cobetter®
filtration

AVL Center

CNAS
ISO17025
ilac-MRA



Liquid & Gas Filtration

For Microelectronics, Pharmaceutical, Fine chemical, Food and Beverage Industries

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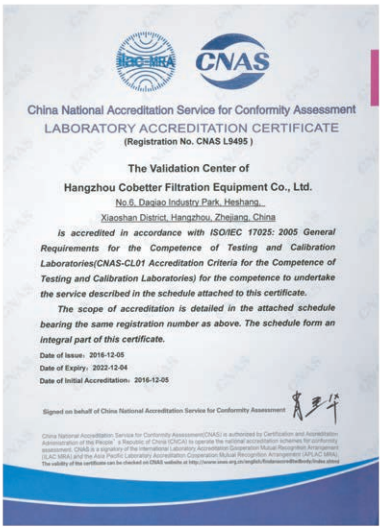
AVL Center

Cobetter Validation Center is committed to providing customers with complete solutions to their various filtration problems. Approved and validated by CNAS (China National Accreditation Service for Conformity Assessment), our Validation Center is divided into 3 branches: Pharmaceutical Validation Laboratory, Industrial Laboratory, and Semiconductor Laboratory.

A Validation Center is established with an area of 7000㎡ and a cumulative investment of over 100 million RMB. Currently there are more than 10 large laboratories, with more than 8 foreign test experts and 100 test engineers. Among them, the Pharmaceutical Validation Laboratory provides pharmaceutical customers every year with more than 2500 Validation Guides, and offers life science customers more than 1800 Technical Reports and Solutions , and accepted on-site inspections by the Beijing Drug Evaluation Center and various provincial bureaus, and were highly praised!



Validation Center Expert Hidetoshi Taketomi
30 Years of Experience with Japanese Laboratory



China National Accreditation Service for Conformity Assessment
LABORATORY ACCREDITATION CERTIFICATE
(Registration No. CNAS L9495)

The Validation Center of
Hangzhou Cobetter Filtration Equipment Co., Ltd.
No.6, Daqiao Industry Park, Heshang,
Xiaoshan District, Hangzhou, Zhejiang, China

is accredited in accordance with ISO/IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories(CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories) for the competence to undertake the service described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule form an integral part of this certificate.

Date of Issue: 2016-12-05
Date of Expiry: 2022-12-04
Date of Initial Accreditation: 2016-12-05

Signed on behalf of China National Accreditation Service for Conformity Assessment



Service items

- Microbiological Challenge
- Extractables and Leachables
- Chemical Compatibility
- Product-wetted Integrity Test
- Customized Filtration Solutions
- Filtration Process Optimization
- Ultra-filtration Process Optimization and Validation
- Single Use System Solutions and Validation
- Particle Distribution And Efficiency Testing
- Pollutant Analysis

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Filter Validation Guide

The key equipment in the sterilization filtration process is the sterilizing-grade filter. According to the "Pharmaceutical GMP Guidelines-Sterile Drugs" and "Sterilization filtration technology and application guide" in version of 2010, the confirmation and validation items are summarized in the following table:

Criteria		Sterile filter for filtration products that can not be sterilized in final container	Sterile filter for terminal sterilized products
Confirmation of selection of sterilizing-grade filter for each model(Filter manufacturer)	Correlation between the standard bacteria retention test data and the integrity test value of each type of sterilizing-grade filter	Recommended	Recommended
	Extractables Analysis	Recommended	Recommended
	Raw Materials Biosafety	Recommended	Recommended
Confirmation of sterilization grade filters for each batch (Filter manufacturer)	Each batch of sterile grade filters is sampled for bacterial retention standard test, and the continuous validity of the correlation with the integrity test value is confirmed	Recommended	Recommended
	Integrity Test	Recommended	Recommended
	Sample Inspection e.g. PH,Bacterial Endotoxin, TOC and Cleanliness	Recommended	Recommended
	Thermal Resistance Test	Recommended	Recommended
Process Validation	Bacterial Retention	Required	Optional
	Extractables and Leachables	Required	Required
	Chemical Compatibility	Required	Required
	Integrity Test	Optional	Optional
	Absorption	Evaluate	Evaluate



