

Water for Injection (WFI) in bulk

Water for Injection (WFI) by definition is water that is intended for use in the manufacture of medicines for parenteral administration whose solvent is water (WFI in bulk), or water that is used to dissolve or dilute substances or preparations for parenteral administration (heat-sterilised WFI). WFI in bulk from Biochrom AG is sterile-filtered and intended for *in vitro* use. WFI in bulk is suitable for use in the manufacture of media for biopharmaceutical production or for the manufacture of buffers. All solutions produced by Biochrom AG for cell culture and buffers are based on WFI in bulk water quality.

The sterile-filtered WFI in bulk from Biochrom AG is sterile-filtered and bottled aseptically in a class A cleanroom environment. It has very low conductivity and a very low concen-

tration of organic components (TOC, total organic carbon). In order to ensure that the water is of sufficient quality, in addition to the in-process monitoring of the electrical conductivity, the microbiological parameters are also regularly monitored, and the following parameters are amongst those that are determined: number of colony-forming units (CFU) of aerobic bacteria or the level of bacteria endotoxins. These WFI in bulk parameters are within the appropriate limits (see table 40, p 89).

Biochrom AG offers WFI in bulk for bioprocessing purposes delivered “just-in-time”, with a normal shelf life of 3 months. Appropriate single-use bags (10 – 1000 litres) are used to store, and ship the water.



Filling of the containers



Personnel lock