SCOTT CART AQUA

PRODUCT VALIDATION GUIDE

PURIFY & FINISH

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1.0 INTRODUCTION

ScottCart Aqua **Purify** and **Finish** 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 ScottCart Aqua Purify and Finish 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 Laboratories.

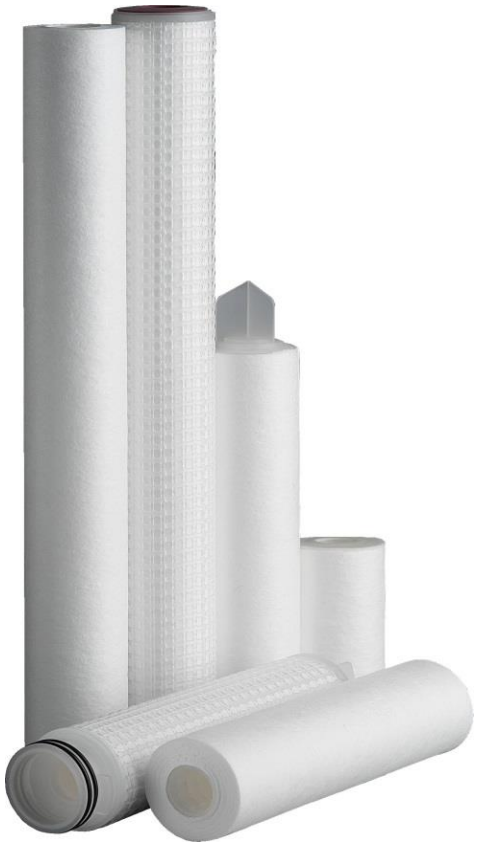
2.0 PRODUCT SPECIFICATION

2.1 Cartridge Description

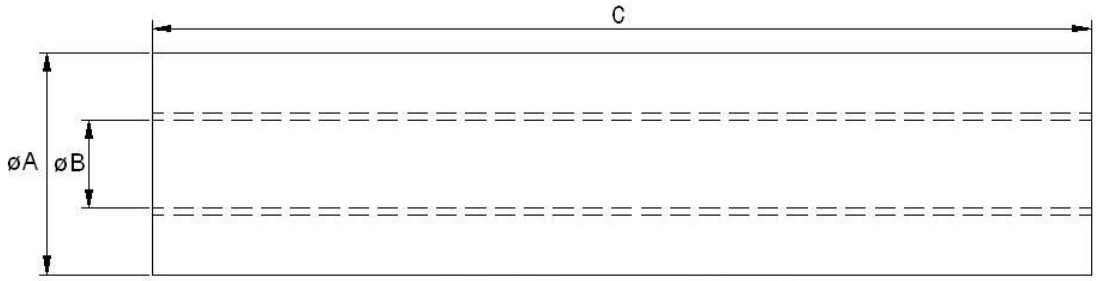
Purify and **Finish** cartridges feature gradient density, thermally bonded polypropylene spunbonded fibre and are available in a range of pore sizes with nominal removal ratings.

Purify and Finish filter cartridges are manufactured using a polypropylene inner support core with the option of incorporating a voile around the core for additional support of the spunbonded fibre. Plug-in styles are assembled using the latest thermal welding technology. This results in a robust, durable filter assembly, which will withstand a wide range of chemicals, temperatures and other harsh operating conditions.

Purify and Finish cartridges are available to fit most standard housings with either double open-ended seals or with plug in style ‘O’ rings for more critical applications.



