5.2 Summary of Product Characteristics:

5.2.1. Name of the Medicinal Product

1.1 Product Name: BEKRACINE

1.2 Strength: 100 mg

1.3Pharmaceutical Dosage Form: Powder For oral Suspension

5.2.2. Quality and Quantitative Composition:

Qualitative Declaration: Complies to USP Specifications

5.2.3 Pharmaceutical Form: White to off white granular powder converted into orange coloured suspension on addition of water and make volume 60 ml.

5.2.4Clinical Particulars:

1.1Therapeutic Indication:

Bekracine is an orally active cephalosporin antibiotic which has marked *in vitro* bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.
It is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms:

Upper Respiratory Tract Infections (URTI): e.g. otitis media; and other URTI where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk.

Lower Respiratory Tract Infection: e.g. bronchitis.

Urinary Tract Infections: e.g. cystitis, cystourethritis, uncomplicated pyelonephritis.
Clinical efficacy has been demonstrated in infections caused by commonly occuring pathogens including *Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Kliebsiella* species, *Haemophilus influenzae*(beta-lactamase positive and negative), *Branhamella catarrhalis* (beta-lactamase positive and negative) and *Enterobacter*species. Bekracine is highly stable in the presence of beta-lactamase enzymes.
Most strains of enterococci (*Streptococcus faecalis*, group D Streptococci) and Staphylococci (including coagulase positive and negative strains and meticillin-resistant strains) are resistant to Bekracine. In addition, most strains of *Pseudomonas, Bacteriodes fragalis, Listeria monocytogenes* and *Clostridia* are resistant to Bekracine.

1.2 Posology and method of administration

Absorption of Bekracine is not significantly modified by the presence of food. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

Children (Use Paediatric Oral Suspension): The recommended dosage for children is 8 mg/kg/day administered as a single dose or in two divided doses every 12 hours. As a general guide for prescribing in children the following daily doses in terms of volume of Paediatric Oral Suspension are suggested:

6 months up to 1 year: 3.75 ml daily

Children 1-4 years: 5 ml daily

Children 5-10 years: 10 ml daily

Children weighing more than 50 kg or older than 10 years should be treated with the recommended adult dose (200 - 400 mg daily depending on the severity of infection).

The safety and efficacy of cefixime has not been established in children less than 6 months.

In the treatment of infections due to *Streptococcus pyogenes*, a therapeutic dosage of cefixime should be administered for at least 10 days.

Dosage In Renal Impairment:

Bekracine may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Refer to Table for dose adjustments for adults with renal impairment. Neither hemodialysis nor peritoneal dialysisremoves significant amounts of drug from the body.

Table : Doses for Adults with Renal Impairment

RENAL DYSFUNCTION	**BEKRACINE (CEFIXIME) FOR ORAL SUSPENSION**		
CREATININE CLEARANCE (ML/MIN)	**100 MG/5 ML**	**200 MG/5 ML**	**500 MG/5 ML**
	DOSE/DAY (ML)	**DOSE/DAY (ML)**	**DOSE/DAY (ML)**
60 or greater	Normal dose	Normal dose	Normal dose
21 to 59 * OR renal hemodialysis*	13	6.5	2.6
20 or less OR continuous peritoneal dialysis	8.6	4.4	1.8
* The preferred concentrations of oral suspension to use are 200 mg/5 mL or 500 mg/5 mL for patients with this renal dysfunction			

Method of Administration
Cefixime powder for oral suspension USP is for administration only.

The adsorption of cefixime is not significantly affected by the presence of food. Hence it can be administered with or without food.

For Instruction on reconstitution of the medicinal product before administration.

Duration of Treatment
The usual course of treatment is 7 days. In severe cases, this can be extended to 14 days

1.3 Contraindications:
Patients with known hypersensitivity to Cefixime, other cephalosporin antibiotics or any of the other compo-nents of the product.

Cefixime is also contraindicated in patients with previous, immediate and severe hypersensitivity to Penicillin or any beta-lactum antibiotics and preterm and term newborn infants (0-27 days).

1.4 Special warning and precaution for use
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.
Bekracine should be given with caution to patients who have shown hypersensitivity to other drugs.

Hypersensitivity to penicillins

As with other cephalosporins, cefixime should be given with caution to patients with a history of hypersensitivity to penicillin, as there is some evidence of partial cross-allergenicity between the penicillins and cephalosporins.
Patients have had severe reactions (including anaphylaxis) to both classes of drugs. If an allergic effect occurs with Bekracin the drug should be discontinued and the patient treated with appropriate agents if necessary.

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.

Renal failure acute
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.

Renal impairment
Bekracine should be administered with caution in patients with markedly impaired renal function (See section 4.2 under Dosage in Renal Impairment).

