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

Annmer 500mg (Meropenem for injection USP 500mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Vial Contains:
Sterile Meropenem USP
Equivalent to anhydrous Meropenem…….500 mg
Sterile Sodium Carbonate USP
Equivalent to Sodium……. 45.1 mg
Supplied with an ampoule of 10ml sterile Water for injection BP

3. PHARMACEUTICAL FORM

Powder for injection

4. Clinical particulars

Therapeutic indications

Meropenem is indicated for the treatment of the following infections in adults and children over 3 months of age

- Severe pneumonia, including hospital and ventilator-associated pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections
- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
Meropenem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Posology and method of administration

Reconstitution and Dilution

For direct intermittent IV injection, 10 or 20 mL of sterile water for injection should be added to a vial labeled as containing 500 mg or 1000 mg, respectively, of Meropenem to provide a solution containing approximately 50 mg/mL. The vial should be shaken until dissolution occurs and then allowed to stand until the solution is clear. Reconstituted solutions should be used promptly.
For IV infusion, vials labeled as containing 500 mg or 1000 mg of Meropenem should be diluted in a compatible IV solution. Alternatively, vials labeled as containing 500 mg or 1000 mg may

be reconstituted as directed for direct intermittent IV injection and the resulting solution added to an IV container and further diluted with a compatible IV solution.

Dosage
Meropenem is commercially available as the Trihydrate; potency and dosage of the drug are expressed on the anhydrous basis. To minimize the risk of seizures, recommended Meropenem dosage should not be exceeded, especially in patients with factors known to predispose to seizure activity.

Adult Dosage
Intra-abdominal Infections: The usual adult dosage of Meropenem for the treatment of intra-abdominal infections is 1 g every 8 hours.
Meningitis: For the treatment of bacterial meningitis in adults, some clinicians recommend a dosage of 6 g daily. A dosage of 40 mg/kg every 8 hours daily (up to 6 g daily) has been used in conjunction with Ceftriaxone or Cefotaxime in adults with meningitis.
Respiratory Tract Infections: If Meropenem is used for the treatment of Nosocomial pneumonia (including hospital-acquired, ventilator-associated, or health-care-associated infections), some clinicians recommend that adults receive a dosage of 1 g every 8 hours.
Skin and Skin Structure Infections: The usual adult dosage of Meropenem for the treatment of complicated skin and skin structure infections is 500 mg every 8 hours.
Pediatric Dosage
Children weighing more than 50 kg should receive the usually recommended adult dosage of Meropenem.
Intra-abdominal Infections: For the treatment of intra-abdominal infections, children 3 months of age and older weighing 50 kg or less should receive 20 mg/kg (up to 1 g) every 8 hours.
Meningitis: For the treatment of meningitis, children 3 months of age and older weighing 50 kg or less should receive 40 mg/kg (up to 2 g) every 8 hours.
Skin and Skin Structure Infections: For the treatment of complicated skin and skin structure infections, children 3 months of age and older weighing 50 kg or less should receive 10 mg/kg (up to 500 mg) every 8 hours.

Geriatric Dosage
The manufacturer states that dosage adjustment is not necessary for geriatric patients with creatinine clearances exceeding 50 mL/minute. For geriatric patients with reduced renal function, dosage should be adjusted according to the guidelines for other adults with renal impairment.

Administration
Meropenem for injection USP is administered by IV injection or IV infusion.
Contraindications
Hypersensitivity to the active substance or to any of the excipients.

Hypersensitivity to any other carbapenem antibacterial agent.
Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins or cephalosporins).

Special warnings and precautions for use
The selection of meropenem to treat an individual patient should take into account the appropriateness of using a carbapenem antibacterial agent based on factors such as severity of the infection, the prevalence of resistance to other suitable antibacterial agents and the risk of selecting for carbapenem-resistant bacteria.
Enterobacteriaceae, Pseudomonas aeruginosa and Acinetobacter spp. resistance
Resistance to penems of Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter spp. varies across the European Union. Prescribers are advised to take into account the local prevalence of resistance in these bacteria to penems.

Hypersensitivity reactions
As with all beta-lactam antibiotics, serious and occasionally fatal hypersensitivity reactions have been reported.
Patients who have a history of hypersensitivity to carbapenems, penicillins or other beta-lactam antibiotics may also be hypersensitive to meropenem. Before initiating therapy with meropenem, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.
If a severe allergic reaction occurs, the medicinal product should be discontinued and appropriate measures taken.

