

Face2Vet

A Clinical Update

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Orbifloxacin - An Advanced Fluoroquinolone

Orbifloxacin - A New Era in Veterinary Antimicrobial Therapy

Dear Vets,

Infectious diseases remain one of the most significant constraints on efficient animal production systems in India. These diseases cause significant economic losses due to reduced milk yield and increased treatment costs, also contributing to increased morbidity and mortality. Moreover, sub-clinical infections often go unnoticed, yet silently impair animal performance, reproductive efficiency and overall herd profitability. The presence of biofilms, intracellular pathogens and mixed infections further complicates disease management. In addition, prolonged and indiscriminate use of antibiotics has contributed significantly to emergence and spread of antimicrobial resistance (AMR), posing a serious threat to sustainable Veterinary healthcare and livestock productivity.

These challenges necessitate the adoption of advanced antimicrobial agents with optimised pharmacokinetic pharmacodynamic (PK-PD) profiles, enhanced tissue penetration and proven efficacy against resistant and intracellular pathogens. Novel antimicrobials with targeted mechanisms of action, favourable safety margins and reduced resistance potential are essential for ensuring consistent therapeutic success in modern livestock systems.

This issue of Face2Vet provides a comprehensive, evidence-based overview of Orbifloxacin, highlighting its chemical characteristics, antimicrobial spectrum, PK-PD attributes and clinical evidence. It is intended to support evidence based clinical decision making, promote responsible antimicrobial stewardship and ultimately enhance animal health, productivity and welfare under Veterinary supervision.

We invite you to read this issue and share your valuable feedback or thoughts by scanning the QR code below or by reaching us via email at face2vet@intaspharma.com.

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Introduction

Dairy industry continues to face significant challenges from infectious diseases that negatively impact animal health, milk production, reproductive efficiency and overall farm profitability. Effective control of these diseases is essential not only to safeguard animal health but also to ensure sustainable productivity in modern dairy farming systems.

Antimicrobials form a cornerstone of Veterinary medicine by providing therapeutic, metaphylactic and prophylactic control of bacterial infections. They play a critical role in limiting disease progression, reducing pathogen spread and preserving herd health. However, the clinical effectiveness of many conventional antibiotics has increasingly been compromised by antimicrobial resistance, inadequate tissue penetration and limited efficacy against chronic or intracellular pathogens. These limitations highlight the need for more advanced antimicrobial agents with improved pharmacological performance.

Advanced antibiotics offer strong bactericidal activity, excellent tissue penetration, low plasma protein binding, a prolonged post-antibiotic effect and high bioavailability. These attributes allow for reduced dosing frequency, improved treatment compliance and better clinical outcomes, making them a preferred therapeutic choice for management of common infections.

Overview of Fluoroquinolones

- Fluoroquinolones are a key class of synthetic, broad-spectrum antimicrobials widely used in Veterinary practice due to their rapid, concentration-dependent bactericidal activity and strong efficacy against Gram-positive and Gram-negative bacteria.
- Fluoroquinolones have demonstrated proven clinical effectiveness in treatment of invasive and systemic infections involving the respiratory tract (upper and lower), urinary tract, uterus, skin, soft tissues, wounds, bones, oral cavity, prostate and both external and internal ear.

Orbifloxacin

- Orbifloxacin is a third-generation synthetic fluoroquinolone approved for use in cattle, buffalo, sheep, goats, pigs, dogs and cats.
- It is indicated for treatment of mastitis, pneumonia, cystitis, diarrhoea and other systemic bacterial infections.
- Orbifloxacin can be administered *via* oral, intramuscular, intravenous or subcutaneous routes and demonstrates excellent systemic bioavailability.

Chemical Profile and Structure–Activity Relationship (SAR)

Antibacterial efficacy of Orbifloxacin is a direct result of combined contributions of its chemical profile and various structural components.

Chemical Name: 1-Cyclopropyl-7-[(3R,5S)-3,5-dimethyl-1-piperazinyl]-5,6,8-trifluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.

Molecular Formula: C₁₉H₂₀F₃N₃O₃

The core structure of Orbifloxacin consists of a bicyclic quinolone ring system, which is fundamental to its antibacterial action.

