

CHECKLIST FOR MICROBIAL CONTAMINATION TEST (MCT)

| Validation test | | |
|-----------------|---|--|
| 1. | Total Viable Aerobic Count (Total Aerobic Microbial Count (TAMC) & Total Yeasts and Moulds Count (TYMC)) (aka Suitability of Counting Method) | <p>Method</p> <p>Procedure for validation of MCT should consist of:</p> <ul style="list-style-type: none"> - Method used (Plate Count, Membrane Filtration) - Preparation of test sample (including neutralizing of preservatives for samples that contain preservatives) |
| | | <p>Result (raw data)*</p> <ul style="list-style-type: none"> - Acceptance criteria: Mean count of any test organisms must not differ by a factor greater than 2 (50% – 200%) |
| 2. | Test for Specified Microorganism (aka Suitability of the test) | <p>Method</p> <p>Procedure for validation of Test for Specified Microorganism</p> |
| | | <p>Result (raw data)*</p> <ul style="list-style-type: none"> - Spiked microorganisms must be detected |

| Method for Routine Test | | |
|-------------------------|--|--|
| 1. | Total Viable Aerobic Count (Total Aerobic Microbial Count (TAMC) & Total Yeasts and Moulds Count (TYMC)) | <p>Procedure for Total Viable Aerobic Count should consist of:</p> <ul style="list-style-type: none"> - Method used (Plate Count, Membrane Filtration method). - Preparation of test sample (including neutralizing of preservatives for samples that contain preservatives) |
| 2. | Test for Specified Microorganism | Procedure for Test for Specified Microorganism |

*Raw data must comprise name and strength of product, type of media, batch no of product/media, types of microorganisms, date of test commencement and completion, observation in every interval period, wherever applicable. Actual data must be provided.

Updated : 29 June 2018