

Annex 1 2022 Comparison Factsheet: Aseptic Preparation

The 2022 revision of Annex 1 now states that aseptic preparation of products should be clearly defined, with risks associated and control measures in place including monitoring and review, and well documented.

Line	Wording in 2022 Annex 1
910-912	8.7 Aseptic preparation and processing is the handling of sterile product, containers and/or devices in a controlled environment in which the air supply, materials and personnel are regulated to prevent microbial, pyrogenic and particulate contamination.
920-923	8.9 Precautions to minimize microbial, pyrogenic and particulate contamination should be taken, as per the site's CCS, during the preparation of the aseptic environment, during all processing stages (including the stages before and after bulk product sterilization), and until the product is sealed in its final container.



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