Orbifloxacin possesses three fluorine atoms at C5, C6 and C8 positions, along with a specialized piperazinyl side chain, which distinguish it from other fluoroquinolone antimicrobial agents and collectively confer stronger DNA-gyrase inhibition, superior tissue and intracellular penetration. The Structure–Activity Relationship (SAR) and key benefits of Orbifloxacin are summarised in Table 1.

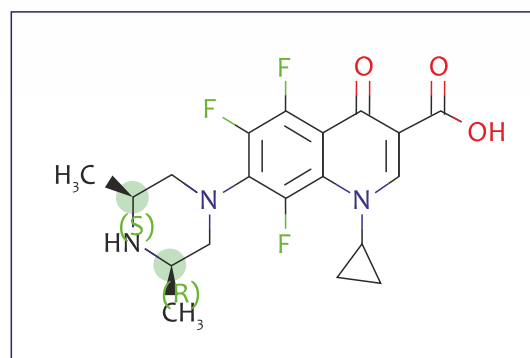


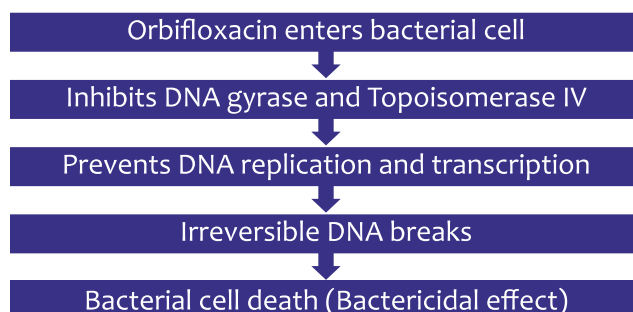
Fig. 1: Chemical Structure of Orbifloxacin

Table 1: SAR of Orbifloxacin

	Structural Position	Unique Scientific Benefits
	Quinolone nucleus (C-3 carboxyl & C-4 keto)	- Binds to DNA gyrase/topoisomerase IV complex - Inhibits bacterial DNA replication and transcription - Produces enhanced bactericidal activity
	N-1 Cyclopropyl substituent	- Enhances overall drug potency - Broadens antibacterial spectrum
	C-5 Fluorine	Improves intracellular and tissue penetration
	C-6 Fluorine	- Enhances inhibition of bacterial target enzymes - Improves penetration through the bacterial cell wall
	C-7 (3S,5R)-3,5-dimethylpiperazinyl ring	- Enhances drug potency - Influences pharmacokinetic properties
	C-8 Fluorine	- Modulates the antibacterial activity spectrum - May reduce CNS adverse effects

Mechanism of Action

Orbifloxacin is a bactericidal antimicrobial that kills bacteria by interfering with DNA replication. It works by inhibiting two essential bacterial enzymes - DNA gyrase (mainly in Gram-negative bacteria) and topoisomerase IV (mainly in Gram-positive bacteria), both of which are required for normal bacterial DNA synthesis. Orbifloxacin inhibits bacterial DNA replication and repair, causing irreversible double-strand DNA breaks that lead to bacterial cell death.



Spectrum of Antimicrobial Activity

- Spectrum of antimicrobial activity refers to range of bacterial pathogens against which an antimicrobial agent is effective.
- Drugs with a broad antimicrobial spectrum are particularly useful in field conditions where infections may be mixed, the causative organism is undiagnosed and rapid therapeutic intervention is required.

- Orbifloxacin exhibits potent, concentration-dependent bactericidal activity against a wide range of clinically important Gram-negative, Gram-positive bacteria, as well as atypical pathogens such as *Mycoplasma* spp.
- Its strong activity against wide range of bacteria makes it especially effective in management of common bacterial infections. Additionally, its efficacy against *Mycoplasma*, which are inherently resistant to many cell-wall-targeting antibiotics, enhances its therapeutic value.
- The broad spectrum of activity, combined with favourable pharmacokinetic properties such as wide systemic distribution and high tissue penetration, makes Orbifloxacin a reliable and practical choice for empirical therapy in Veterinary practice. The antimicrobial spectrum of Orbifloxacin is summarized in Table 2.

