

Filtration Solutions



Introduction

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In today's demanding economic environment, the pharmaceutical industry ure to develop new and cated medicines. The uirement to innovate and inufacturing operations. high quality products creening and drving proife Science industries. armaceuticals, drugs) otions, creams, lipsticks) als (functional food, vors) als (pesticides, herbicides, solutions that meet the ost stringent compliance ory standards (e.g. FDA; roduction: all crucial veaving to fabrication of filters uality and traceability experience in life science duction costs ocess safety d product quality

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.

The Sefar answer to the new requirements

Sefar's unique position integrating all crucial production steps from weaving to fabrication of our ready-to-use filters allows us to design our SEFAR® PHARMA-Grade line of controlled and compliant filters specifically for use in pharmaceutical applications.

SEFAR® PHARMA-Grade

Fabrics

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 Sefar QA-Analyses 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).

Fabrication

Sefar has established a specially designed fabrication process to meet the 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
- Packaging and labeling

The most important change to classical fabrication is the strict limitation of the selection of usable fabrics and component items / accessories:

- Only specifically designated nonfiltering components and supply items / 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 ex-ceed 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.

SEFAR[®] PHARMA fabrication is available for centrifuge liners and bags, fluid bed dryer bags and dryer/blender sleeves.

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.

Fluid bed dryers Fluid bed dryer bags

Anatomy of the Sefar fluid bed dryer bag



Tube

- New: welded tubes (without stitching holes) to minimize product loss
- Conductive fabrics
- Standard diameter 160 mm



Flat cap

- Conductive ribbon to ensure full conductivity
 Stable sandwich construction
- (fabric-felt-fabric) to avoid dead spaces

Cap Tube



Cone cap – Stable sandwich construction (fabric-felt-fabric) to avoid dead spaces



Skirt Skirt with zipper





Sefar is one of the world's leading producers of fabrics and finished bags for fluid bed dryers.

Whether you are drying, agglomerating or spray coating, Sefar has the right material for your demanding application.

Our SEFAR® PHARMA-Grade line complies with leading pharmaceutical companies requirements (production according GMP regulations and documentation according FDA regulations).

Main features

- New: Tubes welded (no stitching holes)
- Unique certification of electrical resistance
- Excellent resistance to wear and abrasion
- Extremely durable construction
- Increased surface area
- Complete range of PHARMA-Grade fabrics incl. conductive fabrics
- Exceptional resistance to premature blinding
- High flow rates combined with efficient particle retention
- Perfect fit for all dryer makes
- Smooth surface
- Quality manufacturing with CAD-controlled laser system
- Pharma label

Your benefits

Skirt

- Higher yield (reduced product loss)
- Increased safety (proven conductivity of assembled bag)

Bottom

- No product contamination from loose fibers
- Optimal service life
- Minimized risk of holes forming at the skirt area
- Maximum dryness
- Improved production rates
- Low machine downtime
- Proper bag fit (easy installation)
- Easy cleaning and solid release
- Broad variety of applications

Fluid bed dryers

Connector sleeves

Anatomy of the Sefar connector sleeves

Main features

- Antistatic fabric range
- Customized design (connections and dimensions)
- Customized labeling
- Permeabilities 65-300 l/m²/s
- Good particle retention
- PHARMA-Grade fabric range

Your benefits

- Safety
- Easy installation
- No product contamination from loose fibers
- Proper fit
- Suitable for connecting all types of equipment





Pharma label - Customized Pharma label and ending with flexible O-ring

Fluid bed dryers

Bowl screens

Anatomy of the Sefar bowl screens

Main features

- Soldered or polytherm edge
- With and without center hole
- Wide variety of metal meshes
- Various diameters
- Locked in wires (edge soldered or polytherm)
- Fits all machine sizes

Your benefits

- Easier to use than having roll goods cut in house
- Safer than cutting wire cloth by hand
- Safer installation (no injuries of maintenance people)
- No product contamination by loose wires (as happens with raw cut pieces!)

Not available in all geographical areas





Soldered edge

– Withstands some solvents and

- Lock in of wires



Polytherm edge

- Improved sealing surface
- Better lock in of wires

Vibratory screeners

Pharma screens

Anatomy of the Sefar pharma screen

Center ring

- Exclusively designed for pharmaceutical applications
- Provides a more sanitary construction and eliminates wire migration into your product







Identification

 Serial number and mesh specifications are identified on an embossed plate in the adhesive



Steel ring

- Sefar steel rings are manufactured using T304 stainless steel
- The tubular construction and continuous welding process assure smooth, cleanable and durable sanitary rings



Food grade adhesives

 Pharma Screen products are made using only FDA compliant adhesiives and sealants

Availability and design of this products depend on the geographical area

To help you better meet strict regulatory requirements, Sefar offers vibratory screener replacement screens that have been specifically designed for the pharmaceutical industry.

