stools, in the paediatric patients receiving the suspension was comparable with the incidence seen in adult patients receiving tablets. No data are available in case of paediatric patients with impaired renal or hepatic function.

Geriatric Patients

Clinical studies did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters. These differences were small and do not indicate a need for dosage adjustment of the drug in the elderly.

Patients with Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing CAPD and haemodialysis. Patients on dialysis should be monitored carefully.

Patients with Hepatic Impairment

No data on dosing is available for patients with impaired hepatic function.

4.7 Effects on ability to drive and operate machine

In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

4.8 Undesirable effects

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

The listed adverse reactions mentioned below have been observed during clinical studies and/or during marketed use.

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

The following adverse reaction (Preferred term# or equivalent) will be considered listed:

Blood and lymphatic system disorders:	Eosinophilia Hypereosinophilia Agranulocytosis Leucopenia Neutropenia Granulocytopenia Hemolyticanemia Thrombocytopenia Thrombocytosis
Gastrointestinal disorders:	Abdominal pain

	Diarrhea* Dyspepsia Nausea Vomiting Flatulence
Hepatobiliary disorders:	Jaundice
Infections and infestations:	Pseudomembranous colitis
Investigations	Aspartate aminotransferase increased Alanine aminotransferase increased Blood bilirubin increased Blood urea increased Blood creatinine increased
Nervous system disorders	Dizziness Headache Cases of convulsions have been reported with cephalosporins including cefixime (frequency not known) ** Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment (frequency not known) **
Respiratory, thoracic and mediastinal disorders	Dyspnoea
Renal and urinary disorders	Renal failure acute including tubulointerstitial nephritis as an underlying pathological condition
Immune system disorders, administrative site conditions, skin and subcutaneous tissue disorders:	Anaphylactic reaction Serum sickness-like reaction Drug rash with eosinophilia and systemic symptoms (DRESS) Pruritus Rash Drug Fever Arthralgia Erythema multiforme Stevens-Johnson syndrome Toxic epidermal necrolysis Angio-oedema Urticaria

	Pyrexia Face oedema Genital pruritus Vaginitis

The above mentioned listed adverse reactions have been observed during clinical studies and/or during marketed use.

*Diarrhea has been more commonly associated with higher doses. Some cases of moderate to severe diarrhea have been reported; this has occasionally warranted cessation of therapy. Cefixime should be discontinued if marked diarrhea occurs

** Cannot be estimated from available data

Postmarketing Experience

The following adverse reactions have been reported following the use of cefixime. Incidence rates were less than 1 in 50 (less than 2%).

- ***Gastrointestinal:*** Several cases of documented pseudomembranous colitis were identified in clinical trials. The onset of pseudomembranous colitis symptoms may occur during or after therapy.
- **Hypersensitivity Reactions:** Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angio-oedema, and facial oedema. erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.
- **Hepatic:** Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, and jaundice.
- **Renal:** Transient elevations in BUN or creatinine, acute renal failure.
- **Central Nervous System:** Headaches, dizziness, seizures.
- **Haemic and Lymphatic System:** Transient thrombocytopaenia, leucopaenia, neutropaenia, prolongation in prothrombin time, elevated LDH, pancytopaenia, agranulocytosis, and eosinophilia.
- **Abnormal Laboratory Tests:** Hyperbilirubinaemia.

Other Adverse Reactions

Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis. Spontaneous reported cases of acute generalised exanthematous pustulosis (AGEP) associated with the treatment using cefixime deduce that there is a potential risk for systemic involvement in patients with AEGP.

Adverse Reactions Reported for Cephalosporin-class Drugs

Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction, including cholestasis, aplastic anaemia, haemolytic anaemia, haemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

Reporting of Suspected Adverse Reactions

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme (PvPI) of India by

calling on 1800 267 7779 (Cipla number) or you can report to PVPI on 1800 180 3024. By reporting side effects, you can help provide more information on the safety of this product.

4.9 Overdose and special antidotes:

There is no experience with overdoses with cefixime. Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by haemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Mechanism of Action

As with other cephalosporins, the bactericidal action of cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime. However, cefixime was found to be ineffective against bacteria that produce ESBL enzymes and resistance is seen in such types of bacteria.

Clavulanic acid contains a beta-lactam ring in its structure that binds in an irreversible fashion to beta-lactamases, preventing them from inactivating certain beta-lactam antibiotics, with efficacy in treating susceptible Gram-positive and Gram-negative infections.

Pharmacotherapeutic group: third generation cephalosporin, **ATC code:** J01DD08

Cefixime is an oral third-generation cephalosporin that has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenzae (beta-lactamase positive and negative), Branhamella catarrhalis (beta-lactamase positive and negative) and Enterobacter species. It is highly stable in the presence of beta-lactamase enzymes.

