

least ~~about~~ 24 hours through a virus filter having an effective pore size of maximum 75 nm, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 2000 L/m².

[0012] In one aspect, there is provided use of a virus filter having an effective pore size of maximum 75 nm in a filtration for at least ~~about~~ 24 hours for the removal of viral contaminant from a preparation, said preparation being a cell culture medium or at least one component of a cell culture medium, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 2000 L/m².

[0013] Also disclosed is the use of a preparation, being a cell culture media or at least a component of a cell culture media obtainable according to any method of the present disclosure for cell culture; pharmaceutical, diagnostic and/or cosmetic preparations as well as in food preparations.

[0014] All methods and uses according to the disclosure can operate at a volumetric capacity of at least about 2000 L/m², preferably at least about 3000 L/m², most preferably at least about 5000 L/m². In addition, the preparation is subjected to filtration and the filtration is performed, respectively, for at least 24 hours or for at least about 48 hours up to about 7 months or about 72 hours up to about 3 months. The filtration is performed at a temperature from about 2 °C to about 60 °C, or about 10 to about 40 °C, preferably about 15 to about 37°C.

[0015] In all embodiments of the disclosure filtration is performed at a pressure ranging from about 100 mbar to about 4000 mbar, preferably from about 200 mbar to about 3500 mbar, most preferably from about 1000 mbar to about 3000 mbar.

[0016] In all embodiments of the disclosure the used virus filter achieves at least a 1Log₁₀ reduction value (LRV) for a viral contaminant.

[0017] Surprisingly, it has been found that the volumetric capacity of virus filters can be enormously increased when operating the filtration process for at least about 24 hours. Normally, preparations for cell culture e.g. bulk cell culture media or buffers are filtered batchwise within about 2 to about 10 hours after preparation of the bulk preparations in order to avoid contamination of the preparations by bacterial or viral growth. It has turned out that in practice the maximum capacity of the used virus filters is not nearly exploited in filtration processes filtering the respective preparations within a timeframe of about 2 to about 10 hours. Therefore excessive

CLAIMS

1. A method for removing a viral contaminant from a preparation, said preparation being a cell culture medium or at least a component of a cell culture medium, comprising subjecting said preparation to filtration for at least ~~about~~ 24 hours through a virus filter having an effective pore size of maximum 75 nm, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 2000 L/m².

2. The method of claim 1, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 3000 L/m².

3. The method of claim 2, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 5000 L/m².

4. The method of any one of claims 1-3, wherein said preparation is subjected to filtration for at least ~~about~~ 48 hours up to ~~about~~ 7 months.

5. The method of claim 4, wherein said preparation is subjected to filtration for at least ~~about~~ 72 hours up to ~~about~~ 3 months.

6. The method of any one of claims 1-5, further comprising feeding the filtrate to a cell culture or to at least one component of a cell culture medium.

7. The method of any one of claims 1-6, wherein the filtration is a continuous filtration.

8. The method of any one of claims 1-7, wherein filtration is performed at a temperature from ~~about~~ 2 °C to ~~about~~ 60 °C.

9. The method of claim 8, wherein the filtration is performed at a temperature from ~~about~~ 10

°C to ~~about~~ 40 °C.

10. The method of claim 9, wherein the filtration is performed at a temperature from ~~about~~ 15 °C to ~~about~~ 37°C.

11. The method of any one of claims 1-10, wherein said virus filter achieves at least a 1 Log₁₀ reduction value (LRV) for a viral contaminant.

12. The method of claim 11, wherein said virus filter achieves at least a 4 LRV for a viral contaminant.

13. The method of claim 12, wherein said virus filter achieves at least a 6 LRV for a viral contaminant.

14. The method of any of claims 1-13 where filtration is performed using two or more filters arranged in series, in parallel or a mixture of both.

15. The method of claim 14, wherein filtration is performed using two filters arranged in parallel in a system of tubes comprising a Y-shaped junction and wherein each filter is in fluid communication with a branch of the Y-shaped junction and a preparation supply source.

16. The method of any of claims 1-15, wherein filtration is performed at a pressure ranging from ~~about~~ 100 mbar to ~~about~~ 4000 mbar.

17. The method of claim 16, wherein the filtration is performed at a pressure ranging from ~~about~~ 100 mbar to ~~about~~ 3500 mbar.

18. The method of claim 17, wherein the filtration is performed at a pressure ranging from ~~about~~ 1000 mbar to ~~about~~ 3000 mbar.

19. The method of any of claims 1-18, wherein said virus filter is autoclavable.

20. The method of any of claims 1-19, wherein the cell culture medium comprises soy hydrolysate.

21. Use of a virus filter having an effective pore size of maximum 75 nm in a filtration for at least 24 hours for the removal of viral contaminant from a preparation, said preparation being a cell culture medium or at least one component of a cell culture medium, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 2000 L/m².

22. The use of claim 21, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 3000 L/m².

23. The use of claim 22, wherein the filtration operates at a volumetric capacity of at least ~~about~~ 5000 L/m².

24. The use of any one of claims 21-23, wherein filtration is performed for at least ~~about~~ 48 hours up to ~~about~~ 7 months.

25. The use of claim 24, wherein said preparation is subjected to filtration for at least ~~about~~ 72 hours up to ~~about~~ 3 months.

26. The use of any one of claims 21-25, wherein the filtration is a continuous filtration.

27. The use of any one of claims 21-26, wherein filtration is performed at a temperature range from ~~about~~ 2 °C to ~~about~~ 60 °C.

28. The use of claim 27, wherein the filtration is performed at a temperature from ~~about~~ 10 °C to ~~about~~ 40 °C.

29. The use of claim 28, wherein the filtration is performed at a temperature from ~~about~~ 15 °C to ~~about~~ 37°C.

30. The use of any one of claims 21-29, wherein said virus filter achieves at least a 1 Log₁₀ reduction value (LRV) for a viral contaminant.
31. The use of claim 30, wherein said virus filter achieves at least a 4 LRV for a viral contaminant.
32. The use of claim 31, wherein said virus filter achieves at least a 6 LRV for a viral contaminant.
33. The use of any one of claims 21-30, where filtration is performed using two or more filters arranged in series, in parallel or a mixture of both.
34. The use of claim 33, wherein filtration is performed using two filters arranged in parallel in a system of tubes comprising a Y-shaped junction and wherein each filter is in fluid communication with a branch of the Y-shaped junction and a preparation supply source.
35. The use of any one of claims 21-34, wherein filtration is performed at a pressure ranging from ~~about~~ 100 mbar to ~~about~~ 4000 mbar.
36. The use of claim 35, wherein the filtration is performed at a pressure ranging from ~~about~~ 100 mbar to ~~about~~ 3500 mbar.
37. The use of claim 36, wherein the filtration is performed at a pressure ranging from ~~about~~ 1000 mbar to ~~about~~ 3000 mbar.
38. The use of any one of claims 21-37, wherein said virus filter is autoclavable.
39. The use of any one of claims 21-38, wherein the cell culture medium comprises soy hydrolysate.