SCOTT CART AQUA

PRODUCT VALIDATION GUIDE

CLARIFY

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1.0 INTRODUCTION

Scott Laboratories **Clarify** filter cartridges are used in high specification filtration applications must conform to strictly defined manufacturing and quality standards.

This guide describes the validation testing of the **Clarify** cartridges from which the product claims and the manufacturing and quality standards have been derived. This information is designed to help the customer select the appropriate filter product for their critical applications and to provide the information necessary to show compliance with regulatory authority requirements.

The data presented in this guide is a partial representation of the large amount of engineering work required to provide filter users with a high quality cartridge. If further information is required, please contact Scott Labs Filters.

2.0 PRODUCT SPECIFICATION

2.1 Cartridge Description

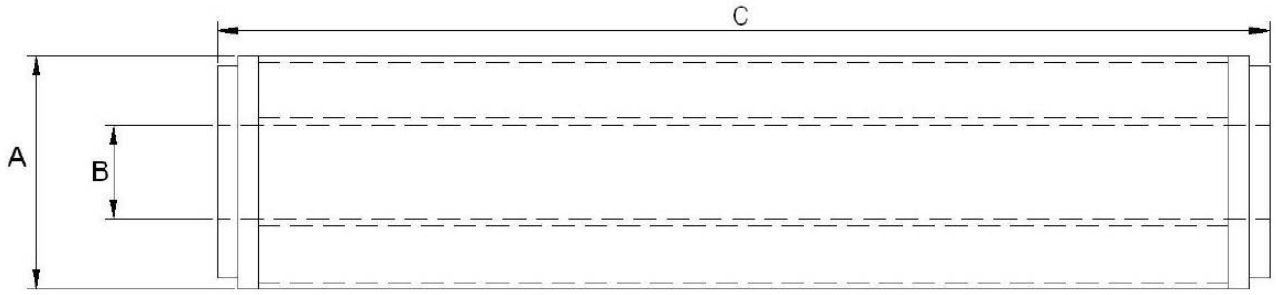
Clarify cartridges feature a sintered carbon block combined with a spunbonded polypropylene fibre pre-filtration layer to produce a unique, high performance filter.

The use of extremely high purity coconut based carbon combined with the novel construction method results in a block filter that outperforms its rivals by up to 5 times.

Clarify filter cartridges are manufactured using the latest thermal welding technology, thus eliminating the high risk of bypass associated with commonly used adhesive bonded constructions. This results in a robust, durable filter assembly, which will withstand a wide range of chemicals, temperatures and other harsh operating conditions.

Clarify cartridges are available in 10”, 20” and 30” double open ended sizes.

2.2 Nominal Dimensions



Double Open Ended Cartridge

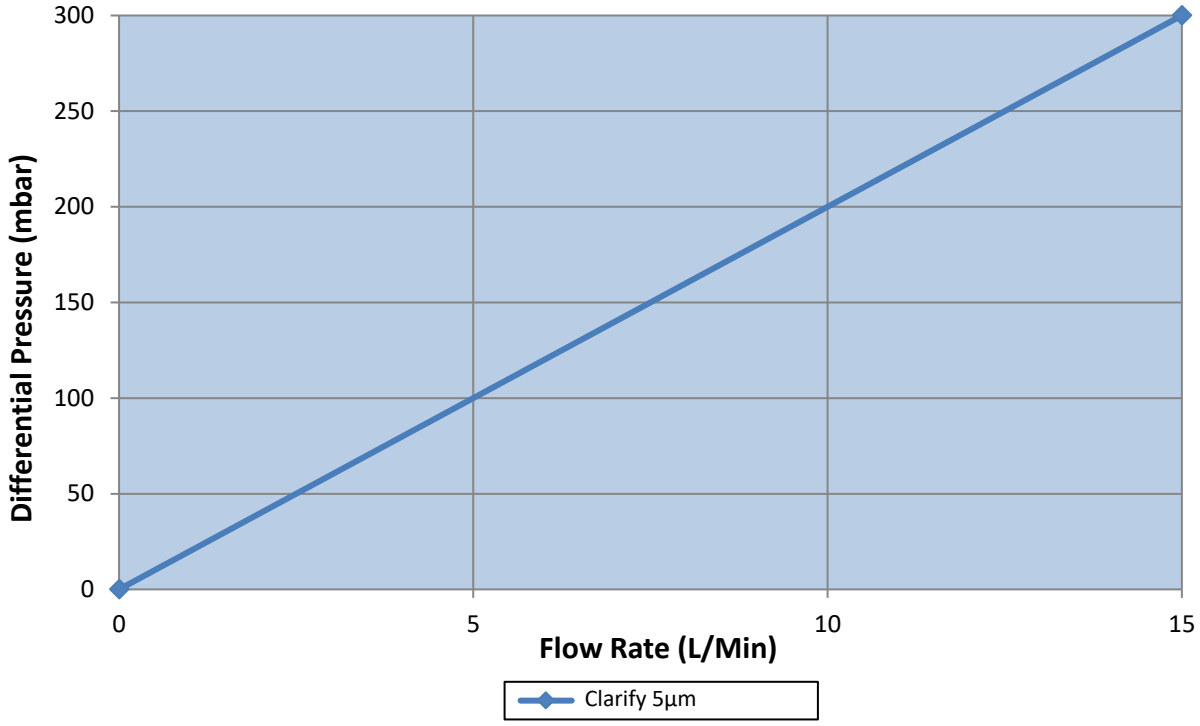
Nominal Cartridge Length	Dimensions (mm)		
	ØA	ØB	C
10"	68.5	27	250
20”	68.5	27	509
30”	68.5	27	762