Antibiotic-associated colitis
Antibiotic-associated colitis and pseudomembranous colitis have been reported with nearly all anti-bacterial agents, including meropenem, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of meropenem (see section 4.8). Discontinuation of therapy with meropenem and the administration of specific treatment for Clostridium difficile should be considered. Medicinal products that inhibit peristalsis should not be given.

Seizures
Seizures have infrequently been reported during treatment with carbapenems, including meropenem

Hepatic function monitoring
Hepatic function should be closely monitored during treatment with meropenem due to the risk of hepatic toxicity (hepatic dysfunction with cholestasis and cytolysis) (see section 4.8).
Use in patients with liver disease: patients with pre-existing liver disorders should have liver function monitored during treatment with meropenem.

Direct antiglobulin test (Coombs test) seroconversion
A positive direct or indirect Coombs test may develop during treatment with meropenem.
Concomitant use with valproic acid/sodium valproate/valpromide
The concomitant use of meropenem and valproic acid/sodium valproate/valpromide is not recommended

Paediatric population
Meronem is licensed for children over 3 months of age. There is no evidence of an increased risk of any adverse drug reaction in children based on the limited available data. All reports received were consistent with events observed in the adult population.

Interaction with other medicinal products and other forms of interaction
No specific medicinal product interaction studies other than probenecid were conducted. Probenecid competes with meropenem for active tubular secretion and thus inhibits the renal excretion of meropenem with the effect of increasing the elimination half-life and plasma concentration of meropenem. Caution is required if probenecid is co-administered with meropenem.
The potential effect of meropenem on the protein binding of other medicinal products or metabolism has not been studied. However, the protein binding is so low that no interactions with other compounds would be expected on the basis of this mechanism.
Decreases in blood levels of valproic acid have been reported when it is co-administered with carbapenem agents resulting in a 60-100 % decrease in valproic acid levels in about two days. Due to the rapid onset and the extent of the decrease, co-administration of valproic acid/sodium valproate/valpromide with carbapenem agents is not considered to be manageable and therefore should be avoided.

Oral anti-coagulants
Simultaneous administration of antibiotics with warfarin may augment its anti-coagulant effects. There have been many reports of increases in the anti-coagulant effects of orally administered anti-coagulant agents, including warfarin in patients who are concomitantly receiving antibacterial agents. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of the antibiotic to the increase in INR (international normalised ratio) is difficult to assess. It is recommended that the INR should be monitored

frequently during and shortly after co-administration of antibiotics with an oral anti-coagulant agent.

Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of meropenem in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity .

As a precautionary measure, it is preferable to avoid the use of meropenem during pregnancy.

Lactation

It is unknown whether meropenem is excreted in human milk. Meropenem is detectable at very low concentrations in animal breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from meropenem therapy taking into account the benefit of therapy for the woman.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. However, when driving or operating machines, it should be taken into account that headache, paraesthesiae and convulsions have been reported for meropenem.

Undesirable effects

Summary of the safety profile

In a review of 4,872 patients with 5,026 meropenem treatment exposures, meropenem-related adverse reactions most frequently reported were diarrhoea (2.3 %), rash (1.4 %), nausea/vomiting (1.4 %) and injection site inflammation (1.1 %). The most commonly reported meropenem-related laboratory adverse events were thrombocytosis (1.6 %) and increased hepatic enzymes (1.5-4.3 %).

Tabulated risk of adverse reactions

In the table below all adverse reactions are listed by system organ class and frequency: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (< 1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table 1		
System Organ Class	**Frequency**	**Event**
Infections and infestations	Uncommon	oral and vaginal candidiasis
Blood and lymphatic system disorders	Common	thrombocythaemia
	Uncommon	agranulocytosis, haemolytic anaemia, thrombocytopenia, neutropenia, leukopenia, eosinophilia
Immune system disorders	Uncommon	anaphylaxis , angioedema
Psychiatric disorders Nervous system disorders	Rare Common	delirium headache
	Uncommon	paraesthesia
	Rare	convulsions
Gastrointestinal disorders	Common	diarrhoea, abdominal pain, vomiting, nausea
	Uncommon	antibiotic-associated colitis
Hepatobiliary disorders	Common	transaminases increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased
	Uncommon	blood bilirubin increased
Skin and subcutaneous tissue disorders	Common	rash, pruritus
	Uncommon	toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme , urticaria
	Not known	drug reaction with eosinophilia and systemic symptoms, acute generalised exanthematous pustulosis.
Renal and urinary disorders	Uncommon	blood creatinine increased, blood urea increased
General disorders and administration site conditions	Common	inflammation, pain
	Uncommon	thrombophlebitis, pain at the injection site

Paediatric population
Meropenem is licensed for children over 3 months of age. There is no evidence of an increased risk of any adverse drug reaction in children based on the limited available data. All reports received were consistent with events observed in the adult population.