Table 2: Orbifloxacin: Broad Spectrum of Activity Against Key Bacterial Pathogens

Gram-Negative Bacteria	Gram-Positive Bacteria	Atypical Bacteria
<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	<i>Mycoplasma bovisrhinitis</i>
<i>Proteus mirabilis</i>	<i>S. intermedius</i>	<i>Mycoplasma bovis</i>
<i>Klebsiella pneumoniae</i>	<i>S. pseudintermedius</i>	<i>M. hyopneumoniae</i>
<i>Pasteurella</i> spp.	Coagulase-positive <i>Staphylococci</i>	<i>Ureaplasma diversum</i>
<i>Enterobacter</i> spp.	<i>Streptococcus equisimilis</i>	<i>Chlamydia</i> spp.
<i>Salmonella</i> spp.	β -hemolytic <i>Streptococci</i>	—
<i>Haemophilus parasuis</i>	<i>Enterococcus faecalis</i>	—
<i>Actinobacillus pleuropneumoniae</i>	—	—
<i>Pseudomonas aeruginosa</i>	—	—

Antimicrobial Potency

- Antimicrobial potency is the ability of an antimicrobial agent to inhibit bacterial pathogens at low concentrations. This property is commonly assessed by Minimum Inhibitory Concentration (MIC).
- Lower MIC values (Table 3) indicate higher antimicrobial potency and serve as an important factor in selecting effective treatment options in Veterinary practice.

Table 3: Orbifloxacin MIC against Major Bacteria

Bacteria	Isolated from	MIC Value ($\mu\text{g/ml}$)
<i>Staphylococcus aureus</i>	Bovine	0.50
<i>Streptococcus</i> spp.	Diseased animals	0.39-3.13
<i>Escherichia coli</i>	Bovine	0.06
<i>Mannheimia haemolytica</i>	Cattle	0.125–0.50
<i>Mannheimia haemolytica</i> serotype A1	Cattle	0.06
<i>Pasteurella multocida</i>	Bovine	0.05
<i>Salmonella dublin</i>	Calves	1.56
<i>Salmonella typhimurium</i>	Calves	0.20

Pharmacokinetic Profile

Orbifloxacin has been extensively evaluated across multiple Veterinary species. These studies demonstrate that Orbifloxacin possesses favourable pharmacokinetic properties - making it suitable for treatment of both systemic and localised infections in animals. The ADME profile and pharmacokinetic parameters (Fig. 3) of Orbifloxacin in ruminants are described below.

Absorption

- Orbifloxacin is rapidly absorbed after intramuscular (IM) administration showing high bioavailability (>100%).
- Peak plasma concentration is reached within 1–1.5 hours, ensuring a rapid onset of action, especially preferred in acute infections.

- After intravenous administration, the drug distributes quickly into body tissues, ensuring effective tissue penetration.
- Oral absorption is rapid, ensuring effective systemic availability.

Distribution (🦷 🐄)

- Orbifloxacin distributes widely throughout the animal body and has a high volume of distribution which indicates excellent penetration into body tissues.
- It achieves high concentrations in the lungs, udder and other soft tissues, making it highly effective for treatment of mastitis, respiratory infections and other systemic bacterial infections.
- Orbifloxacin is able to penetrate inside cells, which helps in eliminating intracellular pathogens that are often difficult to treat with routine antimicrobials.

Low Plasma Protein Binding Advantage

- Orbifloxacin shows very low plasma protein binding (approximately 14-18 %), resulting in a high proportion (~ 85%) of free, active drug in systemic (blood) circulation.
- After absorption, Orbifloxacin circulates in blood, mainly in two forms-free (unbound, active) and protein-bound, with protein binding being reversible (Fig. 2).
- The unbound (active) Orbifloxacin molecules freely distributes into tissues, ensuring rapid access to infected sites.
- A higher concentration of free drug provides a faster onset of action and enhanced bacterial killing effect.
- As only the unbound drug is pharmacologically active, Orbifloxacin's low protein binding translates into superior clinical efficacy and better infection control.
- The protein-bound fraction remains pharmacologically inactive and does not contribute to antibacterial activity.