2.2 Nominal Dimensions

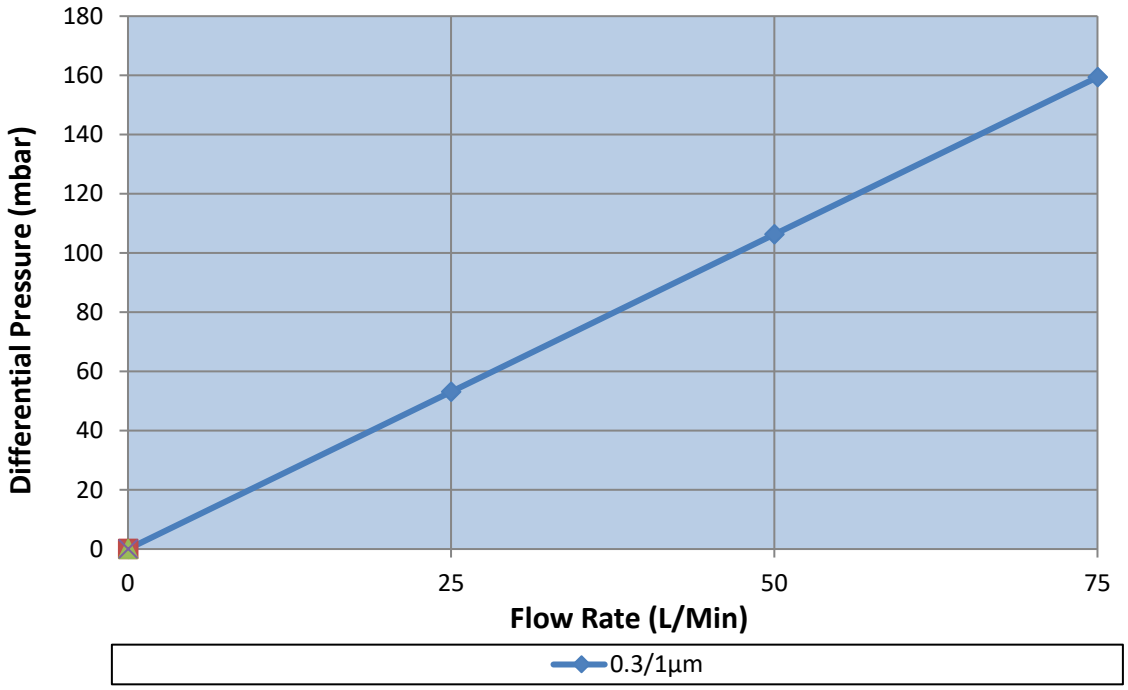


Double Open Ended Cartridge

Nominal Cartridge Length	Dimensions (mm)		
	ØA	ØB	C
10”	64	28	254
20”	64	28	508
30”	64	28	762

2.3 Flow Characteristics

10” long cartridges were tested in a **ScottCart Aqua** housing using filtered, clean water 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.

The maximum allowable differential pressure (ΔP) is dependent upon the operating temperature as illustrated in the following table:

Temperature °C/F	Maximum Differential Pressure, Bar (Forward Flow)
	Polypropylene Core
20/68	4.0
30/86	3.5
40/104	2.5
50/122	1.5
70/158	0.5
80/176	0.25
100/212	0

The values above should be treated as maximum differential pressures for short term use under the operating conditions stated without causing cartridge collapse problems. Scott Labs 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.

From available collapse testing data of cores at elevated temperatures, typical collapse pressures were significantly above the maximum differential pressures set for this range of filters by Scott Labs, and therefore allow a substantial safety margin.

3.0 QUALITY ASSURANCE

3.1 Product Traceability

As part of ScottCart Aqua's 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
Spunbonded Fibre	Polypropylene
Core	Polypropylene

4.1 Material Compliance

All materials of construction used in the manufacture of 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.

The cartridges also meet the biological safety requirements for plastics as specified in the United States Pharmacopoeia (Class VI Plastics (121°C) Testing) as described in section 5.1.

This product family meets 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/212°F.

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, the 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 minimizing 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 fiber production stages taking place at temperatures in excess of 200°C/392°F 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.

4.3 Statement on Plasticizers & Phthalates

We do not use in the manufacture or intentionally add plasticizers or phthalates to this range of cartridge filters. However, based upon information from the raw material suppliers, the polypropylene resins used may typically contain trace amounts of phthalates as a result of residual catalyst components. These trace levels of phthalates are typically at very low ppm levels.

5.0 VALIDATION

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

- USP Class VI Plastics (121°C/250°F) Testing
- Extractable Substances
- Potable Water Regulations

5.1 USP Class VI Plastics (121 °C) Testing

As part of the validation process, samples of this range of cartridge filters have been tested by an independent laboratory in accordance with the Biological Reactivity Tests *in vivo* for Class VI Plastics (121°C) as described in the United States Pharmacopeia.

The study included the following three tests on cartridge components or extracts of the components prepared at 121°C for one hour (the most stringent of the options detailed):

- Acute Systemic Injection Test
- Intracutaneous Test
- Implantation Test

All test results were shown to meet all the requirements of the USP Class VI-121ºC Plastics Test.

5.2 Testing for Extractable Substances

As part of the validation process for this range of filters, cartridge samples have been tested for extractables, and the levels in aqueous extracts were typically below the current USP limits defined for Water for Injection. This range of cartridge filters exhibit low levels of non-volatile residues.

5.3 Potable Water Approvals

5.3.1 Water Regulations Advisory Scheme (WRAS)

This range of double open ended cartridges have passed the UK Water Bylaws Scheme/WRC ‘Full Test of Effect on Water Quality (BS6920: Part 3) - Cold Water use,’ and is therefore suitable for use with potable water. The cartridge has been accredited with the Approval No.1202503.