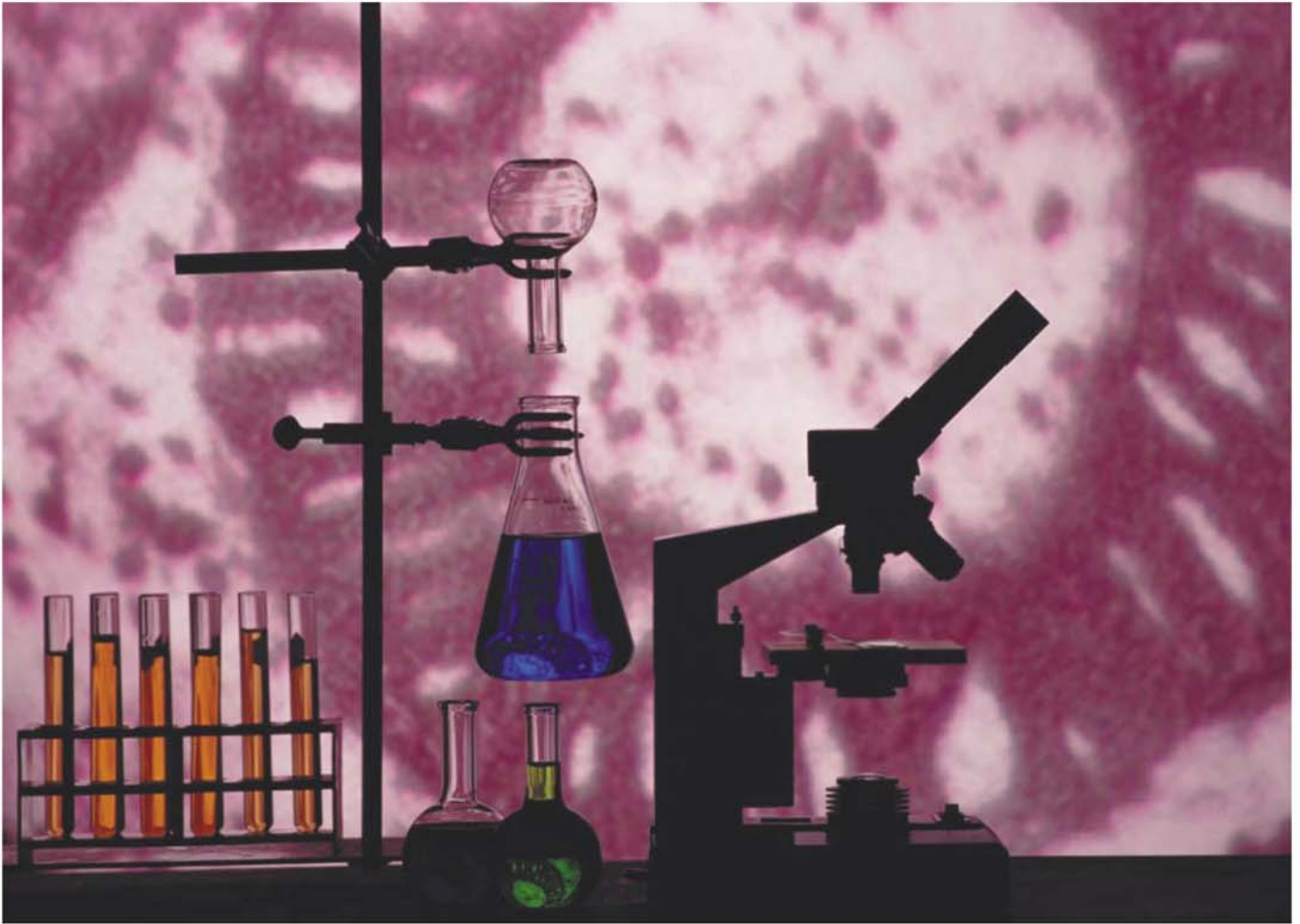


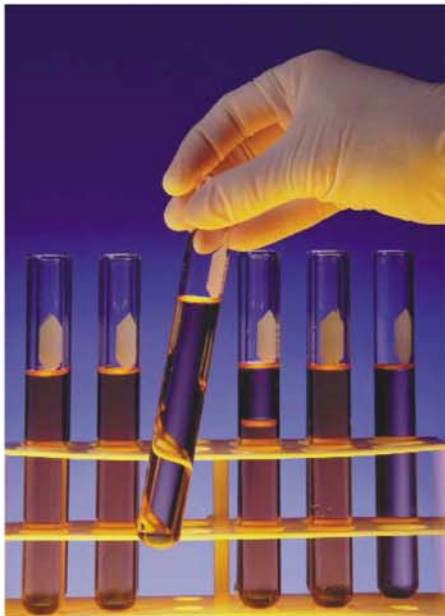


**PROCESS FILTRATION APPLICATIONS
PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES**

**Donaldson®
Ultrafilter®**



Ultrafilter in the pharmaceutical industry and the biotechnology

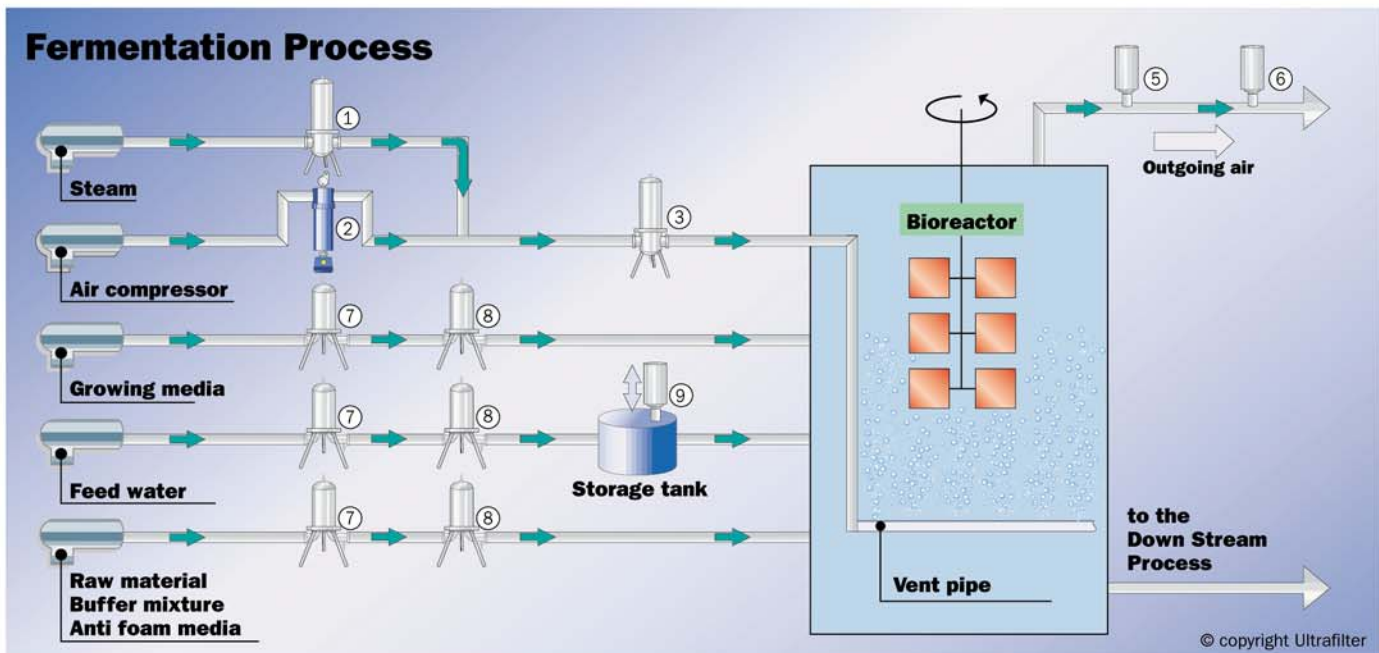


Infusion solvents, serums, vaccines, plasma. These are only some of the products of the pharmaceutical industry that are produced to meet the highest standards concerning quality and purity. **Ultrafilter** offers filter systems which have been developed to match the requirements of the pharmaceutical industry and biotechnology for numerous applications. In order to ensure consistent quality of the final products the entire manufacturing process must be