【Sterilizing–Grade Filters Technology and Application Guide】

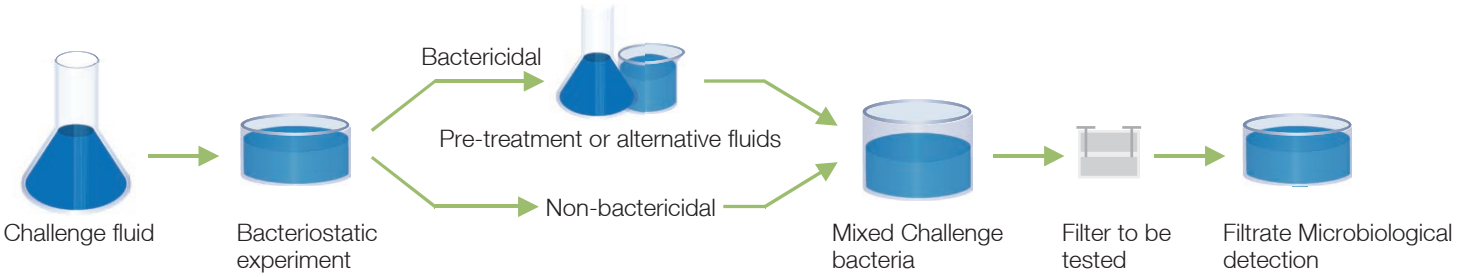
Remarks: The sterilization filter of the same specification and model is used for multiple batch filtration of the same liquid product. It is necessary to adopt a risk assessment method based on a full understanding of product and process risks. Evaluating whether the filter can be used repeatedly.

Microbiological Challenge

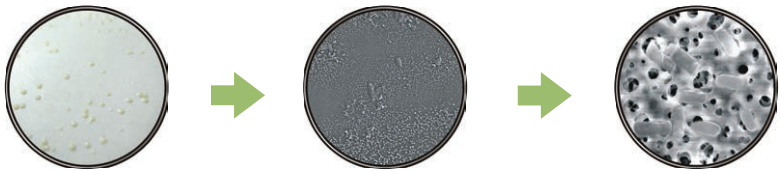
- Sterilizing-grade filter——refers to a filter that can retain **10^7 CFU** of Brevundimonas diminuta **(*Brevundimonas diminuta*,ATCC19146)** per square centimeter of effective filtration area under process conditions.
- Microbiological challenge is the only way to confirm if the filter is sterilizing-grade.



Microbiological Challenge Basic Process



Microbiological Challenge Process Analysis



Brevundomonas deficient colonies (*Brevundimonas diminuta*, ATCC19146)

5000 times (*Brevundimonas diminuta*, ATCC19146)

SEM (*Brevundimonas diminuta*, ATCC19146)



We will scientifically evaluate the impact of your products and processes on the challenge bacteria, and based on this, we will tailor a reasonable test method that can withstand the argument to provide you with reliable bacteria challenge results.

Extractables and Leachables

Overview

Extractables

Under extreme conditions (such as organic solvents, extreme high temperatures, ionic strength, pH, contact time, etc.), chemical substances can be extracted from the process media contact surface of filters and other component materials.



Leachables

Chemical substances that migrate into pharmaceutical products or process fluids from materials in contact with products or non-contact products under storage or conventional process conditions.