Paediatric use
Safety of cefixime in premature or newborn infant has not been established.
Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of antibiotic-associated diarrhoea. Pseudomembranous colitis is associated with the use of broad-spectrum antibiotics (including macrolides, semi-synthetic penicillins, lincosamides and cephalosporins); it is therefore important to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment.
Management of pseudomembranous colitis should include sigmoidoscopy, appropriate bacteriologic studies, fluids, electrolytes and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be excluded.

1.5 Interaction with other medicinal products and other form of interactions

Anticoagulants

In common with other cephalosporins, increases in prothrombin times have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy.

Cefixime should be administered with caution to patients receiving coumarin-type anticoagulants, e.g. warfarin potassium. Since cefixime may enhance effects of the anticoagulants, prolonged prothrombin time with or without bleeding may occur.

Other forms of interaction

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 Coombs test has been reported during treatment with cephalosporin antibiotics, therefore it should be recognised that a positive Coombs test may be due to the drug.

1.6 Pregnancy and lactation:

Pregnancy
For Cefixime, no clinical data on exposed pregnancy are available. Animal Studies do not indicate direct or indirect harmful effect with respect to pregnancy, embryonal/foetal development, parturition or postnatal development

Caution should be exercised when prescribing to pregnant women. Cefixime should not be used in pregnant mothers unless considered essential by the physician.

Breast-feeding
It is unknown whether cefixime is excreted in human milk and non clinical studies have shown excretion of cefixime in animalmilk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with cefixime should be made taking into account the benefit of breast-feeding to the child and the benefit of cefixime therapy to the woman. However, until further clinical xperience is available, Cefixime should not be prescribed to breast-feeding mothers,

Fertility
Animal Studies do not indicate any harmful effect with respect to Fertility; however, no clinical data are available.

1.7 Effect on ability to drive and use machine:

Cefixime has no known influence on the ability to drive and use machine. However, side effect may occur (see section 1.8), which may influence the ability to drive and use machines.

1.8 Undesirable effects
Bekracine 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 Haemolytic anaemia Thrombocytopenia Thrombocytosis
Gastrointestinal:	Abdominal pain Diarrhoea* Dyspepsia Nausea Vomiting Flatulance

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
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 eaosinophilia 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.

Preferred term in MedDRA (v.14.0)
*Diarrhoea has been more commonly associated with higher doses. Some cases of moderate to severe diarrhoea have been reported; this has occasionally warranted cessation of therapy. Bekracine should be discontinued if marked diarrhoea occurs

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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BEKRACINE
CEFIXIME FOR ORAL SUSPENSION USP
Part – I: Administrative

1.9 Overdose

There is no experience with overdoses with Bekracine.
Adverse reactions seen at dose levels up to 2 g Bekracine in normal subjects did not differ from the profile seen in patients treated at the recommended doses. Cefixime is not removed from the circulation in significant quantities by dialysis.
No specific antidote exists. General supportive measures are recommended.

5.2.5 Pharmacological Properties

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

Mechanism of Action

Cefixime is a semisynthetic cephalosporin antibacterial drug [see**Microbiology**].

Microbiology

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.

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 microorganisms, both *in vitro* and in clinical infections [see **Indications and Usage**.]
Gram-positive Bacteria
Streptococcus pneumoniae
Streptococcus pyogenes
Gram-negative Bacteria

Escherichia coli
Haemophilus influenzae
Moraxella catarrhalis
Neisseria gonorrhoeae
Proteus mirabilis

The following *in vitro* data are available, but their clinical significance is unknown. At least 90 percent 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 due to 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

Susceptibility Test Methods

When available, the clinical microbiology laboratory should provide cumulative reports of *in vitro* susceptibility test results for antimicrobial drugs used in local hospitals and practice areas to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquiredpathogens. These reports should aid the physician in selecting an antibacterial drug for treatment.

Dilution Techniques
Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method[1,2] (broth and/or agar). The MIC values should be interpreted according to criteria provided in Table 3.

Diffusion Techniques

Quantitative methods that require measurement of zone diameters can also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized test method.[2,3] This procedure uses paper disks impregnated with 5 mcg cefixime to test the susceptibility of bacteria to cefixime. The disc diffusion breakpoints are provided in Table.

Table: Susceptibility Interpretive Criteria for Cefixime

PATHOGEN	MINIMUM INHIBITORY CONCENTRATIONS (MCG/ML)			DISK DIFFUSION ZONE DIAMETER (MM)		
	S	I	R	S	I	R
Enterobacteriaceae[1]	≤ 1	2	≥ 4	≥ 19	16 to 18	≤ 15
Haemophilus influenzae[2,3]	≤ 1	NA	NA	≥ 21	NA	NA
Neisseria gonorrhoeae[3,4]	≤ 0.25	NA	NA	≥ 31	NA	NA

[1]Do not test *Morganella* species by disk diffusion
[2]Test *Haemophilus influenzae* using Haemophilus Test Medium (HTM)
[3]The current absence of resistant isolates precludes defining any results other than "susceptible" Isolates yielding results other than susceptible should be subjected to additional testing.
[4]Test *Neisseria gonorrhoeae* using GC agar base and 1% defined growth supplement. Minimum inhibitory concentrations are determined using the agar dilution method.