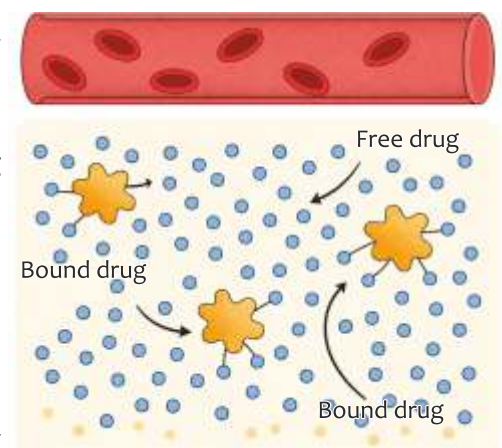


Fig. 2: Plasma Protein Binding of Orbifloxacin

Metabolism (🦷)

- Orbifloxacin undergoes minimal metabolism in liver (mainly through the cytochrome P_{450} enzyme system), therefore, only a small portion of drug is converted into metabolites.
- Minimal metabolism keeps the drug in its active form for a longer duration, enhancing its effectiveness. This results in prolonged and sustained antibacterial activity, which helps maintain therapeutic drug levels and improves treatment success.

Excretion (Elimination) (🦷)

- Orbifloxacin is primarily eliminated *via* kidneys, with renal excretion being the main route of drug elimination.
- A small portion of drug is excreted through bile and faeces, supporting complete clearance from body after therapy.

Pharmacokinetic Parameters 🎲

Maximum Plasma Concentration (C_{max} - $\mu\text{g/ml}$)

- C_{max} is the maximum (peak) plasma concentration of Orbifloxacin achieved after administration, reflecting the extent of drug absorption into systemic (blood) circulation.
- The achieved C_{max} values of Orbifloxacin after IM administration (1.21 $\mu\text{g/ml}$ in cattle, 1.53 $\mu\text{g/ml}$ in goats and 1.66 $\mu\text{g/ml}$ in sheep) demonstrate adequate peak plasma concentrations, which are critical for strong antibacterial activity, enhanced bacterial killing, early clinical recovery and improved therapeutic success rates.

Time to Reach Peak Plasma Concentration (T_{max} - h)

- T_{max} is the time required for Orbifloxacin to reach its peak plasma concentration after administration, reflecting the rate at which drug enters systemic circulation.
- A short T_{max} of Orbifloxacin (approximately 1–1.5 hours) indicate rapid systemic absorption, enabling early achievement of peak therapeutic plasma concentrations and a rapid onset of antibacterial activity, which is critical for effective infection control.

Area Under Plasma Drug Concentration (AUC- $\mu\text{g}\cdot\text{h/mL}$)

- The area under plasma concentration–time curve ($\text{AUC}_{0-\infty}$) represents the total systemic exposure of Orbifloxacin over time, indicating how much active drug is available in body to act against infection.
- Orbifloxacin shows strong and consistent AUC values across studies with IM administration ($5.98\text{--}13.23 \mu\text{g}\cdot\text{h/mL}$) and IV administration ($6.15\text{--}13.76 \mu\text{g}\cdot\text{h/mL}$), reflecting high drug availability in systemic circulation.
- These robust AUC values confirm adequate and sustained therapeutic plasma concentrations, supporting effective antibacterial activity, prolonged drug action and effective clinical efficacy of Orbifloxacin in animals.

Bioavailability (F%)

- Bioavailability refers to fraction of an administered drug dose that reaches the systemic circulation in an active form, reflecting the efficiency of drug absorption after administration.
- The very high intramuscular absolute bioavailability of Orbifloxacin ($>101\%$) ensures complete and reliable systemic drug exposure, indicating efficient absorption with minimal loss at injection site.
- This high bioavailability provides predictable therapeutic plasma concentrations, supporting a rapid onset of antibacterial action and consistent clinical efficacy at recommended doses.

Volume of Distribution at Steady State (V_{dss} -L/Kg)

- The apparent volume of distribution at steady state (V_{dss}) indicates how extensively a drug distributes from the bloodstream into body tissues, with higher values reflecting better tissue penetration.
- Orbifloxacin shows a high V_{dss} ($\sim 0.9\text{--}1.3 \text{ L/kg}$), indicating wide distribution throughout the animal's body, rapid movement from blood into tissues, effective penetration to infection sites and consequently efficient bacterial killing and effective treatment outcomes in animals.