Main features

- Every screen made of new materials
- All components meet 21 CFR regulations
- Sanitary construction elimination of crevices (potential breeding ground for bacteria)
- Rings made of T304 stainless steel
- Rings with smooth, cleanable and durable sanitary surface
- Only FDA compliant material used for adhesives and sealants
- Unique marking of screen mesh specification on SS ring
- All screens available with certification of mesh and opening size
- Consistent tension across the screen
- Broad range of high quality meshes

- No contamination associated with the use of revamped material
- No contamination associated with crevices
- No wire migration into your product
- Reduced risk of using wrong screen and ruining your valuable product
- Long lifetime
- Optimized products for various screening applications
- Traceability and compliance information

Bag strainers Strainer bags

Strainer bags are available in a huge variety of designs (drawstring, wire ring, flanged and special designs) and materials (micron-rated, high efficiency meshes or felts). We show you just a few examples.

Availability and design of this products depend on the geographical area

















Centrifuges Centrifuge liners

Anatomy of the Sefar centrifuge liners



Endless liners

 Welded connections with overlap (25 mm) or head to head (15 mm)





Edges: welded ribbon edge – Suited for liners made from DLW or fabrics without backing cloth

Sefar centrifuge liners have all been designed to take account of the special conditions in the centrifuge. Fabrication techniques and fabrics are chosen to optimize the overall productivity of the centrifuge and special attention is given to the most demanding requirements.

Sefar's centrifuge liners excel when processing pharmaceuticals or chemicals having particle sizes ranging from coarse to very fine. Working with Sefar means drawing from a worldwide pool of design engineering resources to help you master the most difficult centrifuge applications.



Edges: taped sewn (with backing fabric) - Suited for all liners (with and without backing fabrics)



Edges: hemmed welded (with backing fabric) – Suited for all liners (with and

without backing fabrics)



Edges: Cut

 Suited for liners made from DLW or fabrics without backing cloth

Main features

- SEFAR[®] PHARMA-Grade fabrics and fabrication
- Fixation adapted to your filter machine
- Connections welded whenever technically possible
- Quality manufacturing eliminates common wrinkling and folding problems
- Filters with integrated (SEFAR TETEX® DLW) or separate backing cloth
- DLW liners ideal for peeler units or where plow tolerances are narrow
- Full spectrum of polymers
- Smooth surfaces
- Wide range of pore sizes and permeabilities
- Wide range of fabric material (e.g. Polypropylene, Polyester, Nylon, PEEK)
- Surface finishing (e.g. calendering)
- Pharma labelling

- Minimized product loss
- High yield
- High end product purity
- Low machine down time
- Easy installation
- Perfect fit in any filter machine
- Maximum cloth life
- Exceptional chemical compatibility and thermal resistance (e.g. CIP cleaning)
- Easy cleaning
- Documentation and traceability
- Superior cake release (no clogging)
- Minimal product contamination
- through fiber loss

Centrifuges Centrifuge bags

Anatomy of the Sefar centrifuge bags





Filter zone – Drainage with DLW (integrated backing cloth)



Cone

For discharge and fixation

 Various customized styles of cone openings are available

Sefar offers innovative solutions for any type of basket centrifuges.

Fabrication techniques and fabrics are chosen to optimize the overall productivity of the centrifuge and special attention is given to the most demanding requirements.

Our precision woven fabrics are designed in a wide variety of weave styles using the advantages of mono- and/or multifilament fibers. After final surface treatment our fabrics are ready to meet the most stringent requirements of our demanding customers



Lifting ring – For lift up and discharge

Main features

- SEFAR[®] PHARMA-Grade fabrics and fabrication
- Fixation adapted to your filter machine
- Seam reinforcements
- Quality manufacturing eliminates common wrinkling and folding problems
- Filters with integrated (SEFAR TETEX[®] DLW) or separate backing cloth for improved drainage and cycle times
- Customized styles including lifting straps, special flanges or hubs and cone openings
- Smooth surfaces
- Wide range of pore sizes and permeabilities
- Wide range of fabric material (e.g. Polypropylene, Polyester, Nylon, PEEK)
- Surface treatments (e.g. calendering)
- Pharma labelling



Filter zone – Drainage with separate backing cloth

- Minimized product loss
- High yield
- High end product purity
- Low machine downtime
- Easy installation
- Perfect fit in any filter machine
- Maximal cloth life
- Exceptional chemical compatibility and thermal resistance
- Easy cleaning
- Superior cake release (no clogging)
- Documentation and traceability
- Minimal fiber migration with welded design

Inverting centrifuges

Inverting centrifuge bags

Anatomy of the Sefar inverting centrifuge bags





Filter zone Filter fabric SEFAR TETEX® MULTI

 for maximal particle retention and good strength and cloth flexibility

Sefar filter cloths for Heinkel inverting filter centrifuges

Heinkel and Sefar are the two cuttingedge specialists in solid/liquid separation for the life science industries – a position gained through the development of innovative technologies and compliance with the most stringent quality and safety requirements. Our separation equipment and filter media are in worldwide use in factories of almost all the well-known pharmaceutical enterprises. Today the names of Heinkel and Sefar are synonymous with excellence in separation.

