Claims:

1. Unit for continuous ultrafiltration of a product stream which contains biopharmaceutical and biological macromolecular products, comprising at least one capillary ultrafiltration module, characterized in that
   - at least one pump conveys the product stream into the capillaries of the ultrafiltration module,
   - a positive displacement pump conveys the product stream from the capillaries and
   - at least one further pump passes the washing fluid over the outside of the capillaries,
   - the unit includes no measure for circulating the product stream and the washing fluid into the ultrafiltration module.

2. Unit according to Claim 1, comprising a means for controlled removal of the washing fluid from the ultrafiltration module used.

3. Unit according to one of Claims 1 or 2, characterized in that several capillary ultrafiltration modules are connected in series or in parallel.

4. Method for continuous ultrafiltration of a feed stream containing biopharmaceutical and biological macromolecular products in the unit for continuous ultrafiltration, characterized in that the feed stream is washed with a washing fluid via at least one capillary ultrafiltration membrane of a capillary ultrafiltration module, in that the feed stream is conveyed into the capillary and the washing fluid is conveyed over the outside of the capillary, in that the feed stream and the washing fluid are continuously fed into the ultrafiltration module, and is continuously removed from the ultrafiltration module, in that the feed stream and the washing fluid is not circulated into the ultrafiltration module and the removal of the product stream is regulated such that no undesired net flows can pass from the capillary interior to the capillary exterior or vice versa.

5. Method according to Claim 4, characterized in that in the unit for continuous ultrafiltration the product in the feed stream is at most concentrated by a factor of 2 or diluted by a factor of 2.

6. Method according to one of Claims 4 or 5, characterized in that the washing fluid is passed in cross-current or countercurrent, preferably in countercurrent, to the feed stream.

7. Method according to one of Claims 4 to 6, characterized in that several capillary ultrafiltration modules in series or in parallel and the maximum pressure drop over the membranes of the capillary ultrafiltration modules does not exceed 1 bar.

8. Production plant, comprising at least one unit for continuous ultrafiltration of a product stream containing biopharmaceutical and biological macromolecular products according to one of Claims 1 to 3.

9. Production plant according to Claim 8, further comprising at least one concentration unit connected with the unit for continuous ultrafiltration.

10. Production plant according to Claim 9, characterized in that the concentration unit comprises:
- a pump for conveying the product stream into a concentration loop comprising one or more membrane modules with a permeate outlet, a pump for circulation in the concentration loop and a deaeration bag, and
- a pump for conveying the protein-containing solution out of the concentration loop
- alternatively a pump for flow through a single-use, single-pass membrane module.

Claims

1. Unit for continuous ultrafiltration of a product stream which contains biopharmaceutical and biological macromolecular products, comprising at least one capillary ultrafiltration module, characterized in that
   - at least one pump conveys the product stream (=feed) into the capillaries of the ultrafiltration module,
   - a positive displacement pump conveys the product stream from the capillaries and
   - at least one further pump passes a washing fluid over the outside of the capillaries,
   - the unit includes no measure for circulating the product stream and the washing fluid into the ultrafiltration module and
   - the ultrafiltration unit is bubble free on both the feed side and the jacket side via a priming procedure in which both the feed side and the jacket side are flushed with buffer solution until no more gas bubbles escape from the dialysis module.

2. Unit according to Claim 1, comprising a means for controlled removal of the washing fluid from the ultrafiltration module used.

3. Unit according to one of Claims 1 or 2, characterized in that several capillary ultrafiltration modules are connected in series or in parallel.

4. Method for continuous ultrafiltration of a feed stream containing biopharmaceutical and biological macromolecular products in the unit for continuous ultrafiltration, characterized in that the feed stream is washed with a washing fluid via at least one capillary ultrafiltration membrane of a capillary ultrafiltration module, in that the feed stream is conveyed into the capillary and the washing fluid is conveyed over the outside of the capillary, in that the feed stream and the washing fluid are continuously fed into the ultrafiltration module, and is continuously removed from the ultrafiltration module, in that the feed stream and the washing fluid is not circulated into the ultrafiltration module and the removal of the product stream (comprising the retentate) is regulated such that no undesired net flows can pass from the capillary interior to the capillary exterior or vice versa and wherein the ultrafiltration module is bubble freeon both the feed side and the jacket side via a priming procedure in which both the feed side and the jacket side are flushed with buffer solution until no more gas bubbles escape from the dialysis module.

5. Method according to Claim 4, characterized in that in the unit for continuous ultrafiltration the product in the feed stream is at most concentrated by a factor of 2 or diluted by a factor of 2.

6. Method according to one of Claims 4 or 5, characterized in that the washing fluid is passed in cross-current or countercurrent, preferably in countercurrent, to the feed stream.

7. Method according to one of Claims 4 to 6, characterized in that several capillary ultrafiltration modules in series or in parallel and the maximum pressure drop over the membranes of the capillary ultrafiltration modules does not exceed 1 bar.

8. Production plant, comprising at least one unit for continuous ultrafiltration of a product stream containing biopharmaceutical and biological macromolecular products according to one of Claims 1 to 3.

9. Production plant according to Claim 8, further comprising at least one concentration unit connected with the unit for continuous ultrafiltration.

10. Production plant according to Claim 9, characterized in that the concentration unit comprises:
    - a pump for conveying the product stream into a concentration loop comprising one or more membrane modules with a permeate outlet, a pump for circulation in the concentration loop and a deaeration bag, and
    - a pump for conveying a protein-containing solution out of the concentration loop
    - alternatively a pump for flow through a single-use, single-pass membrane module.