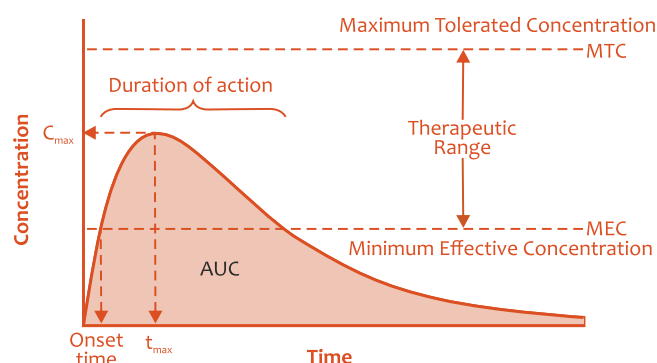


Fig. 3: Plasma Drug Concentration-Time Profile

Clinical Studies on OrbiVet (Orbifloxacin)

Study 1 Therapeutic efficacy of Orbifloxacin in treatment of bovine mastitis (Dr. S.V. Singh).

Introduction

The study was conducted at Teaching Veterinary Clinical Complex, Kumarganj and the Government Veterinary Hospital, Anand Nagar Bhitari, Faizabad on 25 lactating animals comprising 13 cows and 12 buffaloes aged between 4 and 7 years. All animals had calved 15 days to 2 months prior to study and showed a history of acute swelling of one or two teats and associated quarters in last 2-3 days. Most cases had received prior intramammary or parenteral antibiotic treatment by local practitioners without clinical improvement.

Clinical Observations and Diagnosis

Clinical examination of affected quarters revealed swollen, firm udders that were hot and painful on palpation. Milk from affected teats ranged from watery to curdled, depending on the severity of infection. Temperature, pulse rate and respiration rate, remained within normal physiological ranges. Diagnosis was based on clinical findings and confirmed using standard mastitis diagnostic tests, including white side test, california mastitis test and bromothymol blue strip. Milk samples were collected aseptically and subjected to antibiotic sensitivity testing. Antibiotic sensitivity results revealed resistance to Procaine penicillin, Ampicillin, Chloramphenicol and Erythromycin, while sensitivity was observed to Amoxicillin, Gentamicin, Enrofloxacin and Tetracycline.

Treatment Protocol

Affected animals were treated with Inj. Orbifloxacin (**OrbiVet**) @ 20 ml intramuscularly (IM), along with supportive therapy of Inj. Meloxicam (**Melonex**) @ 10 ml IM and Inj. Chlorpheniramine maleate (**Anistamin**) @ 10 ml IM for five consecutive days. Udder condition and milk quality were monitored daily and changes were recorded.

Results

Out of the 25 treated animals, 19 animals (10 cows and 9 buffaloes; 76%) showed complete clinical recovery after five days of treatment. In remaining six animals, therapy was extended for an additional three days, resulting in complete recovery in two more cases. Four animals progressed to gangrenous mastitis due to advanced disease at presentation. Overall, 84% of animals achieved complete recovery within 5-8 days of Orbifloxacin (**OrbiVet**) therapy.

Conclusion

The results of clinical study demonstrate that Orbifloxacin (**OrbiVet**) is highly effective in the treatment of clinical mastitis in cattle and buffaloes, particularly in cases involving resistance to commonly used antibiotics. Its high clinical recovery rate and favourable response profile support the use of Orbifloxacin (**OrbiVet**) as a reliable systemic therapeutic option in bovine mastitis.

Study 2 Therapeutic evaluation of Orbifloxacin (**OrbiVet**) orally in gastrointestinal infection in ruminants (Ghoke and Thorat, 2024).

Introduction

Effective management of gastrointestinal infections in ruminants requires antimicrobial agents that provide high therapeutic efficacy while minimising the risk of antimicrobial resistance. Fluoroquinolones have emerged as an important class of antimicrobials in Veterinary medicine due to their broad-spectrum activity, reliable absorption and favourable pharmacokinetic properties. Among Veterinary specific fluoroquinolones, Orbifloxacin offers effective activity against key enteric pathogens, making it a suitable option for gastrointestinal infections in ruminants. Therefore, the present study was undertaken to evaluate the clinical efficacy of oral Orbifloxacin (**OrbiVet Bolus**) in bovine gastrointestinal tract infection.

