

filter area has to be used. In contrast thereto, it has been found that due to the use of the method of the present disclosure, the volumetric capacity of the used costly virus filters can be better exploited leading to a 2 to 100-fold increase of the volumetric capacity while maintaining the filter integrity. Although a 2 to 3-fold increase of volumetric capacity already has a great impact to the production process and the related production costs, with the method according to the disclosure an up to 100-fold increase or even more can be achieved. This offers great opportunities and makes viral removal cost efficient even with costly virus filters that now can be used to further improve viral safety in cell culture processes, in particular in upstream viral removal of cell culture processes, pharmaceutical, diagnostic and/or cosmetic and food processes.

[0017a] In one aspect, the present disclosure provides an apparatus comprising a bioreactor and a virus filter, wherein the virus filter is inline of the medium feed line of the bioreactor, wherein the virus filter has an effective pore size of maximum 75 nm, and wherein the virus filter is for removing a viral contaminant from a preparation, said preparation being a cell culture medium or at least one component of a cell culture medium, and wherein the apparatus has a volumetric capacity of at least 2000 L/m².

[0017b] In another aspect, the present disclosure provides a method comprising utilizing a cell culture medium for preparing a cell culture, a pharmaceutical preparation, a diagnostic preparation, a cosmetic preparation or a food preparation, wherein the cell culture medium is prepared by a method comprising:

a) subjecting a preparation to filtration for at least 24 hours through a virus filter having an effective pore size of maximum 75 nm, wherein the preparation is a cell culture medium or at least one component of a cell culture medium, and wherein the filtration operates at a volumetric capacity of at least 2000 L/m².

[0018] Specific preferred examples of the present disclosure will become evident from the following more detailed description of certain examples and the claims.

CLAIMS

1. An apparatus comprising a bioreactor and a virus filter, wherein the virus filter is inline of the medium feed line of the bioreactor, wherein the virus filter has an effective pore size of maximum 75 nm, and wherein the virus filter is for removing a viral contaminant from a preparation, said preparation being a cell culture medium or at least one component of a cell culture medium, and wherein the apparatus has a volumetric capacity of at least 2000 L/m².
2. The apparatus of claim 1, wherein the bioreactor is a chemostat reactor, a perfusion reactor, or a fed batch reactor.
3. The apparatus of any of claims 1-2, wherein the filter comprises two or more filters arranged in series, in parallel, or both.
4. The apparatus of claim 3, wherein the filter comprises 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.
5. The apparatus of any of claims 1-4, wherein the virus filter is autoclavable.
6. The apparatus of any of claims 1-5, wherein the cell culture medium is a cell culture medium comprising a soy hydrolysate or a cell culture medium comprising animal derived components.
7. A method comprising utilizing a cell culture medium for preparing a cell culture, a pharmaceutical preparation, a diagnostic preparation, a cosmetic preparation or a food preparation, wherein the cell culture medium is prepared by a method comprising:
 - a) subjecting a preparation to filtration for at least 24 hours through a virus filter having an effective pore size of maximum 75 nm, wherein the preparation is a cell culture

medium or at least one component of a cell culture medium, and wherein the filtration operates at a volumetric capacity of at least 2000 L/m².

8. The method of claim 7, wherein the filtration operates at a volumetric capacity of at least 3000 L/m², or at least 5000 L/m².
9. The method of any of claims 7-8, wherein the preparation is subjected to filtration for at least 48 hours to 7 months, or for at least 72 hours to 3 months, or for at least 10 days to 2 months.
10. The method of any of claims 7-9, wherein the cell culture medium is prepared by a method further comprising:
 - b) feeding the filtrate to a cell culture medium or to at least one component of a cell culture medium.
11. The method of any of claims 7-10, wherein the filtration is a continuous filtration.
12. The method of any of claims 7-11, wherein the filtration is performed at a temperature of from 2°C to 60°C, or from 10 °C to 40°C, or from 15°C to 37°C.
13. The method of any of claims 7-12, wherein the virus filter achieves at least a 1 Log₁₀ reduction value (LRV) for a viral contaminant, or at least a 4 Log₁₀ reduction value (LRV) for a viral contaminant, or at least a 6 Log₁₀ reduction value (LRV) for a viral contaminant.
14. The method of claim 13, wherein the viral contaminant is a member of the viral family of Orthomyxoviridae, Arenaviridae, Paramyxoviridae, Rhabdoviridae, Coronaviridae, Flaviviridae, Picornaviridae, Togaviridae, Arteriviridae, RetParvoviridae, Bunyaviridae, Caliciviridae, Retroviridae, Circoviridae, Adenoviridae, Poxviridae, Herpesviridae, Iridoviridae or Reoviridae.

15. The method of any of claims 7-14, wherein the filtration is performed using two or more filters arranged in series, in parallel, or both.
16. The method of claim 15, wherein the 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.
17. The method of any of claims 7-16, wherein the filtration is performed at a pressure ranging from 100 mbar to 4000 mbar, or from 100 mbar to 3500 mbar, or from 1000 mbar to 3000 mbar, or from 1000 mbar to 2000 mbar.
18. The method of any of claims 7-17, wherein the virus filter is autoclavable.
19. The method of any of claims 7-18, wherein the cell culture medium comprises soy hydrolysate.