

5. MICROBIOLOGICAL ATTRIBUTES [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

Where appropriate, the microbiological attributes of the dosage form should be discussed including, for example, the rationale for not performing microbial limits testing for nonsterile products and the selection and effectiveness of preservative systems in products containing antimicrobial preservatives. If the product has inherent anti-microbial properties, these should be described here as well.

For sterile products, the integrity of the container closure system to prevent microbial contamination should be addressed. Preservative selection, level, and effectiveness should also be discussed.

If product is non-sterile, see Q6A Decision Tree #8.