

## Sterility Test - Minimum Sample Requirements

\*Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

### *Parenteral Preparations*



Not more than 100 containers	10% or 4 containers, whichever is greater
More than 100 but not more than 500 containers	10 containers
More than 500 containers	2% or 20 containers, whichever is less
For large volume parenterals	2% or 10 containers, whichever is less

### *Ophthalmic and Other Noninjectable Preparations*

Not more than 200 containers	5% or 2 containers, whichever is greater
More than 200 containers	10 containers

If the product is presented in the form of single dose containers, apply the scheme shown above for preparations for parenteral use.



\*Source: USP - Sixth Interim Revision Announcement: STERILITY TESTS. The United States Pharmacopeial Convention, Rockville, MD, 2016, [www.usp.org/sites/default/files/usp/document/harmonization/gen-method/q11\\_pf\\_ira\\_34\\_6\\_2008.pdf](http://www.usp.org/sites/default/files/usp/document/harmonization/gen-method/q11_pf_ira_34_6_2008.pdf). Page 6-7. Table 3

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