

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.



Fluid bed dryer

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).



Fluid bed dryer bag



Centrifuge liner



Centrifuge bag



Vent dust bag

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 theselection 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 toensure 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.



SEFAR® PHARMA fabrication

Customer Info No. 8 Filtration Solutions



Headquarters

Sefar AG

Hinterbissastrasse 12
9410 Heiden
Switzerland

Phone +41 71 898 57 00
Fax +41 71 898 57 21

filtration@sefar.com
www.sefar.com

Subsidiaries Europe

Sefar Ltd.

Bury – England
Phone +44 161 765 3530
sales@sefar.co.uk

Sefar Fyltis S.A.S.

Lyon Cedex 03 – France
Phone +33 472 13 14 15
vente@sefar-fyltis.fr

Sefar GmbH

Edling – Germany
Phone +49 8071 90400 0
info@sefar.de

Sefar Italia S.r. l.

Collegno – Italy
Phone +39 011 42 001
info@sefar.it

Sefar B.V.

Lochem – Netherlands
Phone +31 573 25 82 50
info@sefar.nl

Sefar sp. z o.o.

Poznan – Poland
Phone +48 511 467 467
info-pl@sefar.com

Sefar Maissa S.A.

Cardedeu – Spain
Phone +34 93 844 47 11
info.maissa@sefar.com

Sefar Filtrasyon San. ve Tic. Ltd. Sti.

Ankara – Turkey
Phone +90 312 287 34 14
info.tr@sefar.com

Subsidiaries Americas

Sefar Inc.

Depew – USA
Phone +1 800 995 0531
filtration@sefar.us

Sefar BDH Inc.

Saguenay – Canada
Phone +1 418 690 0888
info.bdh@sefar.com

Sefar Tenyl Tecidos Técnicos Ltda.

Guarulhos – Brazil
Phone +55 11 2137 1555
contato.brasil@sefar.com

Sefar S.A. de C.V.

Cuautitlan Izcalli – Mexico
Phone +52 55 5394 8689
info.mexico@sefar.com

Subsidiaries Australia & New Zealand

Sefar Pty. Ltd.

Huntingwood – Australia
Phone +61 2 8822 1700
oceaniasales@sefar.com

Sefar Filter Specialists (NZ) Ltd.

Auckland – New Zealand
Phone +64 9 622 3330
salesnz@sefar.com

Subsidiaries Asia

Sefar Filtration Solutions (Suzhou) Ltd.

Suzhou – China
Phone +86 512 6283 6383
info.cn@sefar.com

Sefar Filtration (India) Pte. Ltd.

Thane – India
Phone +91 2522 294034 /35 /36
info.in@sefar.com

Sefar Singapore Pte. Ltd. Indonesia

Jakarta Barat – Indonesia
Phone +62 21 5890 2065 /66 /68
info.id@sefar.com

Sefar Co. Ltd.

Osaka – Japan
Phone +81 64 709 1070
info.jp@sefar.com

Sefar Fabrication (M) Sdn Bhd

Johor – Malaysia
Phone +60 7 867 7188
info.my@sefar.com

Sefar Singapore Pte. Ltd.

Singapore
Phone +65-6299 9092
info.sg@sefar.com