

TBD 081-NYSTATIN

INTENDED USE

Nystatin NS 100 Units discs are used for antimicrobial susceptibility testing of fungal cultures

COMPOSITION

Ingredients	Concentration(s)
Nystatin	100 Units/disc

APPEARANCE

Filter paper discs of 6mm diameter with printed "NS 100" on centre of each side of the disc.

PRINCIPLE

Antimicrobial susceptibility testing (AST) of bacterial and fungal isolates is a common and important technique in most clinical laboratories. The results of these tests are used for selection of the most appropriate antimicrobial agent(s) for treatment against the infectious organisms. Till the 1950s, laboratories were lacking in the methodologies and equipment for the accurate determination of in vitro responses of organisms to antimicrobial agents. Bauer et al (1) began the development of standardized methods for antimicrobial susceptibility testing, using disc diffusion system. However, the susceptibility results may not always correlate with the patient's response to therapy. The response of an infected patient to antimicrobial agent(s) is a complex interrelationship of host responses, drug dynamics and microbial activity. Antimicrobial susceptibility tests are either quantitative or qualitative. Disc diffusion test is a qualitative test method. The National Committee for Clinical Laboratory Standards (NCCLS), now known as Clinical Laboratory Standards Institute (CLSI) has published comprehensive documents regarding the disc diffusion systems. The agar disc diffusion test is the most convenient and widely used method for routine antimicrobial susceptibility testing. In subsequent and current practice, antimicrobial impregnated paper discs are applied onto the agar surface. Based on the Bauer-Kirby Method, standardized reference procedures for the disc systems were published by WHO and FDA and are periodically updated by the CLSI (formerly NCCLS). For any antimicrobial testing, Quality control or clinical testing, the method to be followed is the same as mentioned above.

However, few precautions are to be maintained while handling of the Sensitivity discs,

- On receipt the discs are to be immediately stored at the recommended temperature.
- Medium preparation, Inoculum preparation and incubation to be done as specified

INSTRUCTION FOR USE

Preparation of Inoculum:

1. Inoculum is prepared by picking five distinct colonies of approximately 1mm from 24 hours old culture grown on Sabouraud Dextrose Agar and incubated at $35 \pm 2^\circ\text{C}$. Colonies are suspended in 5ml of sterile 0.85% Saline.
2. Vortex the resulting suspension and adjust the turbidity to yield $1 \times 10^6 - 5 \times 10^6$ cells /ml (i.e. 0.5 McFarland standard).

Test Procedure:

1. Prepare plates with Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye for carrying out susceptibility of antifungal discs. The medium in the plates should be sterile and have a depth of about 4 mm.
2. Dip a sterile non-toxic cotton swab on a wooden applicator into the standardized inoculum (turbidity so adjusted, as to obtain semi confluent growth on the petri plate) and rotate the soaked swab firmly against the upper inside wall of the tube to express excess fluid. Streak the entire agar surface of the plate with the swab three times, turning the plate at 60° angle between each streaking. Allow the inoculum to dry for 5 - 15 minutes with lid in place.
3. Apply the discs using aseptic technique. Deposit the discs with centers at least 24 mm apart.
4. Invert the plates and place in an incubator set to $35 \pm 2^\circ\text{C}$ within 15 minutes after the discs are applied.
5. Examine each plate after 20 - 24 hours of incubation. If plate was satisfactorily streaked the resulting zones of inhibition will be uniformly circular and there will be a semi-confluent lawn of growth. Read at 48 hours only when insufficient growth is observed after 24 hours incubation

Note: For professional use only.



MICROBIOLOGICAL PARAMETERS

Cultural characteristics: Average diameter of zone of inhibition observed on Muller Hinton Agar + 2% Glucose + 0.5 mcg/ml Methylene Blue Dye after 24-48 hours incubation at 35-37°C for standard cultures.

Microorganism	ATCC	Standard zone of inhibition (diameter in mm)
<i>Candida albicans</i>	90028	19-27
<i>Candida parapsilosis</i>	22019	16-25
<i>Candida tropicalis</i>	750	16-21
<i>Candida krusei</i>	6528	15-20
<i>Candida albicans</i>	10231	15-23
<i>Saccharomyces cerevisiae</i>	9763	17-25

PACKAGING













Disc available in three different packaging: Blister pack, Plastic Container and Vial.

STORAGE

Discs should be stored at - 20°C to +8°C under dry conditions, along with the desiccator pouch provided in each individual pack.

REFERENCES

1. Bauer, A.L., Kirby, W.M.M., Sherris, J.C., Turck, M. 1966. Am. J. Clin. Pathol. 45: 493-496.
2. Performance standards of Antimicrobial Disc Susceptibility Tests, CLSI Vol. 32 No.3, Jan 2012

 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 TITAN BIOTECH LTD., A- 902A, RIICO Industrial Area, Phase III, Bhiwadi-301019 Manufacturer
 Temperature Unit	 EC REP MedNet EC-REP GmbH Borkstrasse 10, 48163 Muenster, Germany Authorized Representative	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**

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