Reference	USP PF <1665>	BPOG
Risk Assessment Dimensions	Time	Process Flow Distance
	Temperature	Contact Temperature
	Solvent	Contact Time
	Material properties	Process Fluid Interaction
	Other: Clearance, clinical use	Dilution Ratio

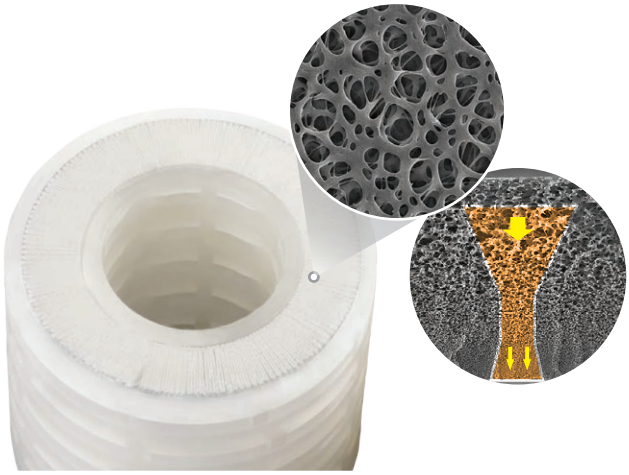
You can entrust us to conduct a security assessment

The methods used by Cobetter

TYPE	Analytical means	Abbreviation	Target
Organic	Headspace–Gas Chromatography –Mass Spectrometry	HS-GC-MS	Volatile Substances
	Direct injection–Gas chromatography –Mass Spectrometry	DI-GC-MS	Volatile and Semi–Volatile Substances
	Ultra Performance Liquid Chromatography –Ultraviolet–Mass Spectrometry	UPLC-UV-MS	Semi–Volatile, Non–Volatile Substances
	High Performance Liquid Chromatography	HPLC	Semi–Volatile, Non–Volatile Substances
	Total Organic Carbon	TOC	Total Organic Carbon
	Fourier Transform Infrared Absorption Spectroscopy	FTIR	Non–Volatile Residue
Inorganic	Inductively Coupled Plasma Mass Spectrometry	ICP-MS	Inorganic Elements
Organic/Inorganic	Non–Volatile Residue	NVR	Non–Volatile Substances
	UV Spectru	UV	UV–Absorbing Substances
	pH	pH	Acidic or Alkaline Substances
	Conductivity	Conductivity	Conductive Lons

Chemical Compatibility Analysis

In the filter selection stage, we need to verify that the filter is compatible with product being filtered



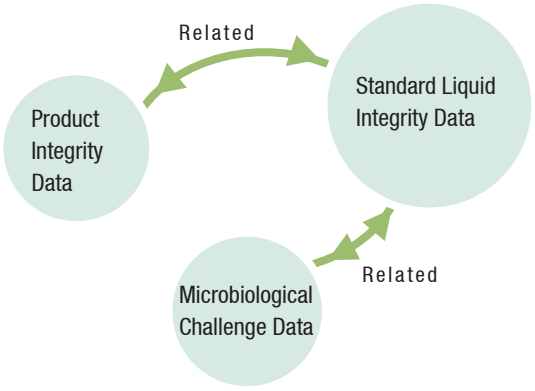
Through the performance parameter and micro-structure test, the chemical compatibility is quanti-fied and presented intuitively, making your filter element selection work easy and effective.



Chemical compatibility is the basis of all validation and requires a comprehensive evaluation method.

Product Integrity Data

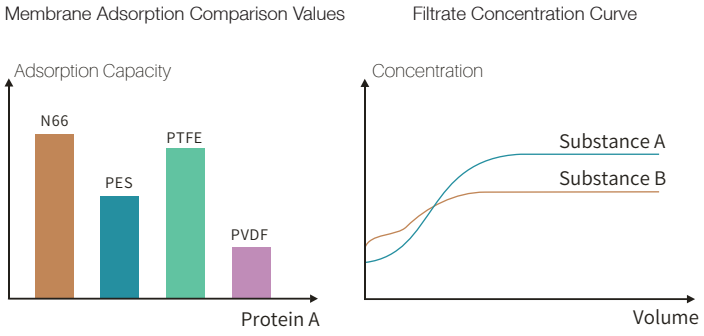
In general, product integrity testing can simplify our operations



Only by establishing the correlation between integrity and microbiological challenge, you can monitor the filter's sterilization performance by monitoring the integrity of the filter, and your integrity test becomes meaningful.