Micron Rating	Nominal Media Surface Area per 10” filter (m^2)
5	0.55

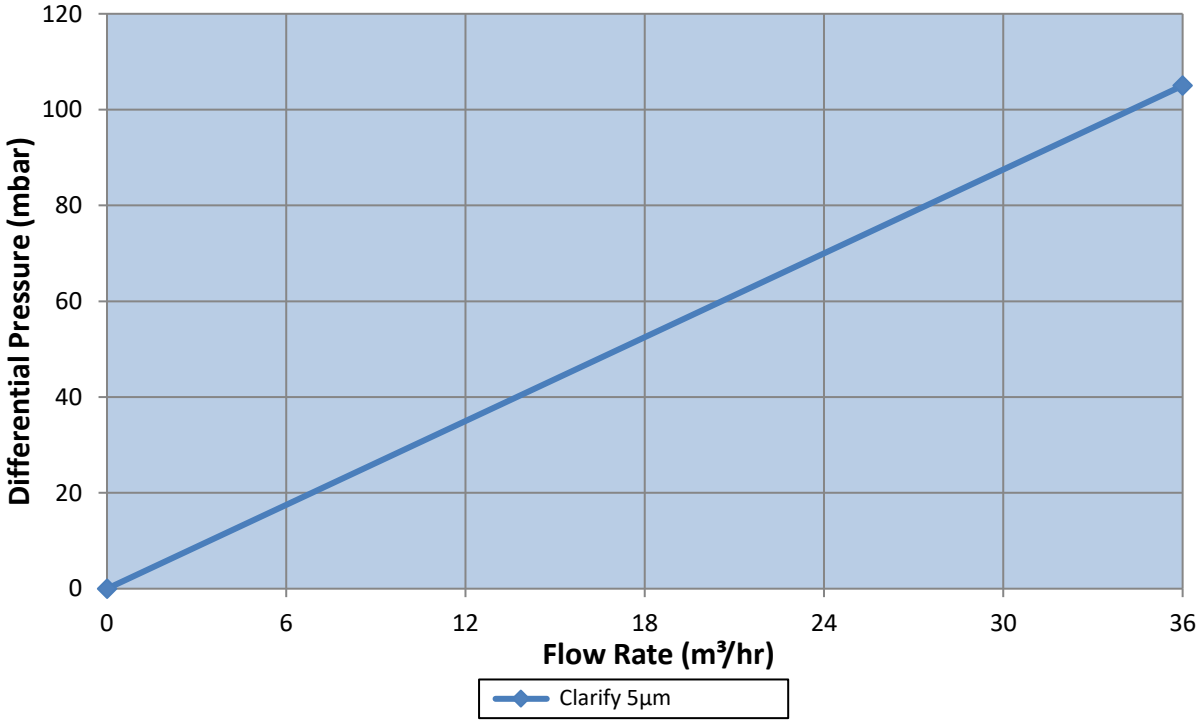
Note: Surface area of shorter and longer filters can be calculated by multiplying pro-rata the value in the table above by the relative length of the filter in question.

2.3 Flow Characteristics

Speeds per 10” cartridge length filtering clean water at 20°C/68°F. Typical pressure drop values obtained from the tests, with the housing pressure drop deducted, are shown below:



Speeds per 10” cartridge length filtering air at 20°C/68°F. Typical pressure drop values obtained from the tests, with the housing pressure drop deducted, are shown below:



2.4 Maximum Operating Temperatures and Differential Pressure

The maximum recommended operating temperature for this range of filters is 80° C/176°F.

Scott Laboratories recommend that this range of filters are changed at a differential pressure of 2.5 bar in normal service. The maximum differential pressure allowable may also be limited by the design specification for the filter housing.

It should be noted that the **Clarify** filter is designed primarily for adsorption duties and as such should be changed out when it has reached its adsorption capacity. This is very likely to be before it reaches a high differential pressure, as the particulate removal and adsorption functions are entirely unrelated to each other.

3.0 QUALITY ASSURANCE

3.1 Product Traceability

As part of Scott Laboratories' Quality Assurance System, accredited to BS EN ISO 9001:2015, full product traceability is assured by the following methods:

Each filter is identified by the following methods:-

Code number
Embossed along the cartridge, showing material type, pore size and lot number.

Part Number
Printed (In alpha-numerical and barcode form) on both the inner and outer packaging labels.

Batch Number
Printed (in alpha-numerical form) on both the inner and outer packaging labels.

These identifying numbers allow full product traceability back to raw material lot numbers. The date the filter was manufactured and sealed in the bag is shown on the bag label.