Overdose
Relative overdose may be possible in patients with renal impairment if the dose is not adjusted .Limited post-marketing experience indicates that if adverse reactions occur following overdose, they are consistent with the adverse reaction profile, are generally mild in severity and resolve on withdrawal or dose reduction.
Symptomatic treatments should be considered.
In individuals with normal renal function, rapid renal elimination will occur.
Haemodialysis will remove meropenem and its metabolite.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
Pharmacotherapeutic group: antibacterials for systemic use, carbapenems
ATC code: J01DH02

Mode of action
Meropenem exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram-positive and Gram-negative bacteria through binding to penicillin-binding proteins (PBPs).

Pharmacokinetic/Pharmacodynamic (PK/PD) relationship
Similar to other beta-lactam antibacterial agents, the time that meropenem concentrations exceed the MIC (T>MIC) has been shown to best correlate with efficacy. In preclinical models meropenem demonstrated activity when plasma concentrations exceeded the MIC of the infecting organisms for approximately 40 % of the dosing interval. This target has not been established clinically.

Mechanism of resistance
Bacterial resistance to meropenem may result from: (1) decreased permeability of the outer membrane of Gram-negative bacteria (due to diminished production of porins) (2) reduced affinity of the target PBPs (3) increased expression of efflux pump components, and (4) production of beta-lactamases that can hydrolyse carbapenems.
Localised clusters of infections due to carbapenem-resistant bacteria have been reported in the European Union.
There is no target-based cross-resistance between meropenem and agents of the quinolone, aminoglycoside, macrolide and tetracycline classes. However, bacteria may exhibit resistance to

more than one class of antibacterials agents when the mechanism involved include impermeability and/or an efflux pump(s).

Breakpoints
European Committee on Antimicrobial Susceptibility Testing (EUCAST) clinical breakpoints for MIC testing are presented below.

EUCAST clinical MIC breakpoints for meropenem (2013-02-11, v 3.1)

Organism	**Susceptible (S) (mg/l)**	**Resistant (R) (mg/l)**
Enterobacteriaceae	≤ 2	> 8
Pseudomonas spp.	≤ 2	> 8
Acinetobacter spp.	≤ 2	> 8
Streptococcus groups A, B, C and G	note 6	note 6
Streptococcus pneumoniae[1]	≤ 2	> 2
Viridans group streptococci[2]	≤ 2	> 2
Enterococcus spp.	--	--
Staphylococcus spp.	note 3	note 3
Haemophilus influenzae[1, 2] and Moraxella catarrhalis[2]	≤ 2	> 2
Neisseria meningitidis[2,4]	≤ 0.25	> 0.25
Gram-positive anaerobes except Clostridium difficile	≤ 2	> 8
Gram-negative anaerobes	≤ 2	> 8
Listeria monocytogenes	≤ 0.25	> 0.25
Non-species related breakpoints[5]	≤ 2	> 8	Non-species related breakpoints[5]

[1]Meropenem breakpoints for Streptococcus pneumoniae and Haemophilus influenzae in meningitis are 0.25 mg/l (Susceptible) and 1 mg/l (Resistant)
Isolates with MIC values above the susceptible breakpoint are very rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the result is confirmed the isolate sent to a reference laboratory. Until there is evidence regarding clinical response for confirmed isolates with MIC values above the current resistant breakpoint they should be reported resistant.
[2] Susceptibility of staphylococci to carbapenems is inferred from the cefoxitin susceptibility.

[3] Breakpoints relate to meningitis only.
[4] Non-species related breakpoints have been determined using PK/PD data and are independent of MIC distributions of specific species. They are for use only for organisms that do not have specific breakpoints. Non species related breakpoints are based on the following dosages: EUCAST breakpoints apply to meropenem 1000 mg x 3 daily administered intravenously over 30 minutes as the lowest dose. 2 g x 3 daily was taken into consideration for severe infections and in setting the I/R breakpoint.
6 The beta-lactam susceptibility of streptococcus groups A, B, C and G is inferred from the penicillin susceptibility.
-- = Susceptibility testing not recommended as the species is a poor target for therapy with the drug. Isolates may be reported as R without prior testing.
The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.
The following table of pathogens listed is derived from clinical experience and therapeutic guidelines.

