Oritavancin

Antibiotic disc for susceptibility testing of Gram-positive bacteria.

DESCRIPTION

Oritavancin, formerly LY333328, is a lipoglycopeptide with broad-spectrum activity against Gram-positive pathogens, such as staphylococci, including methicillin resistant *Staphylococcus aureus* (MRSA), streptococci and enterococci. This antimicrobial agent causes cell death by inhibiting cell wall synthesis as well as depolarizing and permeabilizing the cellular membrane of susceptible organisms.

Oritavancin (ORBACTIV®), has been recently approved by the FDA and EMA for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI) caused by *Staphylococcus aureus* (including methicillin-susceptible and methicillin–resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Great benefits, compared to other drugs having similar therapeutic indications, derive from its single, once-only dosing regimen administered by intravenous infusion.

As claimed by the drug's Manufacturer as well, to reduce the development of drug-resistant bacteria and maintain the effectiveness of oritavancin and other antibacterial drugs, ORBACTIV® should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. Therefore, the confirmation of susceptibility of a given isolate to oritavancin becomes of primary importance.

CONTENTS OF THE PACKAGES

The 50-test box contains 1 cartridge with 50 discs packed in a desiccant envelop.
The 250-test box contains 5 desiccant envelops, each containing 1 cartridge with 50 discs.
Each package also contains a transparent plastic resealable pouch.

GATHERING AND KEEPING SAMPLES

The colonies that are to be subjected to the susceptibility test are taken up by culture media that have been previously swabbed with the sample under examination. In the case of mixed colonies the bacterial strains must be purified before they are swabbed on the plate for the susceptibility test.

TEST PROCEDURE

1. Suspend well-isolated colonies from an overnight agar plate into saline to achieve a 0.5 McFarland standard turbidity.
2. Using a sterile cotton swab, streak the inoculum over the entire area of a cation-adjusted Mueller Hinton agar plate. Allow excess moisture to be absorbed. Use plates that have a **dry surface** (no visible moisture on the surface) only.
3. Apply Oritavancin discs on the inoculated agar plates.
4. Incubate at 35 ± 2°C for 24 hours in ambient atmosphere.

EVALUATING THE RESULTS

At the end of the incubation period, measure the inhibition zone diameters (mm) with zone edges read as the point showing no obvious growth as detected with the unaided eye. Ignore any internal colonies present in the inhibition halo.

QUALITY CONTROL

The following quality control strains are used as outlined under TEST PROCEDURE:

Microorganism		Zone Range (mm)
Staphylococcus aureus	ATCC® 29213	18-21
Staphylococcus aureus	ATCC® 25923	17-21
Staphylococcus aureus	ATCC® 700698	10-14
Staphylococcus aureus	ATCC® 700699	6-10

LIMITS

Diffusion susceptibility tests use an *in vitro* technique and cannot therefore reproduce the extremely complex *in vivo* conditions. Nevertheless, it is a useful and important tool that helps the clinician choose the correct therapy. Many variable factors influence the final result of the diffusion susceptibility test. The main ones are: the culture medium used, impregnation of the discs, inoculation of the medium, temperature, time and incubation atmosphere of the plates, pre-incubation and pre-diffusion conditions, depth of the medium, etc.

PRECAUTIONS

The discs cannot be classified as being hazardous according to current legislation but fall within the specific field of application where a safety data sheet must be supplied because they can cause phenomena of sensitization in sensitive subjects if they come into contact with the skin.
The discs are disposable products, intended for professional use only. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

STORAGE

Store the unopened package at -20°C to +8°C till the expiry date. Leftover discs from an opened cartridge should be stored at 2-8°C for no more than 7 days. Reinsert the cartridge containing unused discs into the desiccant envelop and then into the resealable pouch. Return the cartridge to the refrigerator as soon as the application of the discs has been completed. Dispose of expire discs.

ELIMINATING USED MATERIAL

After use, the discs and the material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.