Clavulanic acid is an irreversible 'suicide' inhibitor of intracellular and extracellular beta-lactamases, demonstrating concentration-dependent and competitive inhibition. It has a high affinity for the class A beta-lactamases. This wide range of beta-lactamases, which includes the plasmid-mediated TEM and SHV enzymes, is found frequently in members of the Enterobacteriaceae, Haemophilus influenza and Neisseria gonorrhoeae spp. The chromosomally mediated beta-lactamases of Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Bacteroides fragilis and Moraxella catarrhalis are also inhibited, as are the extended-spectrum beta-lactamases. The frequency of beta-lactamase-mediated resistance has continued to rise over the years, but the majority of clinically significant beta-lactamases are inhibited by clavulanate.

Resistance

Resistance to cefixime in isolates of Haemophilus influenzae and Neisseria gonorrhoeae is most often associated with alterations in penicillin-binding proteins (PBPs). Cefixime may have limited activity against Enterobacteriaceae-producing extended-spectrum beta-lactamases

(ESBLs). Pseudomonas species, Enterococcus species, strains of Group D streptococci, Listeria monocytogenes, most strains of staphylococci (including methicillin-resistant strains), most strains of Enterobacter species, most strains of Bacteroides fragilis, and most strains of Clostridium species are resistant to cefixime.

Antimicrobial Activity

Cefixime has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections:

Gram-positive Bacteria

Streptococcus pneumoniae

Streptococcus pyogenes

Gram-negative Bacteria

Haemophilus influenzae (beta-lactamase-positive and -negative)

Moraxella catarrhalis

Escherichia coli

Proteus mirabilis

Neisseria gonorrhoeae

Also, clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including Branhamella catarrhalis and Enterobacter species. The following in vitro data are available, but their clinical significance is unknown. At least 90% of the following bacteria exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefixime against isolates of similar genus or organism group. However, the efficacy of cefixime in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive Bacteria

Streptococcus agalactiae

Gram-negative Bacteria

Citrobacter amalonaticus

Citrobacter diversus

Haemophilus parainfluenzae

Klebsiella oxytoca

Klebsiella pneumoniae

Pasteurella multocida

Proteus vulgaris

Providencia species

Salmonella species

Serratia marcescens

Shigella species

5.2 Pharmacokinetic properties

The absolute oral bioavailability of cefixime is in the range of 22-54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals.

From in vitro studies, serum or urine concentrations of 1 mcg/mL or greater were considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or pediatric doses are between 1.5 and 3mcg/ml. little or no accumulation of cefixime occurs following multiple dosing.

The pharmacokinetics of cefixime in healthy elderly (age > 64 years) and young volunteers (11-35) compared the administration of 200 mg doses once daily for 5 days. Mean C-max and AUC values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population.

Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.

Serum protein binding is well characterized for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein binding of cefixime is only concentration dependent in human serum at very high concentrations which are not seen following clinical dosing.

Transfer of 14C-labelled cefixime from lactating rats to their nursing offspring through breast milk was quantitatively small (approximately 1.5% of the mothers' body content of cefixime in the pup). No data are available on secretion of cefixime in human breast milk. Placental transfer of cefixime was small in pregnant rats dosed with labelled cefixime.

5.3 Preclinical safety data

Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

6. Pharmaceutical Particulars

6.1 List of excipients

Microcrystalline Cellulose -102 $

Purified Talc

Magnesium Stearate

Pregelatinized Starch

Croscarmellose Sodium

Magnesium Stearate

Color coat MB4S-B (Clear)

Color coat FC4S-I (White)

Solvent

Isopropyl Alcohol

Dichloromethane

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

24 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 25°C, Protect from moisture. Keep out of reach of children

6.5 Nature and Contents of Container

- Pack 1 Blister of 10 tablets in 1 inner carton.
- Pack 10 such inner cartons in 1 outer carton.
- Pack such Cartons in an export worthy shipper.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

MANUFACTURER:

NAME	:	**GLOBELA LABORATORIES PVT. LTD**
ADDRESS	:	PLOT NO. 5536, ROAD NUMBER 55, SACHIN G.I.D.C, SURAT- 394230 GUJARAT, INDIA.
COUNTRY	:	INDIA
TELEPHONE	:	+91–0261–6158000
E-MAIL	:	glpra@globelapharma.com

APPLICANT:

NAME	:	**SJS LIFE SCEINCE LTD**
ADDRESS	:	H.NO.11, OLU-AKERELE STREET, IKEJA, LAGOS STATE, NIGERIA.
COUNTRY	:	NIGERIA
TELEPHONE	:	+234–8114441430
E-MAIL	:	jkpandey3s@gmail.com

Marketing authorization numbers

Not applicable

Date of first authorization/renewal of the authorization

Not applicable

Date of revision of the text

To be given after approval of the product