

Neisseria gonorrhoeae ATCC 49226		
Tetracycline	30-42	0.25-1
Staphylococcus aureus ATCC 25923		
Minocycline	25-30	--
Tetracycline	24-30	--
Staphylococcus aureus ATCC 29213		
Minocycline	0.06-0.5	--
Tetracycline	0.12-1	--
Streptococcus pneumoniae ATCC 49619		
Tetracycline	0.06-0.5	27-31

5.3 Pharmacokinetic Properties

Following a single dose of minocycline 200 mg administered intravenously to 10 healthy male subjects, serum concentrations of minocycline ranged from 2.52 to 6.61 mcg/mL (average 4.18 mcg/mL) at the end of infusion and 0.82 to 2.64 mcg/mL (average 1.38 mcg/mL) after 12 hours. In a group of 5 healthy male subjects, serum concentrations of minocycline ranged from 1.4 to 6 mcg/mL at the end of the dosing interval following administration of minocycline 100 mg every 12 hours for three days. When minocycline 200 mg once daily was administered for three days, serum concentrations of minocycline were approximately 1 mcg/mL at 24 hours. The serum elimination half-life of minocycline following administration of either minocycline 100 mg every 12 hours or 200 mg once daily was not significantly different and ranged from 15 to 23 hours.

The serum elimination half-life of minocycline ranged from 11 to 16 hours in subjects with hepatic impairment (n=7) and 18 to 69 hours in subjects with renal impairment (n=5). In comparison, the serum elimination half-life of minocycline ranged from 11 to 17 hours following a single dose of oral minocycline 200 mg in healthy subjects (n=12).

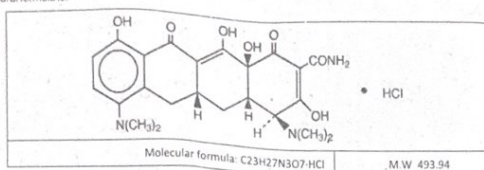
6. Non-clinical Properties

6.1 Animal Toxicology or Pharmacology

Minocycline hydrochloride has been observed to cause a dark discoloration of the thyroid in experimental animals (rats, minipigs, dogs, and monkeys). In the rat chronic treatment with minocycline hydrochloride has resulted in goiter accompanied by elevated radioactive iodine uptake and evidence of thyroid tumor production. Minocycline hydrochloride has also been found to produce thyroid hyperplasia in rats and dogs.

7. Description

Minocycline for Injection, is a sterile formulation of a semisynthetic derivative of tetracycline. The chemical name of minocycline is 4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2,13-dihydro-1,4-benzoxazine-6-carboxamide monohydrochloride.



8. Pharmaceutical Particulars

8.1 Incompatibilities

The medicinal product must not be mixed with other medicinal products.

8.2 Shelf-Life: Refer Pack.

8.3 Package Information: 10 mL USP Type-I vial packed in a carton along with leaflet

8.4 Storage and Handling Instructions: Store Below 25°C. Protect from light. Keep out of reach of children.

9. Patient Counselling Information

NA

10. Details of Manufacturer

Gulf Biosciences Limited

11. Details of Permission or License number with date: G/28/54 1st JAN.2022
G/28/1499 28th JUN.2021

Marketed by:



Questus Pharma Private Limited

Plot No.25-HIG, Survey No.912P, 913P, 941P, 944P, 945 to 962 and 964P, First floor, Phase XV, KPHB Colony, Kukatpally, Medchal-Malkajgiri District, Telangana State, India.
TM - Trade Mark Applied

Manufactured by:
Gulf Biosciences Limited
Unit No. 1, Mfg. Lic. No.: G/28/54
N. H. No. 8, Near Grid, Kabilipore-396424,
Navsari, Gujarat (INDIA)
Unit No. 2, Mfg. Lic. No.: G/28/1499
Survey No. 171, N. H. No. 8, Near grid,
Kabilipore-396424, Navsari, Gujarat, (INDIA).

Minocycline for Injection USP 100 mg

SUCIMIN™

LYOPHILIZED
I.V. USE ONLY

2. Composition:

Each vial contains
Minocycline Hydrochloride U.S.P. equivalent to
Minocycline 100 mg

3. Dosage Form and Strength

Each lyophilized vial contains minocycline hydrochloride U.S.P. 100 mg for reconstitution for solution for infusion.

