

Comparative Evaluation of Sterile Filters in Biopharmaceutical Processes

Dongwoo Baek*

School of Chemical and Biological Engineering, College of Engineering, Institute of Chemical Process (ICP), Seoul National University (SNU), Seoul, Korea

Editorial

Sterile filtration processes are broadly utilized in the creation of biotherapeutics for microorganism expulsion and item sterility. Sterile filtration cycles can be applied to cushion readiness and cell culture media arrangement in biotherapeutics processes, and to definite sanitization or last filling in downstream cycles. Attributable to their wide scope of utilizations in bioprocessing, different 0.2/0.22 μm sterile channels with various polymer materials and ostensible pore sizes are economically accessible.

Sterile filtration processes are broadly utilized in the creation of biotherapeutics like monoclonal antibodies (mAbs) or recombinant DNA-determined proteins. In biotherapeutics creation, sterile filtration is utilized in cradle and cell culture media arrangements for eliminating undesired microorganisms. In downstream cycles, sterile filtration in the last step, called last filling, is performed to guarantee item sterility. Last filling is liked over warm disinfection as it guarantees item steadiness. Contingent upon the application, sterile channels with an ostensible pore size of 0.1/0.2 μm are utilized in sterile filtration. For example, 0.1 μm channels are utilized for prefiltration, before infection filtration for protein total expulsion or mycoplasma evacuation, though 0.2 μm channels are generally applied to eliminate bioburden and undesired particulates of more than 0.2 μm in size. On account of 0.2/0.22 μm channels, the channels should show high maintenance of *Brevundimonas diminuta* (*B. diminuta*), known as the bacterial test (BCT) of sterile filtration. The size of *B. diminuta* is roughly 0.3-0.4 μm . Notwithstanding the bacterial test, sterile channels should breeze through different uprightness assessments to demonstrate their legitimacy in different bioprocesses.

Industrially accessible sterile channels are made out of polymers, for example, polyvinylidene fluoride (PVDF) and polyethersulfone (PES). In sterile filtration, 100 percent protein transmission is accomplished, though protein total statement or pore obstructing causes serious protein fouling, coming about in pervade transition decline and eventual outcome misfortune [1]. To relieve this fouling impact during sterile filtration, the channel surface is changed utilizing a hydrophilic covering to lessen protein adsorption or by adding different excipients to diminish protein collection. Notwithstanding channel fouling by protein, process interruption during media filtration could likewise happen through undesired intermediates or supplement total creation during the filtration interaction.

Albeit different sterile channels are accessible for biotherapeutic creation processes, restricted examinations have explored the filtration execution in view of various channel materials [2-4]. Allmendinger showed that PES

channels show a higher fouling inclination than PVDF channels because of more modest pore size. Be that as it may, their review was centered around the impact of protein types and excipient expansion on protein fouling during sterile filtration, and not on the channel material.

Business sterile channels made of hydrophilic PVDF and PES were contrasted with deference with execution as well as filtration qualities. Both sterile channels showed sterility and high maintenance legitimacy by passing the BCT. The channel attributes showed contrasts with regards to morphology, mean pore distance across, and hydrophilicity. Channel B with a deviated channel morphology with a more modest mean pore width in the retentive locale and a somewhat hydrophilic surface accomplished higher penetrability than channel A. It likewise showed a higher limit with respect to LB stock filtration. The transition decline peculiarity with LB stock was chiefly brought about by fixation polarization or undesired particulate arrangement. Be that as it may, the pace of transition decline by supplement media needs further examination concerning the adsorption component of supplements on the channel surface [5].

Conflict of Interest

None.

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*Address for Correspondence: Dongwoo Baek, School of Chemical and Biological Engineering, College of Engineering, Institute of Chemical Process (ICP), Seoul National University (SNU), Seoul, Korea, E-mail: Dongwoobaek444@gmail.com

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