A report of *Susceptible* (S) indicates that the antimicrobial drug is likely to inhibit growth of the pathogen if the antimicrobial drug reaches the concentration usually achievable at the site of infection. A report of*Intermediate* (I) indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where a high dosage of the drug can be used. This category also provides a buffer zone that prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of Resistant (R) indicates that the antimicrobial drug is not likely to inhibit growth of the pathogen if the antimicrobial drug reaches the concentration usually achievable at the infection site; other therapy should be selected.

Quality Control

Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of supplies and reagents used in the assay, and the techniques of the individuals performing the test.[1,2,3] Standard cefixime powder should provide the following range

of MIC values noted in Table. For the diffusion technique using the 5 mcg disk, the criteria in Table should be achieved.

Table: Acceptable Quality Control Ranges for Cefixime

QUALITY CONTROL ORGANISMS	MINIMUM INHIBITORY CONCENTRATIONS (MCG/ML)	DISK DIFFUSION ZONE DIAMETER (MM)
E.coli ATCC 25922	0.25 to 1	23 to 27
H. influenzae ATCC 49247	0.12 to 1	25 to 33
N.gonorrhoeae ATCC 49226	0.004 to 0.03	37 to 45
S. pneumoniae ATCC 49619	NA	16 to 23
S. aureus ATCC 29213	8 to 32	NA
ATCC = American Type Culture Collection		

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 paediatric doses are between 1.5 and 3 mcg/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 400 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 characterised 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 ^{14}C-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. Placetal transfer of cefixime was small in pregnant rats dosed with labelled cefixime.

Pharmacokinetics

cefixime chewable tablets are bioequivalent to oral suspension. cefixime tablets and suspension, given orally, are about 40% to 50% absorbed whether administered with or without food; however, time to maximal absorption is increased approximately 0.8 hours when administered with food. A single 200 mg tablet of cefixime produces an average peak serum concentration of approximately 2 mcg/mL (range 1 to 4 mcg/mL); a single 400 mg tablet produces an average peak concentration of approximately 3.7 mcg/mL (range 1.3 to 7.7 mcg/mL). The oral suspension produces average peak concentrations approximately 25% to 50% higher than the tablets, when tested in normal adult volunteers. Two hundred and 400 mg doses of oral suspension produce average peak concentrations of 3 mcg/mL (range 1 to 4.5 mcg/mL) and 4.6 mcg/mL (range 1.9 to 7.7 mcg/mL), respectively, when tested in normal adult volunteers. The area under the time versus concentration curve (AUC) is greater by approximately 10% to 25% with the oral suspension than with the tablet after doses of 100 to 400 mg, when tested in normal adult volunteers. This increased absorption should be taken into consideration if the oral suspension is to be substituted for the tablet. Because of the lack of bioequivalence, tablets should not be substituted for oral suspension in the treatment of otitis media [see **Dosage And Administration**]. Crossover studies of tablet versus suspension have not been performed in children.
The 400 mg capsule is bioequivalent to the 400 mg tablet under fasting conditions. However, food reduces the absorption following administration of the capsule by approximately 15% based on AUC and 25% based on Cmax.

Peak serum concentrations occur between 2 and 6 hours following oral administration of a single 200 mg tablet, a single 400 mg tablet or 400 mg of cefixime suspension. Peak serum concentrations occur between 2 and 5 hours following a single administration of 200 mg of suspension. Peak serum concentrations occur between 3 and 8 hours following oral administration of a single 400 mg capsule.

Distribution
Serum protein binding is concentration independent with a bound fraction of approximately 65%. In a multiple dose study conducted with a research formulation which is less bioavailable than the tablet or suspension, there was little accumulation of drug in serum or urine after dosing for 14 days. Adequate data on CSF levels of cefixime are not available.

Metabolism and Excretion
There is no evidence of metabolism of cefixime *in vivo*. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also

excreted in the bile in excess of 10% of the administered dose. The serum half-life of cefixime in healthy subjects is independent of dosage form and averages 3 to 4 hours but may range up to 9 hours in some normal volunteers.