free from any contamination. This aim is reached in a reliable, safe and cost efficient way by **Ultrafilter** membrane filters.

Air and gas filtration

The compressed air in fermentation processes is filtered before it is added to the fermenter through the vent pipe. Nitrogen which is used for pressurizing tanks should also be free from bacteria, pyrogenes and any other particles before it comes in contact with the final product. **Ultrafilter** sterile air filters distinguish themselves by their inherent hydrophobia, a high dirt hold capacity and a low differential pressure. The validated sterile depthfilter P-SRF as well as the membrane filters ultrapolymem® and ultrateflomem® meet the highest quality requirements and have been proven their performance in thousands of applications.

The fermentation process shown in picture 10 shows how **Ultrafilter** filters are used in this application.



Pic. 10: Fermentation process

Filter no.	Application	Recommended ultrafilter filter	Pore size	Page
1	Steam filter for sanitation	Ultrax P-GS	1–25 µm	48
2	Pre filter (air)	Ultradept SMF	0.01 mg/m ³	70
3	Sterile filter	Ultradept II P-SRF Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.99998% 0.1–0.2 µm 0.1–0.2 µm	44 40 42
5 + 6 9	De-aeration of fermentation exhaust air Venting of storage tank	Ultradept II P-BE Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.999% 0.1–0.2 µm 0.1–0.2 µm	46 40 42
7	Prefiltration	Ultrapolyplea P-PP Ultrapolyplea P-PP100	0.2–1 µm 0.8–2.4 µm	32 34
8	Sterile filtration	Ultrasulfomem P-PF-PES	0.1–0.2 µm	38

