

# FILTER VALIDATION SERVICES

DORSAN FILTRATION INDIA PRIVATE LIMITED





#### **Introduction to Dorsan Filtration**

Dorsan Filtration is a globally recognized leader in the design and manufacture of high-quality filtration solutions. Established with a commitment to innovation and excellence, our mission is to provide superior filtration products that meet the diverse needs of industries worldwide, including pharmaceuticals, biotechnology, food and beverage, water treatment, and more. Our state-of-the-art manufacturing facilities and rigorous quality control processes ensure that every product we deliver meets the highest standards of performance and reliability.

#### **Dorsan Filtration India: Expanding Our Expertise**

Dorsan Filtration India has recently expanded its services to include comprehensive filter validation, a critical process in ensuring the safety and efficacy of pharmaceutical products. Our newly established validation lab in India is equipped with advanced technology and staffed by a team of experts dedicated to delivering precise and reliable validation services. This expansion allows us to better serve our clients in the region, providing them with the confidence that their filtration processes meet stringent regulatory requirements.

#### **Focus on Validation**

At Dorsan Filtration, we understand that validation is a cornerstone of pharmaceutical manufacturing. Validation provides documented evidence that a process, system, or product meets its intended purpose. Our comprehensive validation services are designed to help our clients ensure that their filters perform effectively under specified conditions, thereby safeguarding the safety and sterility of their pharmaceutical products. By partnering with us, clients benefit from our extensive experience and expertise, ensuring that their validation needs are met with the highest level of precision and reliability.



### **Our Filter Validation Service**

#### Compatibility Test

Compatibility validation studies provide documented evidence that the filtration process will not adversely affect the filter's physical structure or performance under worst-case conditions. This includes integrity testing, which relates to microbial retention and ensures the filter's compatibility with the specific product being processed.

#### Bacterial Challenge Test

Bacterial challenge testing confirms that the filtration process consistently removes high concentration of bacteria, ensuring a sterile effluent. This test is performed under simulated worst-case conditions to guarantee that microbial retention during actual product processing.

#### Filter Integrity Test

Filter integrity testing is crucial for verifying the performance of the filter before and after use. This test ensures that the filter maintains its structural integrity and functional performance throughout the filtration process, safeguarding against contamination.

#### Extractables Test

Extractables validation studies assess whether the filter or its components release any substances into the product that could alter its safety, identity, strength, quality, or purity. Our thorough analysis ensures that the filter materials are suitable for use in pharmaceutical applications.

#### Leachables Test

Leachables testing identifies and quantifies substances that may leach from the filter into the product during processing. This test is essential to ensure that no harmful contaminants are introduced, thereby maintaining the product's safety and integrity.

#### Adsorption Test

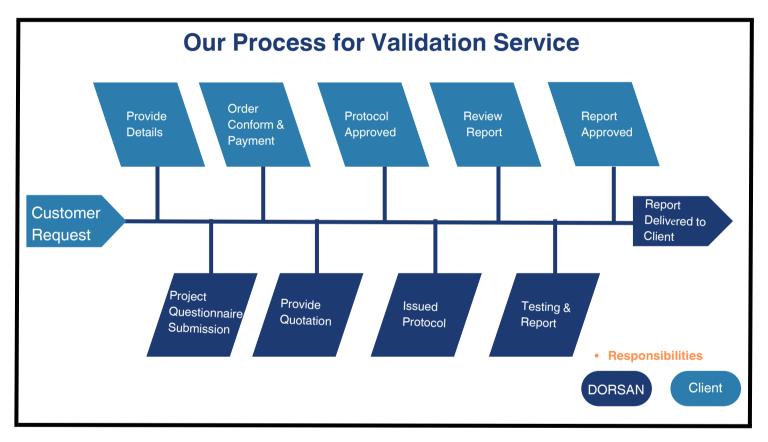
Adsorption validation examines whether the filter absorbs any active ingredients or critical components of the product. This test ensures that the filter does not cause the product to fall below specification for key ingredients, thereby maintaining the product's efficacy and safety.

#### Comprehensive Testing Capabilities

At Dorsan Filtration India, we offer comprehensive in-house testing capabilities. Our facilities include Integrity Testing, Flow Rate Testing, Thickness Measurement, and Chemical Composition Analysis using advanced equipment. We also conduct various small-scale tests on-site to support thorough validation. For specialized needs like Bacterial Challenge and Extractables and Leachables Testing, we collaborate with NABL approved labs to ensure precise results and compliance with industry standards.

#### Why Choose Dorsan Filtration for Validation?

- **Expertise**: Our team of experts has extensive experience in filter validation, ensuring reliable and accurate results.
- State-of-the-Art Facilities: We utilize advanced equipment and facilities to conduct thorough validation tests.
- **Regulatory Compliance**: Our validation services help clients meet stringent regulatory requirements, ensuring product safety and efficacy.
- **Customer Support:** We provide comprehensive support throughout the validation process, from initial consultation to final reporting.
- **Customized Solutions**: We tailor our validation services to meet the specific needs of each client, providing customized solutions that enhance product quality.



## **Contact Us:**

For more information or to discuss your filter validation requirements, please contact us at:

- Email: tech@dorsanfiltration.com, sales@dorsanfiltration.com
- Call: +91 7575025620, +91 9586930620
- Website: www.dorsanfiltration.com

## **DORSAN FILTRATION INDIA PVT LTD.**