REFERENCES

- European Medicines Agency. Orbactiv EMA/55574/2015.
- CLSI M02-A10 (2015) Performance standards for Antimicrobial disk susceptibility tests; Approved Standard - Twelfth edition. Clinical and Laboratory Standards Institute, Wayne, PA.
- EUCAST Addendum (19 April 2015). Clinical breakpoints and QC recommendations for new agents dalbavancin, oritavancin and tedizolid.
- FDA (September 2014) ORBACTIV (oritavancin) Highlights of Prescribing Information.
- Orbactiv® (oritavancin) for injection. The Medicines Company, Ville Saint Laurent, Quebec, Canada.
- Belley A, Arhin FF, Sarmiento I, Deng H, Rose W, Moeck G (2013) Pharmacodynamics of a simulated single 1,200-milligram dose of oritavancin in an in vitro pharmacokinetic/pharmacodynamic model of methicillin-resistant *Staphylococcus aureus* infection. Antimicrob Agents Chemother 57:205–211.
- Matuschek E, DFJ Brown and G Kahlmeter (2013) Development of the EUCAST disk diffusion antimicrobial susceptibility testing method and its implementation in routine microbiology laboratories. Clinical Microbiology and Infection European Society of Clinical Microbiology and Infectious Diseases, CMI, 20, O255–O266

PRESENTATION	Code	Packaging	Ref.
Oritavancin 5 µg	ORI	5 x 50 Discs	9201
Oritavancin 5 µg	ORI	1 x 50 Discs	9201/1

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution,consult accompanying documents	

LIOFILCHEM® s.r.l.

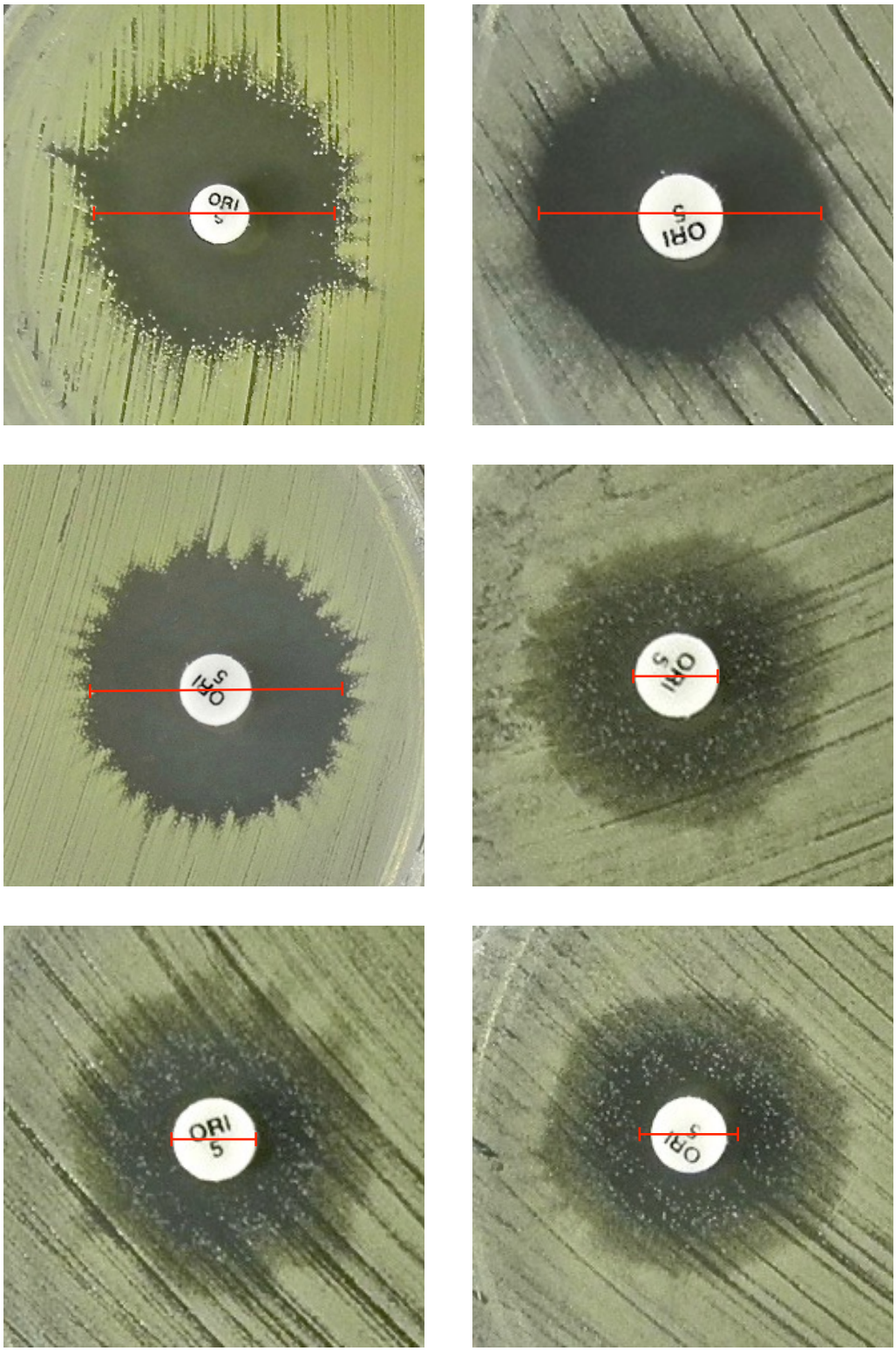
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