4. Clinical Particulars

4.1 Therapeutic Indications

Indicated in the treatment of UTI, respiratory, skin & soft tissue, ENT infections, rickettsial, pneumonia, gonorrhea, uncomplicated urethral, endoservicitor rectal infections, STD, anaerobic infections meningitis.

4.2 Posology and Method of Administration

THE USUAL DOSAGE AND FREQUENCY OF ADMINISTRATION OF MINOCYCLINE DIFFERS FROM THAT OF THE OTHER TETRACYCLINES. EXCEEDING THE RECOMMENDED DOSAGE MAY RESULT IN AN INCREASED INCIDENCE OF SIDE EFFECTS.

Note: Rapid administration is to be avoided. Parenteral therapy is indicated only when oral therapy is not adequate or tolerated. Oral therapy should be instituted as soon as possible. If intravenous therapy is given over prolonged periods of time, thrombophlebitis may result.

For Pediatric Patients above 8 years of Age

Usual pediatric dose: Initial dose of 4 mg/kg, then 2 mg/kg administered over 60 minutes every 12 hours, not to exceed the usual adult dose.

Adults

Usual adult dose: Initial dose of 200 mg, then 100 mg administered over 60 minutes every 12 hours and should not exceed 400 mg in 24 hours.

The lyophilized vial should be reconstituted with 5 mL Sterile Water for Injection IP and immediately further diluted in 100 mL to 1,000 mL with Sodium Chloride Injection IP, Dextrose Injection IP, or Dextrose and Sodium Chloride Injection IP, or in form especially in neutral and alkaline solutions.

When diluted in compatible solutions, the pH usually ranges from 4.5 to 6.0.

Once diluted into an intravenous bag, minocycline for injection may be stored either at room temperature for up to 4 hours or refrigerated at 2 to 8°C (36 to 46°F) for up to 24 hours. Any unused portions must be discarded after that period.

The pharmacokinetics of minocycline in patients with renal impairment (CLCR < 80 mL/min) have not been fully characterized. Current data are insufficient to determine if a dosage adjustment is warranted. The total daily dosage should not exceed 200 mg in 24 hours in patients with renal impairment. However, due to the anti-anabolic effect of tetracyclines, serum levels of magnesium should be monitored in patients with renal impairment.

4.3 Contraindications

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or to any of the components of the product formulation.

4.4 Special warnings and precautions for use

WARNINGS

Tooth Development

Minocycline, like other tetracycline-class antibacterials, can cause fetal harm when administered to a pregnant woman. If any tetracycline is used during pregnancy, or if the patient becomes pregnant while taking these drugs, the patient should be apprised of the potential hazard to the fetus. The use of drugs of the tetracycline class during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).

This adverse reaction is more common during long-term use of the drugs but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.

Skeletal Development

All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in the fetal growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every six hours. This reaction was shown to be reversible when the drug was discontinued.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has been noted in animals treated early in pregnancy.

Dermatologic Reaction

Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) including fatal cases have been reported with minocycline use. If this syndrome is recognized, the drug should be discontinued immediately.

Anti-anabolic Action

The anti-anabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis. Under such conditions, monitoring of creatinine and BUN is recommended, and the total daily dosage should not exceed 200 mg in 24 hours. If renal impairment exists, even usual oral or parenteral doses may lead to systemic accumulation of the drug and possible liver toxicity.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. This has been reported with minocycline.

Central Nervous System Effects

Central nervous system side effects including light-headedness, dizziness or vertigo have been reported. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery while on minocycline therapy. These symptoms may disappear during therapy and usually disappear rapidly when the drug is discontinued.

Clostridium difficile Associated Diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including minocycline, and may range in severity from mild diarrhea 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 strains 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 diarrhea following antibacterial use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

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

Intracranial Hypertension

Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines including Minocycline. Clinical manifestations of IH include headache, blurred vision, diplopia, and vision loss; papilledema can be found on fundoscopy. Women of childbearing age who are overweight or have a history of IH are at greater risk for developing tetracycline associated IH. Concomitant use of isotretinoin and Minocycline should be avoided because isotretinoin is also known to cause pseudotumor cerebri.

Although IH typically resolves after discontinuation of treatment, the possibility for permanent visual loss exists. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Since intracranial pressure can remain elevated for weeks after drug cessation patients should be monitored until they stabilize.

PRECAUTIONS

General

As with other antibacterial preparations; use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, the antibacterial should be discontinued and appropriate therapy instituted.

