

Annex 1 2022 Comparison Factsheet: Water Treatment

The 2022 revision of Annex 1 now has an entire section on water treatment, which also refers to the Pharmacopoeia requirements, biofilms and water for injection (WFI).

Line	Wording in 2022 Annex 1
633-638	6.7 Water treatment plant and distribution systems should be designed, constructed and maintained to minimize the risk of particulates, microbial contamination/proliferation and pyrogens (e.g. sloping of piping to provide complete drainage and the avoidance of dead legs), and prevent the formation of biofilms to ensure a reliable source of water of an appropriate quality. Where filters are included in the system, special attention should be given to the monitoring and maintenance of these filters. Water produced should comply with the current monograph of the relevant Pharmacopoeia.
640-641	6.8 Water systems should be qualified to maintain the appropriate levels of physical, chemical and microbial control, taking seasonal variation into account.
657-659	6.12 To minimize the risk of biofilm formation, sterilization or disinfection or regeneration of water systems should be carried out according to a predetermined schedule and when microbial counts exceed action limits.
663-673	6.13 Regular ongoing chemical and microbial monitoring of water systems should be performed. Alert levels should be based on the qualification or a review of ongoing monitoring data that will identify an adverse trend in system performance. Sampling programs should reflect the requirements of the CCS and include: i. All points of use, at a specified interval, to ensure that representative water samples are obtained for analysis on a regular basis.ii. Potential worst case sampling locations. iii. A sample from the point at the end of the distribution loop each day that the water is used.



Email:
sales@cherwell-labs.co.uk



Website:
www.cherwell-labs.co.uk



Telephone:
01869 355500