Materials and Methods

A clinical study was conducted on 24 bovines (12 adults and 12 calves; cattle and buffaloes) showing diarrhoea, inappetence and reduced or absent rumination. Dietary causes were ruled out through history taking and parasitic infection was excluded by routine coprological examination. Faecal samples were collected for bacterial isolation before and after treatment.

Animals were treated with oral Orbifloxacin (**Orbivet Bolus**) @ 2.5–5 mg/kg b. wt., once daily for 3-5 days, based on clinical response. Treatment efficacy was assessed by clinical recovery and absence of pathogenic bacteria in post-treatment faecal samples.

Results

Oral Orbifloxacin (**OrbiVet Bolus**) treatment resulted in rapid and consistent clinical recovery in both adult bovines and calves suffering from infectious diarrhoea. Average recovery time ranged from 3.5–4.2 days in adults and 3.5–3.8 days in calves, with marked improvement in faecal consistency, appetite and rumination. No adverse reactions were observed following oral administration of **OrbiVet Bolus**. Result of sensitivity test with different concentration of Orbifloxacin revealed indifferent patterns.

Conclusion

Oral administration of Orbifloxacin (**OrbiVet Bolus**) was found to be effective and well tolerated in treatment of diarrhoea of infectious origin in adult cattle, buffaloes and calves. The therapy resulted in consistent clinical improvement without any observed adverse effects. These findings support the safe and practical use of oral Orbifloxacin (**OrbiVet Bolus**) as a therapeutic option for managing infectious gastro-intestinal conditions in bovines under field conditions.

Study 3 Pharmacokinetics of Orbifloxacin in Mehsana goats after intravenous and intramuscular administration (Ghanshyam et al., 2015).

Objective

The present study was undertaken to evaluate the single-dose pharmacokinetics of Orbifloxacin (**OrbiVet**) following intravenous and intramuscular administration in clinically healthy Mehsana goats.

Materials and Methods

A pharmacokinetic study of Orbifloxacin (**OrbiVet**) was conducted in healthy adult Mehsana goats. Twelve goats (25-35 kg body weight, 2-4 years of age) were maintained under standard feeding and management conditions with free access to water. Animals were clinically monitored throughout the study. Goats were divided into two groups of six animals each. One group received Inj. Orbifloxacin (**OrbiVet**) @ 2.5 mg/kg b. wt. intravenously (IV), while the second group received the same dose intramuscularly (IM). Blood samples were collected at regular intervals before and after drug administration to determine plasma drug levels. Plasma Orbifloxacin concentrations were measured using a validated HPLC method and pharmacokinetic parameters were calculated using non-compartmental analysis software.

Results

No local irritation or systemic adverse reactions were observed following intravenous or intramuscular administration of Orbifloxacin (**OrbiVet**), indicating that drug was safe and well tolerated by goats. The semi-logarithmic plasma concentration–time profiles after both routes of administration are presented in Fig. 4, while the pharmacokinetic parameters are summarised in Table 4.

Following intravenous administration, Orbifloxacin showed a high volume of distribution (V_{dss}), indicating extensive tissue distribution, which is desirable for treating systemic bacterial infections. The total body clearance (CLB) values suggest a moderate rate of drug elimination, allowing the drug to remain in body for a clinically useful duration. After intramuscular administration, Orbifloxacin was rapidly absorbed, as reflected by the early attainment of peak plasma concentration (C_{max}) at approximately 1 hour (T_{max}) (Fig. 4).