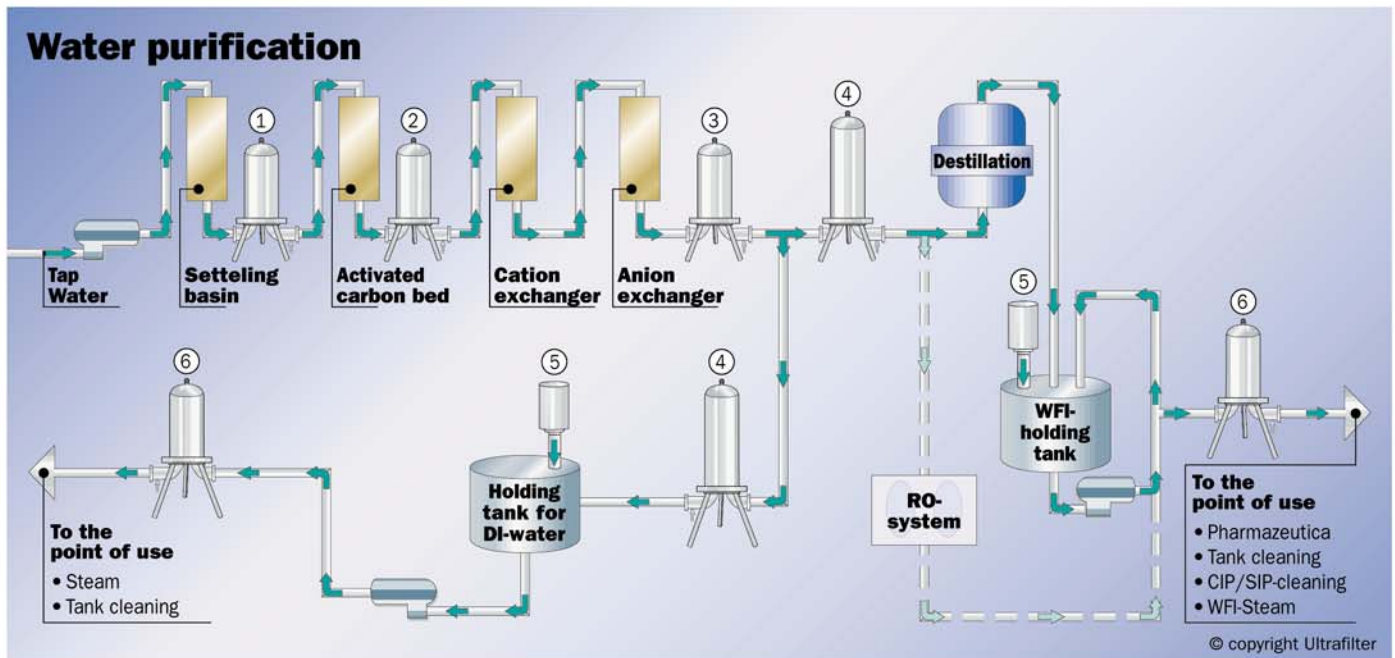
Water filtration

There are two relevant standards concerning the water quality for the pharmaceutical and biotechnology industry:

- WFI, water for injection: This water meets the highest level of requirements. It is used for the adjustment of product concentration, for the production of WFI steam, and for the cleaning of ampoules or vials.
- PW, purified water or deionized water (DI-water) is mainly used for cleaning of bottles and ampoules or as a supply for fermenters. It is also an addition to lotions, creams and used in the production of purest steam for sterilization.

For the production of these water qualities **Ultrafilter** offers the asymmetrical polyethersulfone membrane with retention rates down to 40 Nanometers (= 0.04 µm). This filter medium is characterized by substantially high flow rates and a low differential pressure.

Compared to traditional filter media the differential pressure is 4 to 8 times lower! For the end-user this means the highest safety at low filtration costs. Picture 11 shows a typical process of sterile water treatment.