Hepatotoxicity has been reported with minocycline; therefore, minocycline should be used with caution in patients with hepatic dysfunction and in conjunction with other hepatotoxic drugs.

Incision and drainage or other surgical procedures should be performed in conjunction with antibacterial therapy when indicated.

Minocycline for Injection contains magnesium sulfate heptahydrate. Because magnesium is excreted primarily by the kidney, serum levels of magnesium should be monitored in patients with renal impairment.

Because minocycline for Injection contains magnesium, close monitoring is recommended in patients with heart block or myocardial damage.

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

Information for Patients

Patients should be counseled that antibacterial drugs including minocycline for Injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When minocycline for Injection is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by minocycline for Injection or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibacterials which usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterial drugs, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibacterial. If this

occurs, patients should contact their physician as soon as possible.

4.5 Interaction with other medicinal products and other forms of interaction

Because tetracyclines have been shown to decrease plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracyclines in conjunction with penicillin.

The concurrent use of tetracyclines and methoxyflurane has been reported to result in fatal renal toxicity.

Concurrent use of tetracyclines with oral contraceptives may render oral contraceptives less effective.

Administration of neostigmine should be avoided shortly before, during, and shortly after minocycline therapy. Each drug alone has been associated with pseudotumor cerebri.

Increased risk of epiglottitis when ergot alkaloids or their derivatives are given with tetracyclines.

Minocycline for injection contains magnesium sulfate heptahydrate. Potentially serious drug interactions may occur when intravenous magnesium sulfate heptahydrate is given concomitantly with CNS depressants, neuromuscular blocking agents and cardiac glycosides.

Drug/Laboratory Test Interactions

False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test.

4.6 Special Populations

Carcinogenesis, Mutagenesis, Impairment of Fertility

Dietary administration of minocycline in long-term tumorigenicity studies in rats resulted in evidence of thyroid tumor production. Minocycline has also been found to produce thyroid hyperplasia in rats and dogs. In addition, there has been evidence of oncogenic activity in rats in studies with a related antibacterial, oxytetracycline (i.e., adrenal and pituitary tumors). Likewise, although mutagenicity studies of minocycline have not been conducted, positive results in *in vitro* mammalian cell assays (i.e., mouse lymphoma and Chinese hamster lung cells) have been reported for related antibiotics (tetracycline hydrochloride and oxytetracycline). Segment 1 (fertility and general reproduction) studies have provided evidence that minocycline impairs fertility in male rats.

Pregnancy

Teratogenic Effects
All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of drug exposure. There are no adequate and well-controlled studies on the use of minocycline in pregnant women. Minocycline, like other tetracycline-class antibiotics, crosses the placenta and may cause fetal harm when administered to a pregnant woman. Rare spontaneous reports of congenital anomalies, including limb reduction have been reported in post-marketing experience. Only limited information is available regarding these reports; therefore, no conclusion on causal association can be established. If minocycline is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Nonteratogenic Effects

Labor and Delivery

The effect of tetracyclines on labor and delivery is unknown.

Nursing Mothers

Tetracyclines are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from tetracyclines, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Minocycline is not recommended for use in children below 8 years of age unless the expected benefits of therapy outweigh the risks.

Geriatric Use

Clinical studies of intravenous minocycline did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

4.7 Effects on ability to drive and use machines

Dizziness, vertigo, headache, light-headedness, visual disturbances, tinnitus and impaired hearing (rarely) have occurred following administration of Minocycline. Patients should be warned of these effects and the possible hazard of driving or operating machinery, if affected.

4.8 Undesirable Effects

The following adverse reactions have been observed in patients receiving tetracyclines.

Body as a whole: Fever, and discoloration of secretions.

Gastrointestinal: Anorexia, nausea, vomiting, diarrhea, dyspepsia, stomatitis, glossitis, dysphagia, enamel hypoplasia, enterocolitis, pseudomembranous colitis, pancreatitis, inflammatory lesions (with monilial overgrowth) in the oral and anogenital regions. These reactions have been caused by both the oral and parenteral administration of tetracyclines.

Genitourinary: Vulvovaginitis.

Hepatic toxicity: Hyperbilirubinemia, hepatic cholestasis, increases in liver enzymes, fatal hepatic failure, and jaundice. Hepatitis, including autoimmune hepatitis, and liver failure have been reported.

