5.2 Microbiological Testing, According to the Harmonized Pharmacopoeia

5.2.1 Testing Frequency

5.2.1.1 Non aqueous preparations for oral use:

A risk assessment should be performed to determine the appropriate testing frequency based on the level of risk to the microbiological quality of the product. If the risk assessment demonstrates sufficiently low risk, no testing may be required. The risk assessment, with justification for the proposed testing frequency, must be documented and kept on file.

When testing is performed, excursions from compendial standards should be fully investigated and remedial action, including, where appropriate, revalidation and testing on a more frequent basis, should be undertaken. This is at the discretion of the local QA manager.

5.2.1.2 Prior to completion of the appropriate risk assessment(s), microbiological testing should be performed in accordance with Table I within PAR&D, and as deemed appropriate within Operation sites.

5.2.1.3 All other Non-sterile Dosage Forms:

Each lot of product should be tested for release, unless scientific justification that states otherwise is documented.

5.2.2 Method Development, Validation and Establishment

Results of validation, establishment and monitoring must be fully documented.

R&D is responsible for the establishment of Specifications and Product Specific Methods based on the Pharmacopoeial Standards, which can be converted to product specific methods at the manufacturing sites.

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 *Escherichia coli* (1 g or 1 mL)
Aqueous preparations for oral	10^2	10^1	Absence of *Escherichia coli*

