Filtration in ACI Manufacturing

Biotechnological Production of Hyaluronic Acid

Hyaluronic acid, a natural component of the skin, is produced using biotechnology, among other things, and is then used in cosmetic products to smooth wrinkles and as a moisturizing gel.

ACIs (Active Cosmetic Ingredients) are active ingredients in cosmetic care products.

Active cosmetic ingredients, such as hyaluronic acid, are obtained in chemical and biotechnological processes. The biotechnological manufacturing processes are further differentiated into extraction and fermentation processes.

In the extraction process, active ingredients are derived from natural resources. Fermentation, on the other hand, uses biological processes to produce the active ingredients on an industrial scale with the help of microorganisms or cells.

The active ingredient is then combined with excipients and filled into the final application form, for example as a cream, gel, oil or ointment.

The biotechnological production of ACIs, especially hyaluronic acid, is becoming increasingly important. Analogous to biopharmaceutical production, the process begins with cell cultivation and the provision of cell culture and process media (upstream processing). This is followed by fermentation, cell disruption and cell separation until the cosmetic active ingredient is purified in the final step (downstream processing).

Filtration plays an important role in the industrial biotechnological manufacturing process, such as:

- Protection of fermentation through sterile filtration of cell culture and process media such as nutrients, water, steam and compressed gas
- Separation of cell components and clarification of the active ingredient solution using pre-coat or depth filtration
- Separation of auxiliary materials, such as activated carbon, to protect system components
- Separation of organic residues and precipitates in order to avoid unwanted coloring, contamination or off-flavors
- Clarifying and microbial reduction filtration to protect sterile filters or chromatography columns
- Sterile filtration of liquid active ingredients before filling into large containers

High standards and cGMP (current Good Manufacturing Practice) requirements must be respected to ensure quality and purity.

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Maximum Efficiency and Purity in the Manufacturing of ACIs

As a key component in the manufacturing process of ACIs, filtration systems are used to improve the quality of the end product or protect plant components. Given that the ACIs come into direct contact with filter media, the filtration systems must meet the highest demands in terms of efficiency, purity and cleanability. Therefore, robust, reusable and easy-to-clean filter devices with replaceable filter media are used to prevent cross-contamination.

Eaton offers filtration systems with the ideal pairing of filtration device and depth filter media for every phase of manufacturing ACIs.

In cell separation, the classic BECO COMPACT® PLATE or the enclosed, CIP-capable BECO INTEGRA® PLATE are used as a frame filter for pre-coat and body feed filtration. Frame filters enable the use of filter aids and, in conjunction with depth filter sheets, increase filtration performance, product protection and reliably separate very high cell concentrations.

An additional option for economically separating high cell concentrations is the use of multi-sheet filters equipped with BECO® or BECOPAD® depth filter sheets. Using a baffle plate, they can be combined into several stages to significantly increase the filtration performance.Optionally, double-layer or multi-stage BECODISC® stacked disc cartridges in enclosed BECO INTEGRA DISC stacked disc cartridge housings can also be used.

Activated carbon powder is used specifically in the production of hyaluronic acid for decolorization and color correction. In this case, frame filters with depth filter sheets are suitable for safely separating the activated carbon powder, followed by particle filtration with stacked disc cartridges to protect downstream system components.

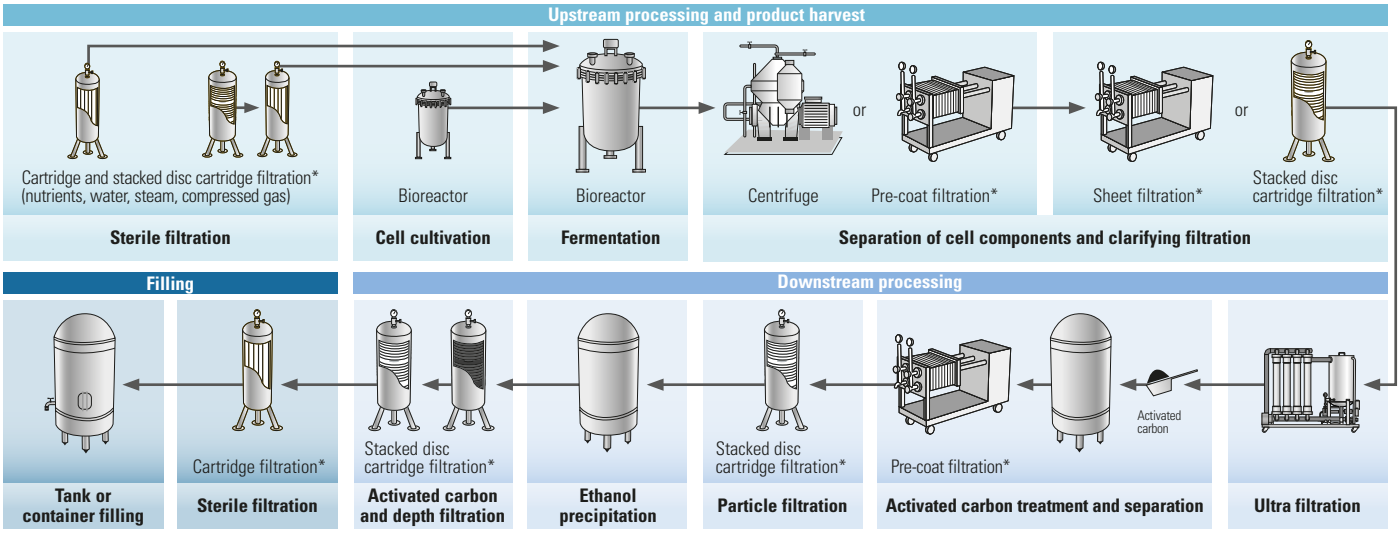
For advanced hygiene and cleaning requirements in the further process, enclosed stacked disc cartridge housings with stacked disc cartridges are the ideal combination.

The BECODISC BC and BECO CARBON™ depth filter media are a clean solution for the adsorptive separation of by-products and discoloration. Since the activated carbon is bound in the filter media and its quantity is precisely defined, they save users from dosing and separating loose activated carbon powder, cleaning the production areas and components and ensure high, reproducible product quality and filtration performance.

Depth filter sheets or stacked disc cartridges offer optimal protection for clarifying filtration or separating fine particles and colloids, for reducing and separating microorganisms, as well as for chromatography columns and membrane filter cartridges.

Before the sterile filling of the active cosmetic ingredients and for the sterile filtration of cell culture and process media before fermentation, pleated BECO membrane filter cartridges that can be tested for integrity are used in enclosed BECO INTEGRA CART cartridge housings. They safely separate microorganisms from different media.

Simplified Process Flow Diagram for Biotechnological ACI Manufacturing



* Eaton depth filter sheets meet national and international quality standards, such as European Directive (EU) 1935/2004 and FDA guidelines (Food and Drug Administration) from the USA. The plastic components of the stacked disc cartridges and filter cartridges (polypropylene) meet European Directive (EU) 10/2011.

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