Application Sheet:

General Pharmaceutical

Filtration in the pharmaceutical industry is a readily understood process ranging from clarification of cough syrups and linctuses through to cold sterilisation of heat labile injectable products. Other applications include sterile filtration of air and feedstocks to fermentation processes, filtration of solvents for tabletting processes, tabletting powder handling and recovery systems, sterile filtration of services including water, air and process gases, sterile filtration of ophthalmic solutions and sterile filtration of serum and growth media.

The industry is well regulated and it is important that any filters used in critical applications are fully supported with validation guides. All Van Borselen Filters' membrane filters, supplied to pharmaceutical customers, meet the following internationally recognised standards:

- A minimum retention of $>10^7$ cfu/cm^2 *Brevundimonas diminuta* per HIMA methodology.
- Manufactured from non-toxic materials of construction, including o-rings and seals.
- Non-fibre releasing.
- Integrity testable by end-user.
- Traceable identification number.
- Manufactured in a clean room environment with a recognised quality system.

In addition, our membrane filters have been validated usingan independent testing laboratory, covering the following critical tests:

- Bacterial challenge tests
- Materials of construction (FDA CFR numbers)
- USP toxicity tests
- MEM elution tests
- Limulus test
- Physicochemical test
- Sterilisation by in-line steam
- Sterilisation by hot water.

Product overview

Pre filtration:

BorsoPleat-P	-	PP Pleated filter
BorsoPleat-K	-	PP Depth Pleated filter
BorsoPleat-M	-	GF Pleated filter

Stirile filtration:

BorsoPES-Aqua	-	PES Membrane filter
BorsoPES-Biological	-	PES Biological Membrane filter
BorsoPTFE	-	ePTFE Membrane filter
BorsoNylo	-	Nylon 6.6 Membrane filter

SmallScale Filters:

BorsoSC-Bioligical	-	PES Biological Membrane
BorsoSC-Aqua	-	PES Membrane filter
BorsoSC-PTFE	-	ePTFE Membrane filter

Capsules:

Capsule filters are pressure tested to guarantee capsule integrity.
All filter housing is high grade polypropylene.
An integrated Vyon® core gives added security.
Operating temperature from 0°C to 50°C (32ºF to 122ºF).
6bar (87psi) operating pressure.
Optional filter materials.

Bio-SD:

FILTRODISC™ BIO SD is the first depth filter using the advantages of the alluvial (cake or precoat) filtration technology in a disposable format. Alluvial filtration is a well-established method in pharmaceutical industries.

Porous Sintered metal:

Cups
Bushings
Sheets
Dics
Tubes

Sanitary filterhousings:

Finish options: 0.8Ra and 0.4Ra internal polish + Electopolish
Connection type options: Tri Clamp, BS4504 Flange PN16, ANSI Flange 150# and more

Van Borselen: Your partner in filtration and separation

Manufacturing of our high performance cost effective products is underpinned by our quality assurance programme, cGMP practices and clean room environment to ensure products meet the stringent requirements of the Pharmaceutical, Generics and Veterinary Medicines industry.

Material Conformity and Validation

The bio-safety of all materials in the manufacture of our cartridges is assured by FDA approval and USP Class VI testing.
Our membrane cartridges have been tested and shown to be 100% retentive in line with HIMA, PDA and ASTM F838-05 guidelines for *Brevundimonas diminuta* challenge (0.2 micron grade). To guarantee the bacterial retention performance of every cartridge, non-destructive integrity testing is performed on each individual module prior to release. A comprehensive validation guide for our cartridges is available on request.

Technical Support Services

Our dedicated test, development and laboratory services underpin our design and development activity, from filtration media and material characterisation, product verification testing to customer systems simulation trials and in service performance evaluation. Our technical support service capabilities include:

Laboratory Services

Filter integrity testing, contaminant identification, filterability testing, filter and media efficiency testing, dirt holding capacity testing, filter failure analysis, compatibility investigation, flow versus pressure drop measurements, particle counting.

Validation Services

Comprehensive validation of filters for pharmaceutical processes to the recommendations of the Parenteral Drug Association (PDA):

Process specific validation Filter
compatibility Retention studies
Microbial challenge tests
Endotoxin and particulate testing
Extractables testing.

On-site Services

Customer plant surveys, process filter optimisation, trouble-shooting, pre-inspection review.

Training (held at customer site or at our technical facilities)

Integrity testing, methods for optimising filtration trains.

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