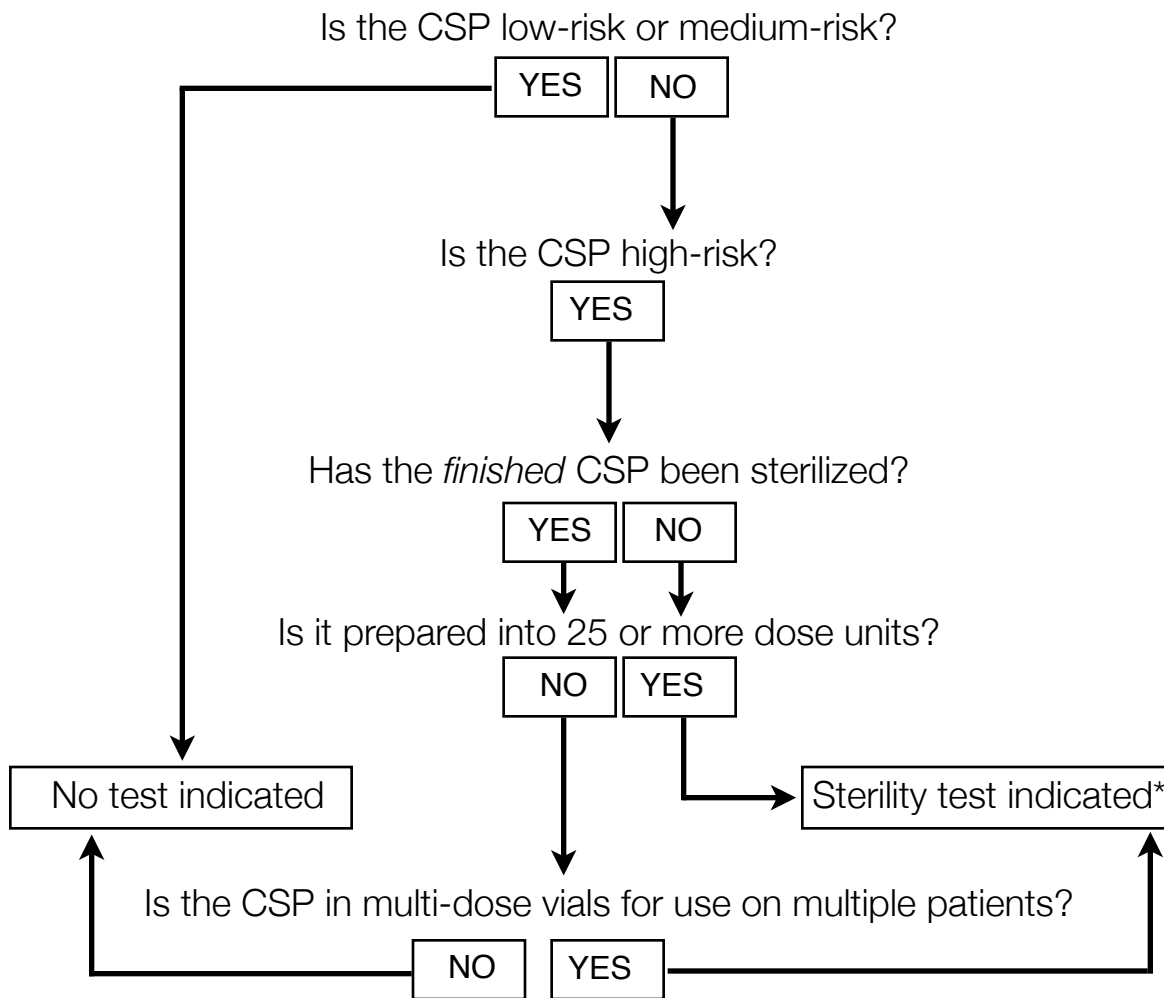


End Product Testing Algorithm USP <797>

Do I Perform a Sterility Test?



Do I Perform an Endotoxin Test?

Follow the same algorithm unless the CSP is intended for topical ophthalmic or inhalation use.

* This algorithm applies to finished CSPs that have not been exposed to temperatures of :
2-8 °C for longer than 12 hours or
> 8 °C for longer than 6 hours

If exposed to these conditions, a sterility test must meet criteria established in USP <71> Sterility Tests, or the beyond use date may not exceed the stated periods.