Commonly susceptible species
Gram-positive aerobes
Enterococcus faecalis[$]
Staphylococcus aureus (methicillin-susceptible)[£]
Staphylococcus species (methicillin-susceptible) including Staphylococcus epidermidis Streptococcus agalactiae (Group B)
Streptococcus milleri group (S. anginosus, S. constellatus, and S. intermedius)
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Gram-negative aerobes
Citrobacter freudii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Morganella morganii
Neisseria meningitides
Proteus mirabilis
Proteus vulgaris

Serratia marcescens
Gram-positive anaerobes
Clostridium perfringens
Peptoniphilus asaccharolyticus
Peptostreptococcus species (including P. micros, P anaerobius, P. magnus)
Gram-negative anaerobes
Bacteroides caccae
Bacteroides fragilis group
Prevotella bivia
Prevotella disiens

Species for which acquired resistance may be a problem
Gram-positive aerobes
Enterococcus faecium[$†]
Gram-negative aerobes
Acinetobacter species
Burkholderia cepacia
Pseudomonas aeruginosa

Inherently resistant organisms
Gram-negative aerobes
Stenotrophomonas maltophilia
Legionella species

Other micro-organisms
Chlamydophila pneumoniae
Chlamydophila psittaci
Coxiella burnetii
Mycoplasma pneumoniae
[$] Species that show natural intermediate susceptibility
[£] All methicillin-resistant staphylococci are resistant to meropenem
[†] Resistance rate ≥ 50% in one or more EU countries.
Glanders and melioidosis: Use of meropenem in humans is based on in vitro B.mallei and B. pseudomallei susceptibility data and on limited human data. Treating physicians should refer to national and/or international consensus documents regarding the treatment of glanders and melioidosis.

5.2 Pharmacokinetic properties
In healthy subjects the mean plasma half-life is approximately 1 hour; the mean volume of distribution is approximately 0.25 l/kg (11-27 l) and the mean clearance is 287 ml/min at 250 mg

falling to 205 ml/min at 2 g. Doses of 500, 1000 and 2000 mg doses infused over 30 minutes give mean Cmax values of approximately 23, 49 and 115 µg/ml respectively, corresponding AUC values were 39.3, 62.3 and 153 µg.h/ml. After infusion over 5 minutes Cmax values are 52 and 112 µg/ml after 500 and 1000 mg doses respectively. When multiple doses are administered 8-hourly to subjects with normal renal function, accumulation of meropenem does not occur.

A study of 12 patients administered meropenem 1000 mg 8 hourly post-surgically for intra-abdominal infections showed a comparable Cmax and half-life to normal subjects but a greater volume of distribution 27 l.

Distribution
The average plasma protein binding of meropenem was approximately 2 % and was independent of concentration. After rapid administration (5 minutes or less) the pharmacokinetics are biexponential but this is much less evident after 30 minutes infusion. Meropenem has been shown to penetrate well into several body fluids and tissues: including lung, bronchial secretions, bile, cerebrospinal fluid, gynaecological tissues, skin, fascia, muscle, and peritoneal exudates.

Metabolism
Meropenem is metabolised by hydrolysis of the beta-lactam ring generating a microbiologically inactive metabolite. In vitro meropenem shows reduced susceptibility to hydrolysis by human dehydropeptidase-I (DHP-I) compared to imipenem and there is no requirement to co-administer DHP-I inhibitor.

Elimination
Meropenem is primarily excreted unchanged by the kidneys; approximately 70 % (50 –75 %) of the dose is excreted unchanged within 12 hours. A further 28% is recovered as the microbiologically inactive metabolite. Faecal elimination represents only approximately 2% of the dose. The measured renal clearance and the effect of probenecid show that meropenem undergoes both filtration and tubular secretion.

Renal insufficiency
Renal impairment results in higher plasma AUC and longer half-life for meropenem. There were AUC increases of 2.4 fold in patients with moderate impairment (CrCL 33-74 ml/min), 5 fold in severe impairment (CrCL 4-23 ml/min) and 10 fold in haemodialysis patients (CrCL <2 ml/min) when compared to healthy subjects (CrCL >80 ml/min). The AUC of the microbiologically inactive ring opened metabolite was also considerably increased in patients with renal impairment. Dose adjustment is recommended for patients with moderate and severe renal impairment.
Meropenem is cleared by haemodialysis with clearance during haemodialysis being approximately 4 times higher than in anuric patients.

Hepatic insufficiency
A study in patients with alcoholic cirrhosis shows no effect of liver disease on the pharmacokinetics of meropenem after repeated doses.

Adult patients
Pharmacokinetic studies performed in patients have not shown significant pharmacokinetic differences versus healthy subjects with equivalent renal function. A population model developed from data in 79 patients with intra-abdominal infection or pneumonia, showed a dependence of the central volume on weight and the clearance on creatinine clearance and age.

