Innovative Pod Platform Delivers Disposable Option for Depth Filtration

Increasing the adoption of disposable technologies in various process steps, including such critical steps as sterile filtration and final filling, has become a major trend in the biopharmaceutical industry. However, because of the large volumes and variability of feed streams in clarification and prefiltration processes, it has not been easy to incorporate today's disposable technologies into depth filtration applications.

In the past, clarification was a multistage process with parallel and serial filtration. In two-stage clarification, followed by prefiltration, issues include yield loss and multiple bulky housings, requiring significant time, resources, and the expense of CIP requirements. To address these issues, Millipore’s Millistak+® HC media combines multiple stages of depth and membrane filtration into a single device, enabling significant process compression in the clarification step and thereby improving yield and reducing CIP.

Even with the media improvements, the lenticular filter design still exhibits inherent limitations and operational issues. These include: heavy equipment requirements (heavy housing domes requiring cranes); time and cost involved with cleaning and validation (excessive CIP fluids); and operator safety (loading heavy filters on and off tall centre posts, and handling messy spent filters). End users seek a system that can deliver the right combination of improved ease of use, reliable performance, safe and efficient operations, and cost effective processing.

The new Pod filter platform from Millipore addresses these concerns. This innovative technology incorporates a completely new, lighter, modular filter design with proven clarification media to provide unprecedented process flexibility. Part of the Mobius™ flexible bioprocessing solutions family, the Pod platform introduces the convenience and economy of disposable technology to a new segment of biotechnology manufacturing. It was designed to increase productivity by shortening cycle time, optimising the use of process liquids, reducing validation efforts and improving overall process economics.

**FLEXIBLE, SCALABLE DESIGN**

Pods are available with 0.1m², 0.5m², and 1m² filtration areas, and fit into either of two expandable holders. The pilot-scale holder can accommodate from 0.1m² to 2m², or up to 5m² with an optional accessory kit. The process-scale holder expands to hold up to 30m².

The variety of configurations that can be formed allows for filter area requirements to be precisely met, making linear scale-up from pilot to process easily achievable. With a very simple adaptor, the Pod platform can be operated in serial filtration mode, running multiple processes or feed streams on the same holder at one time.

**IMPROVED SAFETY AND EASE OF USE**

The lightweight, self-contained design makes the Pod easier and safer to work with than conventional lenticular stacked disc
filters. Pods have handles that allow for easy assembly and change-outs. The interlocking design does not require tools for either assembly or disassembly and the platform can be plumbed easily into a new or existing facility. Disposable adapters connect the Pod filters to process piping, making both installation and set up easy and straightforward.

Because of the Pod platform’s unique design, operators are not exposed to process fluids, and the filters can be blown down before removal to improve yield and reduce the weight of spent filters. This enhances operator safety and reduces the risk of injury due to either biohazard or heavy lifting. The self-contained, all welded integral device does not rely on compression seals, O-rings or gaskets to seal feed from filtrate. Because of this, no product comes into contact with hardware, thereby reducing the need for CIP and minimising the costs associated with water usage, cleaning and validation.

**AVAILABLE WITH PROVEN MILLISTAK+ HC MEDIA**

The Pod filter platform has been launched with Millipore’s Millistak+ HC Media, which incorporates multiple graded-density layers of adsorptive positively charged depth filter media. The successively tighter multimedia layers reduce particle loads when cell culture fluids flow through the filter (Figure 1). The more retentive Millistak+ HC media grades incorporate an additional layer of microporous cellulose membrane to protect downstream equipment and sterile filters.

**DEMONSTRATED ROBUSTNESS, SCALABILITY AND PERFORMANCE**

The Pod platform was tested rigorously by Millipore to validate the robustness of the platform’s construction, evaluate scalability, measure water permeability, determine hold-up volume and evaluate protocols for filter pre-use flushing.

- Device scalability was evaluated on the Pod devices and compared to the conventional Millistak+ HC lenticular stacked disc filters. The tests were undertaken on two media grades, one representing a primary clarification prefilter and the other, a secondary clarification prefilter. The tests confirm that the full area of filter media in the Pod is utilised just as effectively as the conventional stacked disc design.
- A non-destructive depth filter integrity test based on a challenge of aerosolised salt particles was developed for 100 per cent device testing in manufacture. The NaCl aerosol particles are sufficiently small in size to provide a critical challenge of the device to the level of filter media retention. Meant to ensure reliability and consistent performance, the effectiveness of this integrity test has been demonstrated by evaluating the protection capability of downstream membrane filters with an integral Pod versus a Pod with a known defect measuring 0.005 inches.
- The Pod design (Figure 2) was shown to reduce the feed side hold up volume by 73 per cent, compared with a conventional two-high stacked disk cartridge assembly, and by 40 per cent compared with a process-scale stacked disk housing (see Table).

**CONCLUSION**

The Pod filter technology offers numerous advantages over conventional depth filtration. The modular platform is lighter when compared to lenticular stacks, increases flexibility, and saves time and money by using only the exact amount of filter needed. The self-contained Pod platform minimises exposure to biohazardous materials, increasing operator safety. It saves expensive purified water since CIP cleaning requirements are eliminated. The linear scalability of the platform makes scale-up simple and straightforward. And among its most significant features, the Pod platform dramatically lowers hold-up volume by decreasing the waste of valuable product. All this adds up to a faster, completely flexible and more cost-effective solution for depth filtration.

For more information, please contact: Millipore Tech Service at 1-800-MILLIPORE or visit www.millipore.com/pod

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<tr>
<th>Filter Area (m²)</th>
<th>Conventional Cartridge Fill Volume (L)</th>
<th>Pod Filter Fill Volume (L)</th>
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<tbody>
<tr>
<td>1.8</td>
<td>73</td>
<td>7.5 (10%)</td>
</tr>
<tr>
<td>3.6</td>
<td>52</td>
<td>14 (27%)</td>
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<tr>
<td>14.5</td>
<td>97</td>
<td>58 (60%)</td>
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