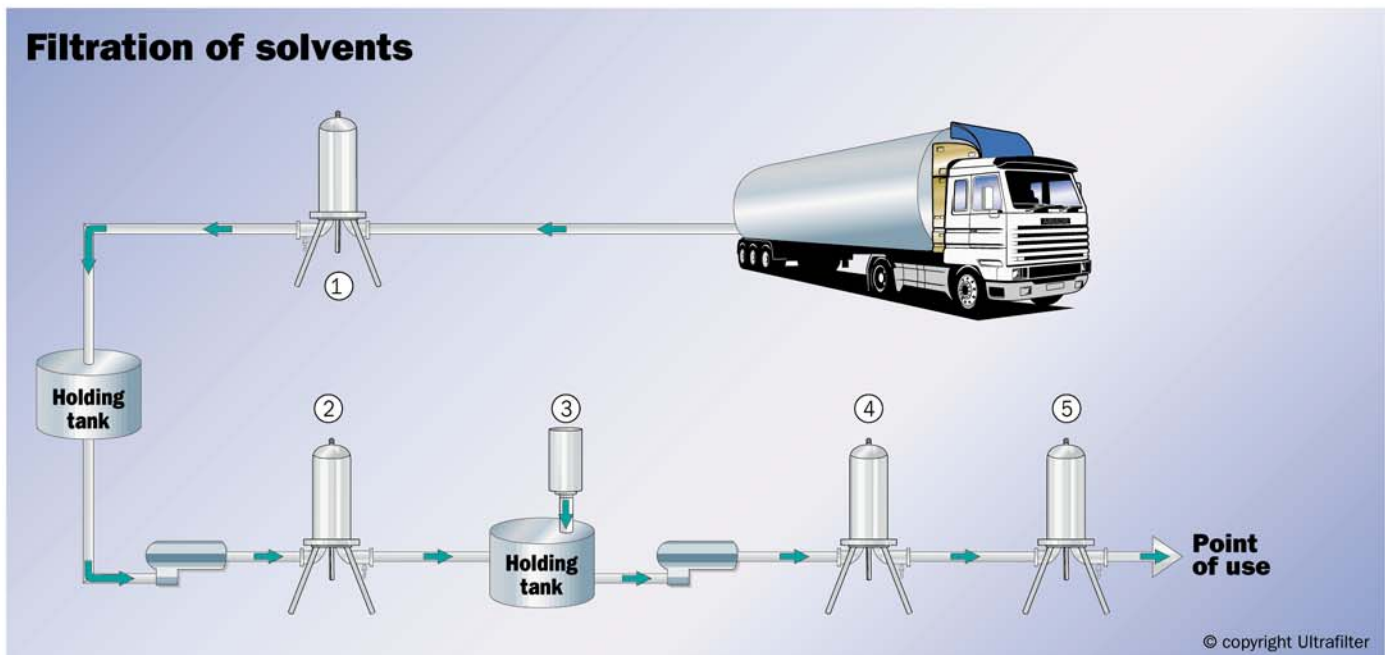
Pic. 11: Refining of water

Filter no.	Application	Recommended ultrafilter filter	Pore size	Page
1	Course particle retention	Ultrapolyplea P-PP	30 µm	32
2	Course particle retention	Ultrapolyplea P-PP	10–30 µm	32
3	Pyrogen reduction and fine particle retention	Ultrapolyplea P-PP Ultrapolyplea P-PP100	0.2–1 µm 0.45–1.2 µm	32 34
4	Sterile filtration of DI-water	Ultrasulfomem P-PF-PES	0.2 µm	38
5	Sterile aeration and de-aeration Venting	Ultradept II P-BE Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.999% 0.1–0.2 µm 0.1–0.2 µm	46 40 42
6	Sterile filter	Ultrasulfomem P-PF-PES	0.04–0.2 µm	38

Chemicals and solvents

Apart from water, chemicals and solvents are important complementary materials in the production of pharmaceutical and biotechnical products. Alcohols, acetones and methylene chlorid are the most frequently used products. All these chemicals are aggressive and therefore the filtration systems have to be adjusted to meet these requirements as well as the usual filtration quality.

Picture 12 shows the filtration of chemicals from raw materials to the final product which the consumer will receive. The following tabulation lists those **Ultrafilter** products which are recommended for filtration to ensure a highly efficient and consistant quality, even in the event that the quality of the raw materials should fluctuate.