Skin: Alopecia, erythema, nodosum, hyperpigmentation of nails, pruritus, toxic epidermal necrolysis, and vasculitis, maculopapular and erythematous rashes. Erythematous dermatitis has been reported. Fixed drug eruptions have been reported. Lesions occurring on the glans penis have caused balanitis. Erythema multiforme and Stevens-Johnson syndrome have been reported. Photosensitivity is discussed above. Pigmentation of the skin and mucous membranes has been reported.

Local Reactions: Injection site erythema and injection site pain.

Respiratory: Cough, dyspnea, bronchospasm, exacerbation of asthma, and pneumonitis.

Renal toxicity: Interstitial nephritis. Elevations in BUN have been reported and are apparently dose related. Acute renal failure has been reported.

Musculoskeletal: Arthralgia, arthritis, bone discoloration, myalgia, joint stiffness, and joint swelling.

Hypersensitivity reactions: Urticaria, angioneurotic edema, polyarthralgia, anaphylaxis/anaphylactoid reaction (including shock and fatalities), anaphylactoid purpura, myocarditis, pericarditis, exacerbation of systemic lupus erythematosus, and pulmonary infiltrates with eosinophilia have been reported. A lupus-like syndrome and serum sickness-like reactions also have been reported.

Blood: Agranulocytosis, hemolytic anemia, thrombocytopenia, leukopenia, neutropenia, pancytopenia, and eosinophilia have been reported.

Central Nervous System: Convulsions, dizziness, hyposthesia, paresthesia, sedation, and vertigo. Pseudotumor cerebri (benign intracranial hypertension) in adults and bulging fontanelles in infants. Headache has also been reported.

Other: Thyroid cancer has been reported in the post-marketing setting in association with minocycline products. When minocycline therapy is given over prolonged periods, monitoring for signs of thyroid cancer should be considered. When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of the thyroid gland. Cases of abnormal thyroid function have been reported.

Tooth discoloration in pediatric patients less than 8 years of age and in adults has been reported.

Oral cavity discoloration (including tongue, lip, and gum) have been reported.

Tinnitus and decreased hearing have been reported in patients on minocycline for injection.

The following syndromes have been reported. In some cases involving these syndromes, death has been reported. As with other serious adverse reactions, if any of these syndromes are recognized, the drug should be discontinued immediately:

Hypersensitivity syndrome consisting of cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, and one or more of the following: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis. Fever and lymphadenopathy may be present.

Lupus-like syndrome consisting of positive antinuclear antibody, arthralgia, arthritis, joint stiffness, or joint swelling; and one or more of the following: fever, myalgia, hepatitis, rash, and vasculitis.

Serum sickness-like syndrome consisting of fever, urticaria or rash; and arthralgia, arthritis, joint stiffness, or joint swelling. Eosinophilia may be present.

Minocycline for injection contains magnesium sulfate heptahydrate. Adverse effects that may be associated with magnesium intoxication include flushing, sweating, hypotension, depressed reflexes, flaccid paralysis, hypothermia, circulatory collapse, cardiac and CNS depression proceeding to respiratory paralysis.

4.9 Overdosage

The adverse events more commonly seen in overdose are dizziness, nausea, and vomiting.

No specific antidote for minocycline is known.

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures. Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis.

5. Pharmacological Properties

5.1 Mechanism of Action

The tetracyclines are primarily bacteriostatic and are thought to exert their antimicrobial effect by the inhibition of protein synthesis. The tetracyclines, including minocycline, have a similar antimicrobial spectrum of activity against a wide range of Gram-positive and Gram-negative bacteria. Cross-resistance of these bacteria to tetracyclines is common.

5.2 Pharmacodynamic Properties

List of Microorganisms

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

Gram-positive Bacteria

Bacillus anthracis

Listeria monocytogenes

Staphylococcus aureus

Streptococcus pneumoniae

Gram-negative Bacteria

Bartonella bacilliformis

Brucella species

Klebsiella granulomatis

Campylobacter fetus

Francisella tularensis

Vibrio cholerae

Yersinia pestis

Acinetobacter species

Enterobacter aerogenes

Escherichia coli

Haemophilus influenzae

Klebsiella species

Neisseria meningitidis

Shigella species

Other Microorganisms

Actinomyces species

Borrelia recurrentis

Chlamydia psittaci

Chlamydia trachomatis

Clostridium species

Entamoeba species

Fusobacterium nucleatum subspecies *fusiforme*

Mycobacterium marinum

Mycoplasma pneumoniae

Propionibacterium acnes

Rickettsia

Treponema pallidum subspecies *pallidum*

Treponema pallidum subspecies *perforans*

Ureaplasma urealyticum

Susceptibility Test Methods

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/CDTIG>.