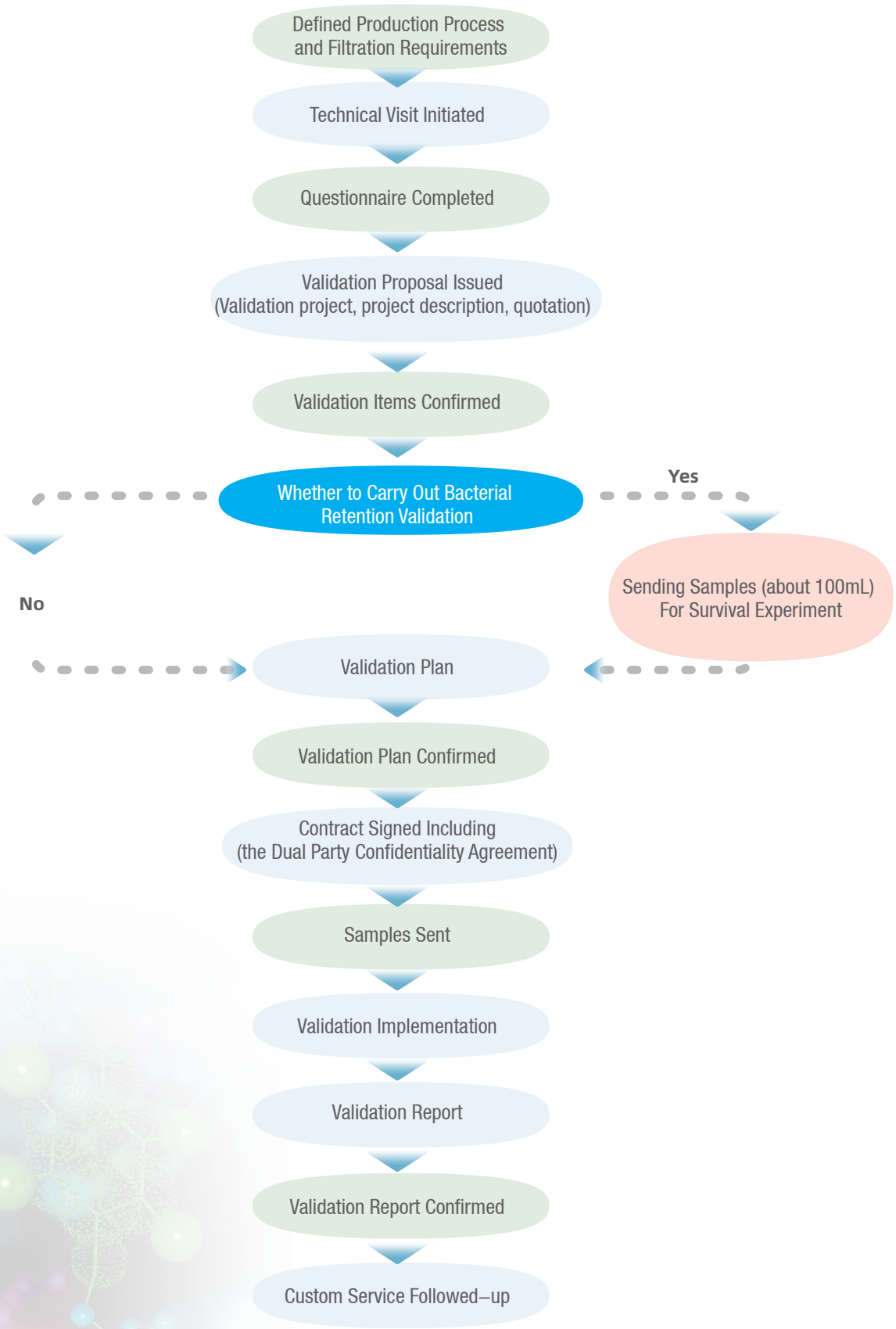
Product Adsorption Analysis

In the production of the product, we need to know whether the product adsorption has an impact on our finished products



It can provide professional product absorption test guidance for pharmaceutical customers.

Validation Procedures





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