

Sterile liquids for industrial cell culture

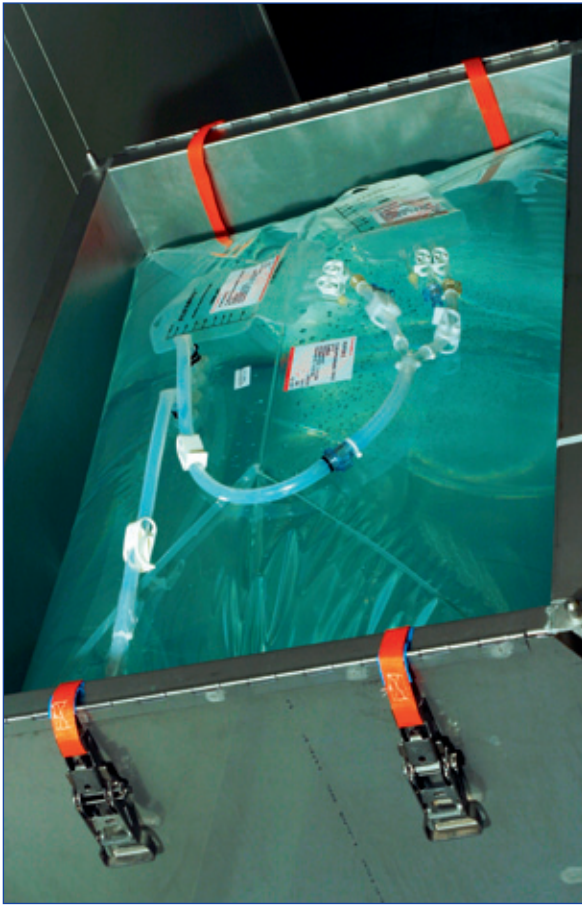
If media, buffer solutions, sodium hydroxide or Water for Injection (WFI): Biochrom AG produces standard catalogue products and custom-made products on industrial scale GMP-compliant. To strictly follow Good Manufacturing Practice requires validation, and documentation of all operational procedures, systems, functions, facilities, materials, and equipment. Biochrom AG has established Standard Operating Procedures (SOPs) for all its manufacturing procedures.

Biochrom's production of sterile cell culturing products is based on its source of highly purified water that meets the WFI in bulk specification of the European Pharmacopoeia and is sterile filtered. Production incorporates a rigorous specification and approval process that includes screening of all incoming related raw materials.



Any building and equipment used in the manufacture, processing, packing or holding of a pharmaceutical drug related product must be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. It is required that the building has adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, product containers, closures, labelling, in-process materials, and to prevent contamination. Operations must be performed within specifically defined areas of adequate size.

Biochrom's production fulfills the highest standards regarding clean room equipment, filtration technology, and production documentation, allowing the production of sterile solutions of up to 4000 litres and dry substances with a volume of up to 20000 litres. The packaging and shipping logistic is optimized according to the production of these charge sizes: corresponding to our customers' requests we also provide the products in PET plastic bottles or in sterile plastic bags with a volume of up to 1000 litres.



On request, we develop sampling systems and tube configurations on sterile bags according to your requirements. Send us a layout of the required sampling – we find the optimal solution, also for complicated requirements.

Ultra pure water for biopharmaceutical production

Biopharmaceutical production methods often require large quantities of “pharmaceutical-grade” ultra pure water. However, this water is only approved as Water for Injection (WFI) for the manufacture (direct or indirect) of medicines if it is of reproducible quality and satisfies the relevant specifications. Depending on local water quality, several processing



Many customers use the chance of „outsourcing“ and already let produce „their“ sterile solutions by Biochrom AG. Benefit from our experience of 30 years!

steps are required in order to manufacture pharmaceutical quality water from the raw material “drinking water”. The microbiological, chemical and physical parameters to be observed are specified in the European Pharmacopoeia (Ph. Eur.) and elsewhere. Validation of WFI manufacture, storage, and shipping is a legal requirement.

SERA

MEDIA

SEPARATING
SOLUTIONS

BUFFERS AND
SOLUTIONS

ULTRA PURE
WATER

ANTIBIOTICS

ENZYMES

CELL CULTURE
REAGENTS

CELL CULTURE
DIAGNOSTICS

CYTOKINES AND
GROWTH FACTORS

MYCOPLASMA
REAGENTS

CELL ATTACH-
MENT FACTORS

INDUSTRIAL
CELL CULTURE