Dilution Techniques

Quantitative methods are used to determine antimicrobial minimal inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized method (2,3). This procedure uses paper disks impregnated with 30 mcg tetracycline or 30 mcg minocycline to test the susceptibility of microorganisms to minocycline. The disk diffusion interpretive criteria are provided in Table 1.

Diffusion techniques

Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size provides an estimate of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized method (2,3). This procedure uses paper disks impregnated with 30 mcg tetracycline or 30 mcg minocycline to test the susceptibility of microorganisms to minocycline. The disk diffusion interpretive criteria are provided in Table 1.

Table 1: Susceptibility Test Interpretive Criteria for Minocycline and Tetracycline

Species	Minimal Inhibitory Concentration (mcg/mL)			Zone Diameter (mm)			Agar Dilution (mcg/mL)		
	S	I	R	S	I	R	S	I	R
Enterobacteriaceae^a									
Minocycline	≤ 4	8	≥ 16	≥ 16	13 - 15	≤ 12			
Tetracycline	≤ 4	8	≥ 16	≥ 15	12 - 14	≤ 11			
Acinetobacter^a									
Minocycline	≤ 4	8	≥ 16	≥ 16	13 - 15	≤ 12			
Tetracycline	≤ 4	8	≥ 16	≥ 15	12 - 14	≤ 11			
Haemophilus influenzae									
Tetracycline	≤ 2	4	≥ 8	≥ 29	26 - 28	≤ 25			
Streptococcus pneumoniae									
Tetracycline	≤ 1	2	≥ 4	≥ 28	25 - 27	≤ 24			
Staphylococcus aureus									
Minocycline	≤ 4	8	≥ 16	≥ 19	15 - 18	≤ 14			
Tetracycline	A 4	8	≥ 16	≥ 19	15 - 18	≤ 14			
Vibrio cholerae^a									
Minocycline	≤ 4	8	≥ 16	≥ 16	13 - 15	≤ 12			
Tetracycline	≤ 4	8	≥ 16	≥ 19	15 - 18	≤ 14			
Neisseria meningitidis^a									
Minocycline	-	-	≥ 26	-	-	≤ 2	-	-	-
Bacillus anthracis^b									
Tetracycline	≤ 1	-	-	-	-	-	-	-	-
Francisella tularensis^b									
Tetracycline	≤ 4	-	-	-	-	-	-	-	-
Yersinia pestis									
Tetracycline	≤ 4	8	≥ 16	-	-	-	-	-	-

^aOrganisms that are susceptible to tetracycline are also considered susceptible to minocycline.

However, some organisms that are intermediate or resistant to tetracycline may be susceptible to minocycline.

^bThe current absence of resistance isolates precludes defining any result other than "susceptible".

If isolates yielding MIC results other than susceptible, they should be submitted to a reference laboratory for further testing.

A report of "Susceptible" indicates that the antimicrobial drug is likely to inhibit growth of the microorganism if the antimicrobial compound reaches the concentrations usually achievable at the site of infection. A report of "Intermediate" 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 high dosage of drug can be used. This category also provides a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the antimicrobial drug is not likely to inhibit growth of the microorganism, if the antimicrobial drug reaches the concentrations usually achievable at the site of infection; 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. Standard tetracycline (class compound) or minocycline powder should provide the following range of MIC values noted in Table 2. For the disk diffusion technique, using the 30 mcg tetracycline or 30 mcg minocycline disk, the criteria in Table 2 should be achieved.

Table 2: Acceptable Quality Control Ranges for Minocycline and Tetracycline

Species	Minimal Inhibitory Concentration (mcg/mL)	Zone Diameter (mm)	Agar Dilution (mcg/mL)
Enterococcus faecalis ATCC 29212			
Minocycline	1 - 4	--	--
Tetracycline	8 - 32	--	--
Escherichia coli ATCC 25922			
Minocycline	0.25 - 1	19 - 25	--
Tetracycline	0.5 - 2	18 - 25	--
Haemophilus influenzae ATCC 49247			
Tetracycline	4 - 32	14 - 22	--