

Microbial Limits Test Harmonization

The United States Pharmacopeia (USP) and the European Pharmacopoeia (EP) have been harmonized so that each utilizes identical test methodologies. The most obvious change for the USP is that there are now two chapters dealing with Microbial Limits: USP<61>Microbial Examination of Nonsterile Products: Microbial Enumeration Tests, and USP<62>Microbiological Examination of Nonsterile Products: Tests for Specified Organisms.

There is a need for all companies utilizing Microbial Limits Testing to revalidate all products and raw materials under the harmonized MLT methods. This requires additional products with specific ingredients in itemized amounts and methods not seen in previous chapters.



Checklist for Harmonized Microbial Limit Testing

- | | |
|--|---|
| <input type="checkbox"/> Incubator | <input type="checkbox"/> Cetrimide Agar Medium |
| <input type="checkbox"/> Saboraud Dextrose Medium | <input type="checkbox"/> Mannitol Salt Agar Medium |
| <input type="checkbox"/> Saboraud Dextrose Agar | <input type="checkbox"/> Staphylococcus aureus – ATCC® 6538* |
| <input type="checkbox"/> Mossel Enterobacter Enrichment Broth | <input type="checkbox"/> Pseudomonas aeruginosa – ATCC® 9027* |
| <input type="checkbox"/> Violet Red Bile Glucose Agar Medium | <input type="checkbox"/> Bacillus subtilis – ATCC® 6633* |
| <input type="checkbox"/> MacConkey Broth | <input type="checkbox"/> Escherichia coli – ATCC® 8739* |
| <input type="checkbox"/> MacConkey Agar | <input type="checkbox"/> Salmonella enterica ssp typhimurium – ATCC® 14028* |
| <input type="checkbox"/> Potato Dextrose Agar | <input type="checkbox"/> Candida albicans – ATCC® 10231* |
| <input type="checkbox"/> Soybean – Casein Digest Agar | <input type="checkbox"/> Aspergillus niger – ATCC® 16404* |
| <input type="checkbox"/> Soybean – Casein Digest Broth | <input type="checkbox"/> Data for growth promotion of all media batches |
| <input type="checkbox"/> Rappaport Vassiliadis Salmonella Enrichment Broth | <input type="checkbox"/> Data for suitability of enumeration schemes |
| <input type="checkbox"/> Reinforced Medium for Clostridia | <input type="checkbox"/> Data for negative controls |
| <input type="checkbox"/> Columbia Agar Medium | <input type="checkbox"/> Review of product specifications |
| <input type="checkbox"/> Xylose-Lysine-Deoxycholate (XLD) Agar | |



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Remel has ALL of the media you need for the harmonized MLT methods.
The media has been formulated to meet or exceed harmonized USP specifications.

Harmonized Microbial Limits Test Media

| Test | Medium | Property | REF | Type/Fill |
|---|---|--|---|---|
| Test for Bile-tolerant Gram-negative Bacteria | Mossel Enterobacter Enrichment Broth | Nutritive for Escherichia coli and Pseudomonas aeruginosa; Selective for Staphylococcus aureus | R112281 R453332 | 100 ml Bottle 500 g |
| | Violet Red Bile Glucose Agar | Nutritive & Indicative for Escherichia coli and Pseudomonas aeruginosa | R110097 R455302 | 15x100 mm Plate 500 g |
| Test for Escherichia coli | MacConkey Broth | Nutritive for Escherichia coli and Selective for Staphylococcus aureus | R112456 R061336 R453822 | 100 ml Bottle 5ml Tube 500 g |
| | MacConkey Agar | Nutritive & Indicative for Escherichia coli | R09542 R01550 R453802 | 10 ml Tube Monoplate 500 g |
| Test for Salmonella entericasspythimurium | RappaportVassiliadisSalmonella Enrichment Broth | Nutritive for Salmonella enterica ssp typhimurium | R117661 R455432 | 10 ml Tube 500 g |
| | XLD Agar | Nutritive & Indicative for Salmonella enterica ssp typhimurium | R01980 R459902 | Monoplate 500 g |
| Test for Pseudomonas aeruginosa | Cetrimide Agar | Nutritive for Pseudomonas aeruginosa and Selective for Escherichia coli | R112040 R01292 R452802 | 200 ml Bottle Monoplate 500 g |
| Test for Staphylococcus aureus | Mannitol Salt Agar | Nutritive for Staphylococcus aureus and Selective for Escherichia coli | R01580 R453902 | Monoplate 500 g |
| Test for Clostridia | ReinforcedMediumforClostridia | Nutritive for Clostridium sporogenes | R112548 R455402 | 100 ml Bottle 500 g |
| | Columbia Agar Medium | Nutritive for Clostridium sporogenes | R110165 R455412 | Monoplate 500 g |
| TestforCandidaalbicans | Sabouraud Dextrose Broth | Nutritive for Candida albicans | R112558 R112559 | 990 ml Bottle 90 ml Bottle |
| | Sabouraud Dextrose Agar 5.6 | Nutritive & Indicative for Candida albicans | R112562 R01768 R112551 R454462 | 100 ml Bottle Monoplate 500 ml 500 g |

Harmonized Microbial Limits Test Enumeration Agars

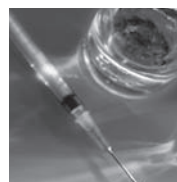
| Agar | Incubation Parameters | REF | Type/Fill |
|-------------------------------|------------------------------|--------------------|-----------------|
| Soybean – Casein Digest Agar | 30-35°C not more than 3 days | R112700 R455002 | 500 ml 500 g |
| Soybean – Casein Digest Broth | 30-35°C not more than 3 days | R112728 R455052 | 500 ml 500 g |
| Potato Dextrose Agar | 20-25°C not more than 5 days | R112535 R454312 | 500 ml 500 g |
| Sabouraud Dextrose Agar 5.6 | 20-25°C not more than 5 days | R112551 R454462 | 500 ml 500 g |



Harmonized Microbial Limits Test Specified Microorganisms

Remel has ALL of the specified ATCC® microorganisms needed to meet or exceed harmonized USP specifications.

| Organism | REF | Type/Fill |
|---|----------|---------------|
| Staphylococcus aureus – ATCC® 6538* | R4737016 | 10 Test/Kit |
| | R4717016 | 100 Tests/Kit |
| Escherichia coli – ATCC® 8739* | R4737085 | 10 Tests/Kit |
| | R4717085 | 100 Tests/Kit |
| Pseudomonas aeruginosa – ATCC® 9027* | R4735210 | 10 Tests/Kit |
| | R4715210 | 100 Tests/Kit |
| Salmonella entericasspythimurium – ATCC® 14028* | R4716000 | 100 Tests/Kit |
| Bacillus subtilis – ATCC® 6633* | R4731221 | 10 Tests/Kit |
| | R4711221 | 100 Tests/Kit |
| Candida albicans – ATCC® 10231* | R4731503 | 10 Tests/Kit |
| | R4711503 | 100 Tests/Kit |
| Aspergillus niger – ATCC® 16404* | R4731100 | 10 Tests/Kit |
| | R4711100 | 100 Tests/Kit |



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