Solutions for pharmaceutical filtration processes

Sefar has provided high quality products to the Pharmaceutical Industry for over 50 years. We offer customized solutions for filtration, screening and drying processes that routinely meet the industry’s most stringent requirements. Sefar integrates all crucial steps from weaving to fabrication in the production of ready-to-use filters and thus ensures the quality and traceability critical to the pharmaceutical industry.

In today’s demanding economic environment, the pharmaceutical industry is under pressure to develop new and more sophisticated medicines. The result is a requirement to innovate and streamline manufacturing operations to reduce production costs while meeting increasingly stringent compliance and regulatory standards.

Current state of the Industry vs. new requirements

According to FDA regulations woven filter media made from polymers can be classified as indirect food additives and thus the yarn polymers should conform to CFR title 21, part 177. Most of the requirements were previously covered by a corresponding declaration of conformity for the general polymer type. However, when looked at more closely, not all yarns specifically meet the exact criteria found in 21CFR177.

It is also common for materials to be run with yarns from multiple sources without stringent traceability procedures. Also, in the production of the polymer yarn and to aid in the weaving process, it is necessary to use certain chemical substances that will remain in some quantity on the yarn surface. GMP-procedures required of pharmaceutical manufacturers state that all product contact areas must be cleaned so as not to alter the safety, purity and efficacy of the drug product. This is done by the user with an industrial pre-wash or inside the filter equipment by CIP or rinsing with a process solvent.
The increasing pressure from regulatory authorities forces the industry to take steps to understand and more closely control those items coming in contact with the drug product. To meet this new challenge Sefar has created a specialized fabric line where these yarn-processing chemicals are quantified through extractable testing and limited in concentration.

### Products (fabricated filters and roll-goods)

Sefar has a unique position integrating all crucial production steps from weaving to fabrication of our ready-to-use filters. With this vertically integrated capability we have designed our PHARMA-Grade line of controlled and compliant filters specifically for use in Pharmaceutical applications.

The most critical items are often those used on the following equipment:

- Horizontal and vertical peeler centrifuges
- Bag centrifuges
- Fluid bed dryers
- Blender/Dryers
- Nutsche filter/Dryers

### SEFAR® PHARMA fabric

The fabric is the most important part of our filtration products. Sefar’s PHARMA-Grade line is a unique selection of our full line of high quality fabrics.

The production of these fabrics has been adapted to meet all of the following criteria:

- The yarn polymers conform to FDA CFR title 21, part 177 (indirect food additives: polymers).
- The yarn polymers conform to Directive 2002/72/EC of August 06, 2002 of the European Community (Directive on plastic materials and articles intended to come in contact with Foodstuffs).

Extractable levels (total extraction with different solvents) are below the tolerable limit of 1000 mg/m² (m² fabric area).
SEFAR® PHARMA fabrication

Sefar has established a specially designed fabrication process to meet the most critical needs of the pharmaceutical industry. Sefar fabrication sites producing PHARMA-Grade products must implement defined GMP-Guidelines in addition to the tight quality control systems already in place.

The guidelines contain directives for:

- Cleanliness and traceability of all material, components and supply items/accessories used for fabrication
- Manufacturing documentation and work instructions
- Quality control and final inspection
- Employee training
- Compliance and implementation of these guidelines at the fabrication plants
- Packaging and labeling

Detailed work instructions specific to PHARMA-Grade products ensure that the stringent requirements of cleanliness, traceability, overall quality and performance are being met. However the most important change to classical fabrication is the strict limitation of the selection of usable fabrics and component items / accessories.

- Only specifically designated non-filtering component and supply item / accessories needed for manufacturing the product are considered as suitable for our Pharma products.
- All supply items / accessories with product contact are either FDA compliant or have been thoroughly evaluated during extraction tests to ensure extractable levels do not exceed the tolerable limit of 1500 mg/m² (m² filter area with product contact)
- Only fabrics from the SEFAR® PHARMA-Grade Fabrics list can be used for PHARMA-Grade fabrication

SEFAR® PHARMA fabrication is available for centrifuge liners and bags, fluid bed dryer bags and vent dust bags. It is also possible to upgrade from standard fabrication to PHARMA fabrication for current applications using fabric and accessories from our list of SEFAR® PHARMA materials and components.

Please advise at the time of inquiry or order if you would like the new PHARMA-Grade fabrication process.
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