1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Ampicillin 250 mg Capsule BP

BRAND NAME: VITACILLIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRODUCT NAME: Ampicillin 250 mg Capsule

Each capsule contains:
Ampicillin Trihydrate BP
Equivalent to Ampicillin…….. 250 mg

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Oral Dosage Hard Gelatin Capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Ampicillin is a broad-spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin-sensitive organisms. Typical indications include: ear, nose and throat infections, bronchitis, pneumonia, urinary tract infections, gonorrhoea, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis, enteric fever, gastro-intestinal infections.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration:

Usual adult dosage (including elderly patients):

Ear, nose and throat infections:	250mg four times a day.
Bronchitis:	Routine therapy: 250mg four times a day. High-dosage therapy: 1 g four times a day.
Pneumonia:	500 mg four times a day.
Urinary tract infections:	500 mg three times a day.
Gonorrhoea:	2 g orally with 1 g probenecid as a single dose. Repeated doses are recommended for the treatment of females.
Gastro-intestinal infections:	500-750 mg three to four times daily.

Enteric:	*Acute:* 1-2 g four times a day for two weeks.
	Carriers: 1-2 g four times a day for four to twelve weeks

Usual children's dosage (under 10 years):

Half adult routine dosage.

All recommended dosages are a guide only. In severe infections the above dosages may be increased, or ampicillin given by injection. Oral doses of ampicillin should be taken half to one hour before meals.

Renal Impairment:

In the presence of severe renal impairment (creatinine clearance <10ml/min) a reduction in dose or extension of dose interval should be considered. In cases of dialysis, an additional dose should be administered after the procedure.

All Patients, Irrespective of Age and Weight

Larger doses may be required for severe or chronic infections. Although ampicillin is resistant to degradation by gastric acid, it should be administered at least one half-hour before or two hours after meals for maximal absorption. Except for the single dose regimen for gonorrhea referred to above, therapy should be continued for a minimum of 48 to 72 hours after the patient becomes asymptomatic or evidence at bacterial eradication has been obtained. In infections caused by hemolytic strains of streptococci, a minimum of 10 days treatment is recommended to guard against the risk of rheumatic fever of glomerulonephritis. In the treatment of chronic urinary or gastrointestinal infections, frequent bacteriologic and clinical appraisal is necessary during therapy and may be necessary for several months afterwards. Stubborn infections may require treatment for several weeks. Smaller doses than those indicated above should not be used.

4.3 Contraindications:

Ampicillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalosporins) or excipients. Ampicillin is also contraindicated in infections caused by penicillinase-producing organisms.

4.4 Special warning and precautions for use

Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.

Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy instituted. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin

are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

Dosage should be adjusted in patients with renal impairment (see section 4.2).

4.5 Drug Interactions

When administered concurrently, the following drugs may interact with ampicillin.

***Bacteriostatic* Antibiotics:** Chloramphenicol, erythromycins, sulfonamides, or tetracyclines may interfere with the bactericidal effect of ampicillin. This has been demonstrated in view, however, the clinical significance of this interaction is not well documented.

Oral Contraceptives: May be less effective and increased breakthrough bleeding may occur. In common with other oral broad-spectrum antibiotics, ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Probenecid: May decrease the renal tubular secretion of ampicillin. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin or ampicillin toxicity.

Allopurinol: Concurrent administration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions.

It is recommended that when testing for the presence of glucose in urine during ampicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of ampicillin, false positive readings are common with chemical methods.

4.6 Pregnancy &Lactation

Pregnancy:

Animal studies with Ampicillin have shown no teratogenic effects. The product has been in extensive clinical use since 1961 and its use in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Ampicillin may be considered appropriate.

Lactation:

During lactation, trace quantities of penicillins can be detected in breast milk. Ampicillin-class antibiotics are excreted in milk. Ampicillin used by nursing mothers may lead to sensitization of infants; therefore, a decision should be made whether to discontinue nursing or to discontinue ampicillin, taking into account the importance of the drug to the mother.

Adequate human and animal data on use of Ampicillin during lactation are not available.

4.7 Effects on ability to drive and use machines:

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Adverse Effects

Hypersensitivity reactions:

If any hypersensitivity reaction occurs, the treatment should be discontinued.

Skin rash, pruritis and urticaria have been reported occasionally. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported.

As with other antibiotics, anaphylaxis (see Item 4.4 – Warnings) has been reported rarely.

Renal effects:

Interstitial nephritis can occur rarely.

Gastrointestinal reactions:

Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis and haemorrhagic colitis have been reported rarely.

Hepatic effects:

As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely. As with most other antibiotics, a moderate and transient increase in transaminases has been reported.

Haematological effects:

As with other beta-lactams, haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia have been reported rarely.

Prolongation of bleeding time and prothrombin has also been reported rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures as required. In patients with renal function impairment, ampicillin-class antibiotics can be removed by hemodialysis but not by peritoneal dialysis. Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

Ampicillin may be removed from the circulation by haemodialysis.

5.0 PHARMACOLOGICAL PROPERTIES:

5. 1 Pharmacodynamics properties

Ampicillin is a broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms. Ampicillin is bactericidal at low concentrations and is clinically effective not only against the gram-positive organisms usually susceptible to penicillin G but also against a variety of gram-negative organisms. It is stable in the presence of gastric acid and is well absorbed from the gastrointestinal

tract. It diffuses readily into most body tissues and fluids; however, penetration into the cerebrospinal fluid and brain occurs only with meningeal inflammation. Ampicillin is excreted largely unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid which inhibits the renal tubular secretion of ampicillin. In blood serum, ampicillin is the least bound of all the penicillins; an average of about 20 percent of the drug is bound to plasma proteins as compared to 60 to 90 percent of the other penicillins. The administration of 500 mg dose of ampicillin capsules results in an average peak blood serum level of approximately 3.0 mcg/mL;

Paediatric population: Penicillins are excreted primarily unchanged by the kidney, therefore, the incompletely developed renal functioning neonates and young infants will delay the excretion of penicillin. Administration to neonates and young infants should be limited to the lowest dosage compatible with an effective therapeutic regimen

5.2 Pharmacokinetic properties

Ampicillin is excreted mainly in the bile and urine with a plasma half-life of 1-2 hours.

5.3 Preclinical Safety Data

No further information of relevance to add.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ampicillin 250 mg Capsule

List of Excipients:

Magnesium stearate
Sodium Lauryl Sulphate
Colloidal anhydrous silica

6.2 Incompatibilities

Not available

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Store in a cool dry place below 30°C. Protect from light.

Keep all medicine away from reach of children.

6.5 Nature and contents of container

10 blisters of 10 capsules are packed in a printed carton.

6.6 Special precautions for disposal and other handling

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

7. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Commercial district B block,
Plot 6, New Makun City,
Along Lagos/Ibadan Expressway,
Klm 53/55 Sagamu, Ogun state.
NIGERIA.

8. WHO PREQUALIFICATION REFERENCE NUMBER
Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION
Not applicable

10. DATE OF REVISION OF THE TEXT
Not applicable