Pic. 12: Filtration of solvents/chemicals

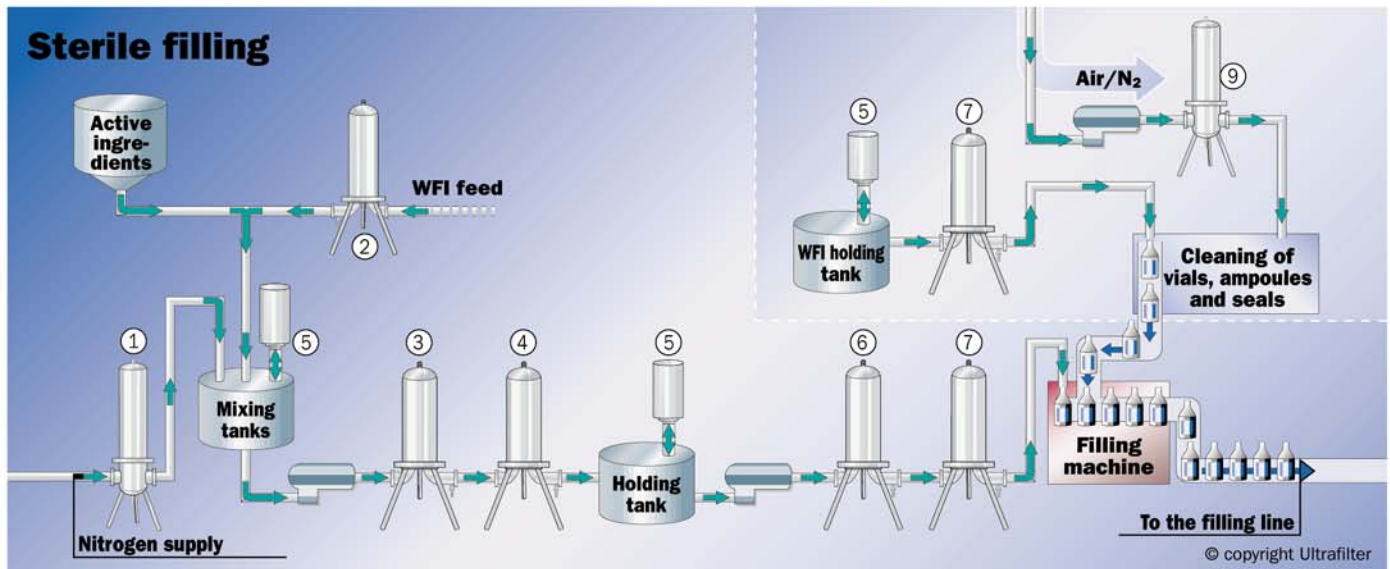
Filter no.	Application	Recommended ultrafilter filter	Pore size	Page
1	Prefiltration of the raw materials	Ultrapolyplea P-PP	30 µm	32
2	Fine filtration	Ultrapolyplea P-PP Ultrapolyplea P-PP100	5–10 µm 3–10 µm	32 34
3	Container de-aeration	Ultradept II P-BE Ultrateflomem P-PF-PT Ultrapolyplea P-PP100	0.01 µm up to 99.999% 1 µm 5–10 µm	46 42 34
4	Pre-filtration	Ultrapolyplea P-PP100	0.8–2.4 µm	34
5	Sterile filtration	Ultrasulfomem P-PF-PES Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.1–0.2 µm 0.1–0.2 µm 0.1–0.2 µm	38 40 42

Sterile filling of pharmaceutical and biological products

Filtration by membrane guarantees sterility in filling pharmaceutical products. This ensures an efficient retention of pyrogenes, living microorganisms and particles at a maximum flow rate. As a prefilter for protecting the membranes ultrapolyplea® depth filters are used. These filter elements have a high dirt hold capacity and low extractables. In storage and holding tanks hydrophobic **Ultrafilter** aeration and de-aeration filters guarantee sterile conditions for storing the sensitive products and exclude a contamination by the ambient air.



The following picture (picture 13) shows the process of sterile filling and the **Ultrafilter** products designed for it.



Pic. 13: Sterile filling

Filter no.	Application	Recommended ultrafilter filter	Pore size	Page
1	Sterile filtration of nitrogen (N ₂)	Ultradept II P-SRF Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.99998% 0.1–0.2 µm 0.1–0.2 µm	44 40 42
2	Sterile filtration	Ultrasulfomem P-PF-PES	0.1–0.2 µm	38
3 + 6	Prefilter	Ultrapolyplea P-PP100	0.8–2.4 µm	34
4 + 7	Sterile filter	Ultrasulfomem P-PF-PES	0.1–0.2 µm	38
5	Sterile aeration and de-aeration of tanks	Ultradept II P-BE Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.999% 0.1–0.2 µm 0.1–0.45 µm	46 40 34
8	Sterile filtration of water for the cleaning of vials/ampoules	Ultrasulfomem P-PF-PES	0.1–0.2 µm	38
9	Nitrogen/air for drying of vials/ampoules	Ultradept II P-SRF Ultrapolymem P-PF-PP Ultrateflomem P-PF-PT	0.01 µm up to 99.99998% 0.1–0.2 µm 0.1–0.2 µm	44 40 42

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