Ref. 9201

Appendix I

Oritavancin

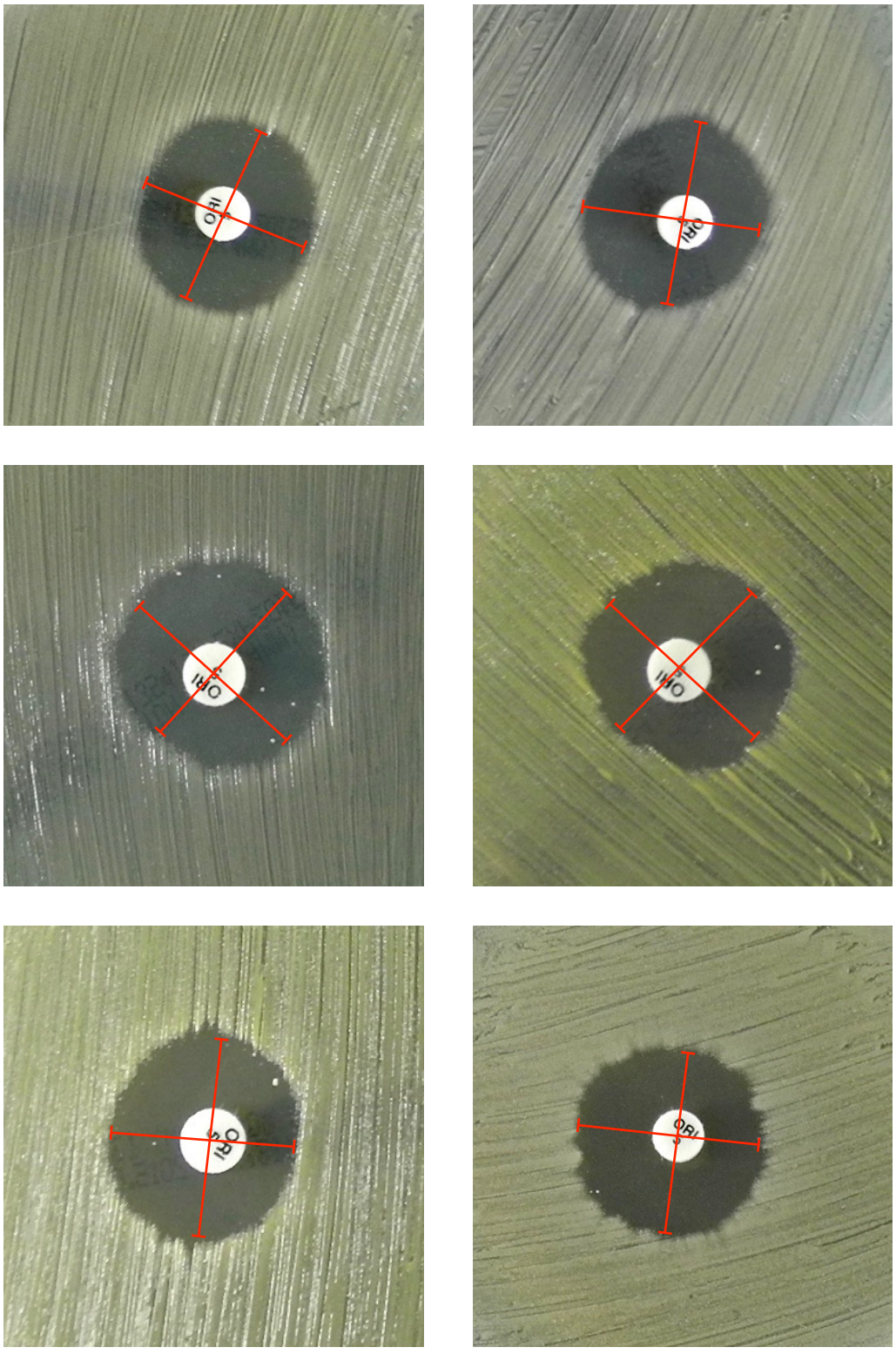
Antibiotic disc for susceptibility testing of Gram-positive bacteria.



(Inhibition zone diameters marked in red)

Troubleshooting

The inhibition zone diameter is the mean value of the longest and shortest diameters.



(Inhibition zone diameters marked in red)

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