Special Populations

***Geriatrics*:** Average AUCs at steady state in elderly patients are approximately 40% higher than average AUCs in other healthy adults. Differences in the pharmacokinetic parameters between 12 young and 12 elderly subjects who received 400 mg of cefixime once daily for 5 days are summarized as follows:

Pharmacokinetic Parameters (mean ± SD) for Cefixime in Both Young & Elderly Subjects

PHARMACOKINETIC PARAMETER	YOUNG	ELDERLY
Cmax (mg/L)	4.74 ± 1.43	5.68 ± 1.83
Tmax (h)*	3.9 ± 0.3	4.3 ± 0.6
AUC (mg.h/L)*	34.9 ± 12.2	49.5 ± 19.1
T½ (h)*	3.5 ± 0.6	4.2 ± 0.4
Cave (mg/L)*	1.42 ±0.50	1.99 ± 0.75
*Difference between age groups was significant. ($p < 0.05$)		

However, these increases were not clinically significant [see **Dosage and Administration**].

Renal Impairment: In subjects with moderate impairment of renal function (20 to 40 mL/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20 mL/min creatinine clearance), the half-life increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by hemodialysis orperitoneal dialysis. However, a study indicated that with doses of 400 mg, patients undergoing hemodialysis have similar blood profiles as subjects with creatinine clearances of 21 to 60 mL/min.

Preclinical safety data

Comparative clinical trials of otitis media were conducted in nearly 400 children between the ages of 6 months to 10 years. *Streptococcus pneumoniae* was isolated from 47% of the patients, *Haemophilus influenzae*from 34%, *Moraxella catarrhalis* from 15% and *S. pyogenes* from 4%.

The overall response rate of *Streptococcus pneumoniae* to cefixime was approximately 10% lower and that of *Haemophilus influenzae* or *Moraxella catarrhalis* approximately 7% higher (12% when beta-lactamase positive isolates of *H. influenzae* are included) than the response rates of these organisms to the active control drugs.

In these studies, patients were randomized and treated with either cefixime at dose regimens of 4 mg/kg twice a day or 8 mg/kg once a day, or with a comparator. Sixty-nine to 70% of the patients in each group had resolution of signs and symptoms of otitis media when evaluated 2 to 4 weeks post-

treatment, but persistent effusion was found in 15% of the patients. When evaluated at the completion of therapy, 17% of patients receiving cefixime and 14% of patients receiving effective comparative drugs (18% including those patients who had Haemophilus influenzae resistant to the control drug and who received the control antibiotic) were considered to be treatment failures. By the 2 to 4 week follow-up, a total of 30%-31% of patients had evidence of either treatment failure or recurrent disease.

Bacteriological Outcome of Otitis Media at Two to Four Weeks Post-Therapy Based on Repeat Middle Ear Fluid Culture or Extrapolation from Clinical Outcome

ORGANISM	CEFIXIME(A) 4 MG/KG BID	CEFIXIME(A) 8 MG/KG QD	CONTROL(A) DRUGS
Streptococcus pneumoniae	48/70 (69%)	18/22 (82%)	82/100 (82%)
Haemophilus influenzae beta-lactamase negative	24/34 (71%)	13/17 (76%)	23/34 (68%)
Haemophilus influenzae beta-lactamase positive	17/22 (77%)	9/12 (75%)	1/1 (b)
Moraxella catarrhalis	26/31 (84%)	5/5	18/24 (75%)
S. pyogenes	5/5	3/3	6/7
All Isolates	120/162 (74%)	48/59 (81%)	130/166 (78%)

[a] Number eradicated/number isolated.
[b] An additional 20 beta-lactamase positive isolates of Haemophilus influenzae were isolated, but were excluded from this analysis because they were resistant to the control antibiotic. In nineteen of these, the clinical course could be assessed and a favorable outcome occurred in 10. When these cases are included in the overall bacteriological evaluation of therapy with the control drugs, 140/185 (76%) of pathogens were considered to be eradicated.

6.0 Pharmaceutical Particulars

6.1 List of excipients

After Reconstitution Each 5 ml Contains:
Sucrose (pharma grade)
Sodium Methyl Hydroxy Benzoate (SMP)
Disodium Edetate
Sodium Benzoate
Colloidal Anhydrous Silica
Xanthan gum FNCS

Sunset yellow FCF
Sodium Carboxy Methyl Cellulose
Orange DC 100 Flavour

6.2 Incompatibilities
None

6.3 Shelf life
2 years

6.4 Special precautions for storage
Storage below 30°C in a dry place.

6.5 Nature and contents of container
60 ml HDPE bottle in a carton along with pack insert.

6.6 Special precautions for disposal and other handling
None

7.0 Marketing Authorization Holder

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8.0 Name and address of Manufacture
Baroque Pharmaceuticals Pvt. Ltd
192/2 & 3, Sokhada-388 620 Tal: Khambhat,
Dist. Anand Gujarat.
India.

9.0 Date of revision of the text

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