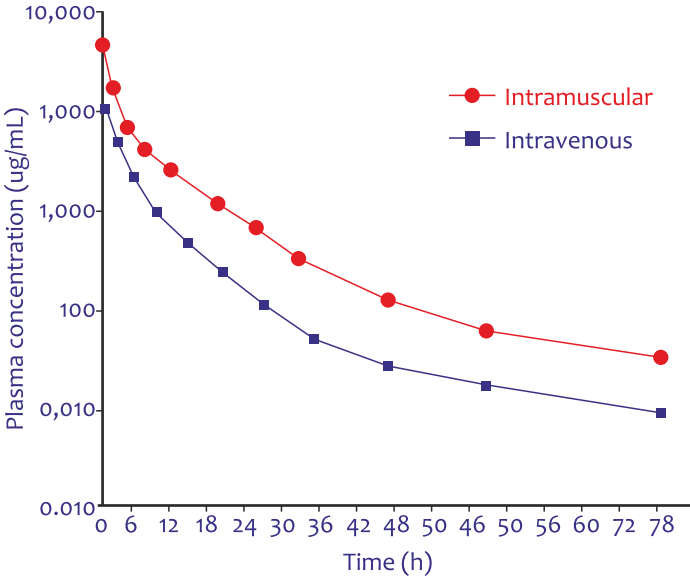


Fig. 4: Plasma Concentrations of Orbifloxacin

The mean absorption time (MAT) indicates sustained absorption from the injection site, while high systemic bioavailability confirms excellent availability of drug after intramuscular dosing. Overall, these results support effective clinical use of Orbifloxacin (**OrbiVet**) in goats, providing adequate drug exposure and persistence for successful antimicrobial therapy under field conditions.

Table 4: Pharmacokinetic Parameters of Orbifloxacin in Goats (IV and IM Routes)

Parameter	Units	IV	IM
Elimination rate constant (β)	h^{-1}	0.020 ± 0.001	0.019 ± 0.001
Elimination half life ($t_{1/2\beta}$)	h	8.63 ± 0.130	7.77 ± 0.058
Overall drug exposure from time zero to infinity ($AUC_{0-\infty}$)	$\mu g \cdot h/ml$	12.65 ± 0.208	19.66 ± 0.216
Apparent volume of distribution based on elimination phase ($V_{d_{area}}$)	L/kg	9.83 ± 0.172	—
Volume of distribution at steady state (V_{dss})	L/kg	2.99 ± 0.038	—
Total body clearance (rate of drug elimination) (CL)	L/kg/h	0.187 ± 0.002	—
Mean residence time in body (MRT)	h	15.57 ± 0.531	21.07 ± 0.478
Mean absorption time from injection site (MAT)	h	—	7.618 ± 0.549
Peak plasma drug concentration (C_{max})	$\mu g/ml$	—	1.76 ± 0.010
Time to reach peak plasma concentration (T_{max})	h	—	1.00 ± 0.00
Absolute bioavailability (F)	%	—	155.5 ± 2.487

Conclusion

Orbifloxacin demonstrated favourable pharmacokinetic properties, including a prolonged half life and good systemic availability, with no observed adverse reactions in goats. These attributes indicate that Orbifloxacin (**OrbiVet**) can be a useful and effective antimicrobial option for treatment of bacterial infections in animals under field conditions.

Conclusion

Given the persistent impact of infectious diseases on animal health and dairy productivity, the selection of effective antimicrobials remains critical in Veterinary practice. Orbifloxacin, a third generation synthetic fluoroquinolone developed exclusively for Veterinary use, possesses a characteristic trifluorinated structure with fluorine atoms at the 5, 6 and 8 positions. This structural configuration confers strong bactericidal activity through inhibition of bacterial DNA gyrase and topoisomerase IV, ultimately leading to bacterial cell death. Its potent antimicrobial efficacy, reflected by low minimum inhibitory concentration (MIC) values ranging from 0.05 to 0.5 µg/mL, provides broad spectrum coverage against Gram-positive, Gram-negative, anaerobic, Mycoplasma and Mycobacterium bacteria. Favourable pharmacokinetic properties including rapid and near complete absorption with bioavailability exceeding 100%, attainment of peak plasma concentrations within 1.0–1.5 hours, low plasma protein binding (~14–18%) and prolonged elimination half life ensure high and sustained concentrations of active drug at the site of infection. With proven effectiveness in the treatment of mastitis, respiratory, urinary, gastrointestinal, skin and other systemic infections across cattle, buffaloes, sheep, goats, pigs, dogs and cats. Orbifloxacin represents a reliable and scientifically validated therapeutic option when used judiciously in Veterinary practice.

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