

5.2.3 Routine Analysis and Suggested Acceptance Criteria, Table I

Acceptance Criteria for Microbiological Quality of Non-Sterile Dosage Forms

Route of Administration	Total Aerobic Microbial Count (cfu/g or cfu/mL)	Total Combined Yeasts/Moulds Count (cfu/g or cfu/mL)	Specified Microorganism(s)
Nonaqueous preparations for oral use	10 ³	10 ²	Absence of <i>Escherichia coli</i> (1 g or 1 mL)
Aqueous preparations for oral	10 ²	10 ¹	Absence of <i>Escherichia coli</i>

Route of Administration	Total Aerobic Microbial Count (cfu/g or cfu/mL)	Total Combined Yeasts/Moulds Count (cfu/g or cfu/mL)	Specified Microorganism(s)
use			(1 g or 1 mL)
Rectal use	10 ³	10 ²	—
Oromucosal use	10 ²	10 ¹	Absence of <i>Staphylococcus aureus</i> (1 g or 1 mL)
Gingival use			Absence of <i>Pseudomonas aeruginosa</i> (1 g or 1 mL)
Cutaneous use			
Nasal use			
Auricular use			
Vaginal use	10 ²	10 ¹	Absence of <i>Pseudomonas aeruginosa</i> (1 g or 1 mL)
			Absence of <i>Staphylococcus aureus</i> (1 g or 1 mL)
			Absence of <i>Candida albicans</i> (1 g or 1 mL)
Transdermal patches (limits for one patch including adhesive layer and backing)	10 ²	10 ¹	Absence of <i>Staphylococcus aureus</i> (1 patch)
			Absence of <i>Pseudomonas aeruginosa</i> (1 patch)
Inhalation use (special requirements apply to liquid preparations for nebulization)	10 ²	10 ¹	Absence of <i>Staphylococcus aureus</i> (1 g or 1 mL)
			Absence of <i>Pseudomonas aeruginosa</i> (1 g or 1 mL)
			Absence of bile-tolerant Gram-negative bacteria (1 g or 1 mL)

Note: When an acceptance criterion for microbiological quality is prescribed, it is interpreted as follows:

- 10¹ cfu: maximum acceptable count = 20;
- 10² cfu: maximum acceptable count = 200;
- 10³ cfu: maximum acceptable count = 2000; and so forth.