Paediatrics
The pharmacokinetics in infants and children with infection at doses of 10, 20 and 40 mg/kg showed Cmax values approximating to those in adults following 500, 1000 and 2000 mg doses, respectively. Comparison showed consistent pharmacokinetics between the doses and half-lives similar to those observed in adults in all but the youngest subjects (<6 months t1/2 1.6 hours). The mean meropenem clearance values were 5.8 ml/min/kg (6-12 years), 6.2 ml/min/kg (2-5 years), 5.3 ml/min/kg (6-23 months) and 4.3 ml/min/kg (2-5 months). Approximately 60 % of the dose is excreted in urine over 12 hours as meropenem with a further 12 % as metabolite. Meropenem concentrations in the CSF of children with meningitis are approximately 20 % of concurrent plasma levels although there is significant inter-individual variability.

The pharmacokinetics of meropenem in neonates requiring anti-infective treatment showed greater clearance in neonates with higher chronological or gestational age with an overall average half-life of 2.9 hours. Monte Carlo simulation based on a population PK model showed that a dose regimen of 20 mg/kg 8 hourly achieved 60 %T>MIC for P. aeruginosa in 95 % of pre-term and 91 % of full term neonates.

Elderly
Pharmacokinetic studies in healthy elderly subjects (65-80 years) have shown a reduction in plasma clearance, which correlated with age-associated reduction in creatinine clearance, and a smaller reduction in non-renal clearance. No dose adjustment is required in elderly patients, except in cases of moderate to severe renal impairment .

5.3 Preclinical safety data
Animal studies indicate that meropenem is well tolerated by the kidney. Histological evidence of renal tubular damage was seen in mice and dogs only at doses of 2000 mg/kg and above after a single administration and above and in monkeys at 500 mg/kg in a 7-day study.
Meropenem is generally well tolerated by the central nervous system. Effects were seen in acute toxicity studies in rodent at doses exceeding 1000 mg/kg.

The IV LD_{50} of meropenem in rodents is greater that 2000 mg/kg.
In repeat ose studies of up to 6 months duration only minor effects were seen including a decrease in red cell parameters in dogs.
Thee was no evidence of mutagenic potential in a conventional test battery and no evidence of reproductive toxicity including teratogenic potential in studies in rats up to 750 mg/kg and in monkeys up to 360 mg/kg.
Thee was no evidence of increased sensitivity to meropenem in juveniles compared to adult animals. The intravenous formulation was well tolerated in animal studies.
The sole metabolite of meropenem had a similar profile of toxicity in animal studies.

6. PHARMACEUTICAL PARTICULARS

List of excipients
No excipients are used in the formulation of Annmer 500mg (Meropenem for injection USP 500mg).

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2years

After reconstitution:
Freshly prepared solutions of Meropenem for injection USP 500mg should be used. However, re-constituted solutions of Meropenem for injection USP 500mg maintain satisfactory potency under the conditions described below. Solutions of intravenous Meropenem for injection USP 500mg should not be frozen.
Intravenous Bolus Administration
Meropenem for injection USP 500mg vials re-constituted with sterile Water for Injection for bolus administration (up to 50 mg/mL of Meropenem for injection USP 500mg may be stored for up to 3 hours at up to 25°C (77°F) or for 13 hours at up to 5°C (41°F).
Intravenous Infusion Administration
Solutions prepared for infusion (Meropenem for injection USP 500mg concentrations ranging from 1 mg/mL to 20 mg/mL) re-constituted with Sodium Chloride Injection 0.9% may be stored for 1 hour at up to 25°C (77°F) or 15 hours at up to 5°C (41°F).
Solutions prepared for infusion (Meropenem for injection USP 500mg concentrations ranging from 1 mg/mL to 20 mg/mL) re-constituted with Dextrose Injection 5% should be used immediately.

6.4 Special precautions for storage
Store below 30°C. Protect from light.
Keep all medicines out of the reach of the children.

6.5 Nature and contents of container
ANNMER 500mg (Meropenem for Injection USP 500mg) is filled in 20 ml USP Type I clear glass vial, sealed with bromo butyl rubber stopper and red coloured flip off seal.

6.6 Special precautions for disposal and other handling
Each vial is for single use only.
Standard aseptic techniques should be used for solution preparation and administration.
The solution should be shaken before use.
Any unused product or waste material should be disposed of in accordance with local requirements.

7.Applicant/manufacturer
Name of the manufacturer:
YELURI FORMULATIONS PVT LTD
Sy.No.296/7/6, IDA Bollaram,
Sangareddy District-502 325,
Telangana, India.