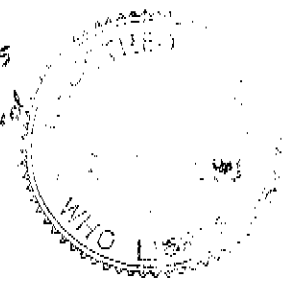




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STERILITY TESTS FOR NON-INJECTABLE PREPARATIONS

The methods are described under the "General requirements and test methods for drug dosage forms".¹

Certain dosage forms such as eye drops, ophthalmic ointments, ointments to be applied to damaged skin, etc., require specific sampling methods and preparation of samples.

For the membrane filtration method and for direct inoculation of the medium, determine the number of containers according to the sampling method proposed. The quantity taken should not be less than the minimum, and not more than the maximum quantity given below. The quantity used for each medium, which should be taken from the mixed sample, is also specified in the table.

Sampling		
Type of preparation	Total quantity to be pooled	Quantity to be used for each medium
Membrane filtration method		
aqueous solution	10 - 100 ml	5 - 10 ml
other preparations soluble in water, isopropyl myristate or other solvents	1 - 10 g	equivalent to 0.5 - 1 g
Direct inoculation method		
liquid preparations	10 - 100 ml	5 - 10 ml
soluble preparations	1 - 10 g	equivalent to 0.5 - 1 g
insoluble preparations to be suspended or emulsified, e.g. ointments	1 - 10 g	equivalent to 0.5 - 1 g

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Using the membrane filtration method the preparation of ointments or creams might additionally need heating up to 40 °C (or exceptionally up to 45 °C). The filtration should be processed as quickly as possible.

¹ Monograph for "Sterility tests" (WHO/PHARM/90.533/Rev.1).