A cooperation for your success

Heinkel and Sefar entered into a close cooperation by combining their knowhow as original machine and filter media manufacturers to develop a new generation of filter cloths specifically serving the needs of inverting filter centrifuges.



Filter zone

- Filter fabric SEFAR TETEX® MONO
- for maximal permeability and optimal cleaning properties (PRD weave)

Main features

- SEFAR® PHARMA-Grade fabrics, specifically designed for inverting filter centrifuges
- SEFAR[®] PHARMA fabrication
- Standardized filter cloths available for all Heinkel inverting filter centrifuges
- Wide range of materials such as Nylon, Polypropylene and Polyester
- Connections are whenever possible welded
- Special design features like wear strips are available
- Surface finishing (smooth surfaces)



Filter zone

- Filter fabric SEFAR TETEX® DLW
- with integrated backing cloth for excellent drainage and stability

- Direct access to the specific filtration process know-how of the original machine manufacturer Heinkel and the filter media manufacturer Sefar
- Optimized filtration performance (throughput and particle retention)
- Easy cake release
- High yield
- Global availability
- Easy ordering process. We need just the centrifuge type (e.g. HF 800) and the filter cloth reference and length (e.g. 05-4-660K PHARMA; 435mm)
- Easy installation and perfect fit
- Chemical compatibility
- Heat resistance
- Support from the Sefar experts for filter products and from Heinkel experts for process optimization
- Minimal product contamination through fiber loss

Nutsches/Dryers

Filter nutsche and dryer bags

Anatomy of the Sefar nutsche bags



Main features

- Exclusive flanged bag design
- Tight sealing
- Impervious sidewall
- Various filter media incl. PEEK for particularly aggressive chemical or thermal environment
- Double layer weave (DLW)

Your benefits

- Optimal gas blow down
- Easy product discharge
- Faster set-up time
- Minimized product loss
- Improved drying for a more consistant product
- Reduced exposure to hazardous material while discharging product
- Faster clean-up
- Reduced downtime

Flange

 Our flanged bag design gives you the thight sealing required for optimum gas blow down while offering the ease of product discharge by conveniently lifting the bag from the unit





Filter zone

 SEFAR TETEX® DLW combines a fine filtration layer with a course backing layer for an excellent drainage and stability under pressurized conditions

Filter nutsche and dryer discs

Anatomy of the Sefar nutsche and dryer discs





Main features

Mounting aid

- Available with cord

- Customized design
- Polypropylene, Polyester, PEEK fabrics
- Double layer weave fabrics
- PHARMA-Grade fabrication

Your benefits

- Optimal fit
- Increased filter performance
- Chemical compatibility
- Thermal resistance
- Documentation and traceability
- DLW reduces wrinkling and improves

filter life

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Sealing and fixation Following edge options are available:

- Hemmed with
- and without cord

Taped with and without cord

– Laser cut

Dryers, Solid Handling Equipment

Vent-off dust bags and sleeves

Anatomy of a Sefar vent-off dust bag



Top options

- Snapring
- Metal ring
- Cord
- Open with hem

Top with Snapring





Sewn - no open edges on product



Round and flat bottom, Open with hem

Introduction.

Welded fabric

Sefar offers a wide range of vent-off dryer bags made of either synthetic fabrics or felts with laminated PTFE membrane. They standardized designs cover all usual options found in pharmaceutical industry.

Main features

- Synthetic antistatic fabrics from our SEFAR[®] PHARMA Grade range
- Felts with laminated PTFE membrane
- Media options with material conformities to FDA CFR and /or EC 10/2011
- Fabrication procedures according to GMP EC 2023/2006
- Finished bags conformity to EC 1935/ 2004 available for chosen media
 Retention of finest particles (felt/membrane < 5 µm, fabric down to 5 µm)

- OEM equivalent bags (fitting all common types of bag vessels)
- Synthetic fabrics washable
- No product contamination by media through open edges
- All material on product side with conformity to FDA or EC codes
- No bypass through needle holes
- High productivity and yield
- All design options with no open edges on product side

Horizontal disc filters

Filter discs

Anatomy of a Sefar filter disc



Sealing, fixation and as mounting aid

- Following edge options are available:
- Hemmed with and without cord
- Taped with and without cord
- Laser cut





Filter zone

- Filter fabric SEFAR TETEX® MULTI
- for maximum particle retention and good mechanical resistance



Filter zone Filter fabric SEFAR TETEX® MONO – for high permeability and easy cleaning



Filter zone Filter fabric SEFAR TETEX® DLW – for increased drainage and lifetime

Main features

- Customized edge design
- Polypropylene, Polyester and PEEK fabrics
- Double layer weave fabrics

- Optimal fit and fixation
- Increased filter performance
- Chemical compatibility
- Thermal resistance
- Documentation and traceability
- Easy mounting

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