3.2 Manufacturing Facilities

This range of filters are manufactured in a controlled clean room environment that generally meets the requirements for ISO 14644-1 Class 8 Cleanrooms. Additionally, well-defined and documented work instructions and quality plans are used to ensure that the highest quality and cleanliness standards are consistently maintained.

They are manufactured in a facility and using processes that have been regularly audited and have been shown to be in compliance with current GMP requirements for suppliers of disposable product contact items to the pharmaceutical and food industries as laid down by the US Food and Drugs Administration (FDA) (specifically with the relevant parts within 21CFR), the European Medicines Agency (EMA) and the Food Regulations relating to the European Community.

All materials of construction used in the manufacturing of this range of filters are certified by the suppliers as free from the main known compounds such as silicone, fluoro compounds, oils and greases that can affect the application of paints and coatings (except for silicone seal options and fluoropolymer components). Furthermore, none of these materials are used in the manufacturing process, and all substances used in the manufacturing area are controlled to ensure that they are free from such materials.

All packaging materials used in direct contact with this range of filters are made from raw materials that do not contain Silicones, Amines or Phthalates, and these chemicals are not knowingly used in the production processes. The packaging is therefore classed as SAP free.

4.0 MATERIALS OF CONSTRUCTION

The following materials are used in the construction of this range of filters:

Component	Material
Filter Media	Coconut Based Carbon
Spunbonded Fibre	Polypropylene
End Caps	Polypropylene
Binder Resin	Polyethylene (PE - UHMW)
Seals	Silicone

4.1 Material Compliance

All the polymeric & elastomeric materials used to manufacture this range of filters meet the FDA requirements in accordance with Code of Federal Regulations, Title 21, parts 174 to 190 as applied to filter cartridges, and/or the appropriate European Guidelines.

All the polymeric materials used to manufacture this range of filters meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

They have been assessed by an external laboratory under the Plastics Materials and Articles in Contact with Foodstuffs Regulations laid out in EC Regulation (EU) No. 10/2011.

All substances identified as being used in the manufacture of the above product family are (a) listed in the above legislation, or (b) not subject to the provisions of the above legislation. Tests have shown that the above product family will meet the global migration limits when tested with food simulants 3% acetic acid, 50% ethanol, 95% Ethanol and iso-octane (aqueous, acidic, alcoholic and high fat products) and are suitable for processes up to 100°C.

The materials in construction of this product family are not subject to the provisions of EC Regulation 1895(2005) and do not use BADGE, BFDGE or NOGE.

Additionally, Scott Laboratories declares that its quality & manufacturing system meets the requirements of EC Regulation 2023(2006) *'The Good Manufacturing Practice Regulation'* for food contact materials.

4.2 BSE/TSE

This range of filters are considered to be in compliance with the European 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 Rev. 3 - July 2011) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Proprietary Veterinary Products (CPVP).

In addition, we certify that they are unlikely to pose a risk for TSE infectivity according to the USP Perspective to Minimize the Potential Risk of TSE Infectivity in Bovine-Derived Articles Used in the Manufacture of Medicinal Products, USP Pharmacopeial Forum, Vol. 30(5), September - October 2004.

Our suppliers' state that either the polymers used in the manufacture of these filters do not contain any Animal Derived Ingredients (ADI's) or that where they do incorporate small amounts of tallow based additives, stearates or other materials that are derived from fatty acids that during processing a re-esterification or hydrolysis process is used with a minimum temperature of 200°C and an appropriate pressure for at least 20 minutes with subsequent processing at the granulation and fibre production stages taking place at temperatures in excess of 200°C for several minutes. According to the EU Scientific Steering Committee on the Safety of Tallow (June 2001) and the recommendation for inactivation of TSE included in the Commission Directive 2000/6/EC and also in the Regulation (EC) N.1774/2002, the above-mentioned treatments ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material.

We certify that our products do not come into contact and are not exposed to any animal derived materials during our manufacturing processes. The suppliers of the raw materials used in the seals fitted to these filters have stated that animal derived materials are not used during their manufacture.

5.0 VALIDATION

The validation exercise covering this range of filters included the following tests described in the subsequent sections:

- Particulate Removal Efficiency
- Chlorine Removal Efficiency

5.1 Particulate Removal Efficiency

As part of the validation process for this range of filters, samples have been tested for filtration efficiency using a modified single pass test methodology with standard test dust, and typically achieved Beta 5000 at their respective micron ratings.

5.2 Chlorine Removal Efficiency

The maximum flowrate recommended for odor, taste and chlorine reduction per 10” filter is 15 liters/minute.

The recommended flowrate for optimum life & reliable chlorine reduction is a maximum of 3.7 liters/minute per 10” filter. This is based on achieving a >96% reduction of 3.0 ppm free chlorine.

Based upon testing carried out on **Clarify** and similar competitor filters, the typical chlorine reduction capacity of a 10” long **Clarify** is expected to be >75,000 liters at a flowrate of 3.7 liters/minute when challenged with water containing 3.0 ppm of free chlorine.