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5 July, 2016

Laboratory Quality Control of Mast Adatabs

Mast Adatabs are freeze dried tablets or pellets of antimicrobial agents in an inert carrier for agar dilution Antimicrobial Susceptibility Testing (AST). They are used by addition to suitable agar medium (such as Mueller Hinton Agar) to give a set content of antimicrobial agent in the agar medium.

The following quality control tests are carried out on Mast Adatabs prior to product release:

1. Raw material tests

Critical raw material such as antimicrobial agents undergo stringent quality control checks prior to use to confirm identity, purity and microbiological performance.

2. Product quality control tests

- a **Physical Characteristics.** Physical checks are carried out to ensure that each Adatab manufactured at Mast is satisfactorily lyophilised and that the colour is according to the specified acceptance criteria.
- b **Bioassay.** A bioassay test is conducted to check that the antimicrobial agent and content in the tablet or pellet are within specified limits. Mueller Hinton Agar plates are inoculated with a McFarland 0.5 equivalent suspension of the specified assay organism. The Mast Adatab/Adavial on test is solubilised in the stated volume of solvent. Also standard solutions of 50%, 100% and 200% of the target content of the antimicrobial agent of the Adatab are made up. Wells in the agar medium are made using a No.5 core borer and 100µl of each test solution added. Agar plates are incubated at 35±1°C for 18-24 hours. After incubation the diameter of the zones of inhibition are measured and recorded. The antimicrobial agent content of each Adatab is calculated using a linear regression method. The acceptance criteria for Adatabs is 90-125% of the stated content.
- c **Microbiological performance.** Mueller Hinton Agar plates are prepared and each inoculated with a McFarland 0.5 equivalent suspension of with one of the following 3 organisms below:-

Organism	Strain details
<i>Escherichia coli</i>	ATCC® 25922
<i>Pseudomonas aeruginosa</i>	ATCC® 27853
<i>Staphylococcus aureus</i>	ATCC® 25923

ATCC is a trademark of the American Type Culture Collection, Manassas, Virginia, USA





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- d **Bioburden.** The appropriate volume of Adatab solution made as for the Bioassay test is aseptically added to 100ml of Columbia Agar. Two petri dish plates are poured each with 50ml of medium and incubated at room temperature and 35±1°C for 40 hours. Plates should show no signs of microbial growth or contamination after this time.

Documentation

All results are recorded on a batch quality control record sheet and are countersigned by two authorised signatories.

Signed:

A handwritten signature in blue ink, consisting of a stylized, flowing line that starts with a small loop and extends to the right.

Dr D Hogben, Quality Assurance and Regulatory Affairs Manager