



Virus Contamination through Upstream Virus Filtration in Bio-Manufacturing Method

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DESCRIPTION

Medical progress as enabled by early plasma products has also revealed biological safety challenges. The combination of donor selection, donation testing and virus reduction processes has effectively addressed these concerns, and today medicinal plasma products feature significant safety margins. The safety tripod concept has since been adapted to biotechnology manufacturing platforms and has also ensured the safety of these products. However, cell-based manufacturing processes have occasionally been exposed to adventitious viruses, leading to manufacturing interruptions and unstable supply situations. The rapid progress of advanced therapy medicinal products (ATMPs) needs an innovative approach to ensure the learning's from more traditional biotechnology help to avoid any unwelcome reminder of the universal presence of viruses. The introduction of up-stream virus clearance steps has already been shown to be valuable for any products too complex for down-stream interventions in the sense of both assuring product safety and continuous supply. The experiments investigated the feasibility of implementing culture media virus filtration with respect to their virus clearance capacities under extreme conditions such as very high process feed loading, very long duration, and multiple process interruptions. Minute virus of mice (MMV) was used as a relevant target virus, and in general, as a model small non-enveloped virus, as these viruses are the main challenge for the investigated virus filters with a stipulated pore-size of about 20 nm. It was found that certain filters especially of the newer 2nd generation are capable of effective virus clearance despite the harsh regimen they were subjected to. At the same time the investigation of biochemical parameters for un-spiked control runs showed the filters to have no measurable impact on the composition of the culture media. Based on these findings, this technology seems to be quite feasible for large volume pre-manufacturing process culture media preparations. However, for active ("live") biopharmaceuticals, such as live virus vaccines, or Advanced Therapy Medi-

nal Products (ATMPs) like cellular therapies and gene therapies, dedicated viral clearance procedures cannot always be applied to the down-stream processes as they would not only inactivate or remove potentially present viral contaminations but equally compromise activity of the biopharmaceutical ingredient. This is especially true for virus filtration, one of the most robust and effective viral clearance procedures that can conceptually remove all pathogens larger than the stipulated pore-size of the filter. Unfortunately, for most live virus vaccines or ATMPs the therapeutic biomolecule is also larger, and thus effective virus clearance is not possible. Furthermore, some large biomolecules, such as von Wille brand Factor (VWF) complexes cannot pass through the smallest type of virus filters which are suitable for the removal of e.g. Parvovirus without significant losses or severe clogging events due to the nature of the molecules.

The production processes of biopharmaceutical products based on eucaryotic expression systems carry an intrinsic risk for viral contaminations. An industry wide data collection of such contamination events revealed that contamination sources were traced primarily to raw materials or cell culture media including specific components thereof, like FBS. Traditionally, to mitigate this risk, the safety tripod concept is applied. The raw materials used in manufacturing of biopharmaceuticals are selected for low risk, under consideration of viral safety aspects, raw materials are tested for potential viral contaminants, and most importantly the main proportion of safety margins is achieved through virus inactivation or removal steps integrated in the "down-stream" manufacturing process.

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CONFLICT OF INTEREST

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