

X-POT[®] CARTRIDGE FILTER DATA SHEET

For use with X-POT Compact, X-POT 6 and X-POT 6+ Models

CARTRIDGE FILTER (BOX OF 4)	
FILTER SIZE	PRODUCT CODES
50u	VX-CFILTERS(4)50MIC
20u	VX-CFILTERS(4)20MIC
5u	VX-CFILTERS(4)5MIC
0.5u	VX-CFILTERS(4)0.5MIC

CARTRIDGE FILTER (BOX OF 20)	
FILTER SIZE	PRODUCT CODES
50u	VX-CFILTERS(20)50MIC
20u	VX-CFILTERS(20)20MIC
5u	VX-CFILTERS(20)5MIC
0.5u	VX-CFILTERS(20)0.5MIC

Introduction

Filter cartridges that are used in high specification filtration applications must conform to strictly defined manufacturing and quality standards.

This guide describes the validation testing of the **SupaGard 07**, the results 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 applications.

SupaGard 07 cartridges feature gradient density, thermally bonded polypropylene spunbonded fibre and are available in a range of pore sizes with nominal removal ratings.

SupaGard 07 filter cartridges are manufactured using a 314 Stainless Steel inner support core. This results in a robust, durable filter assembly, which will withstand a wide range of chemicals, temperatures and other harsh operating conditions.

Quality Assurance

All **SupaGard 07** filter cartridges are issued with a Certificate of Conformity detailing part number, description and customer order details for each delivery.

Contamination Control & Cleanliness Standards

All **SupaGard 07** filter cartridges are manufactured in a controlled clean-room environment using well defined and documented work instructions and quality plans, thus ensuring 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 the **SupaGard 07** range are certified as silicone free (except for silicone seal options). Furthermore, no silicone is used in the manufacturing process, and all substances used in the manufacturing area are controlled to ensure that they are silicone free.

All packaging materials used in direct contact with VEXO® Filter cartridges 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.

Product Traceability

VEXO® Quality Assurance System, accredited to BS EN ISO 9001:2008, assures full product traceability. Each filter cartridge is identified by the following methods:

Code number

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

Part Number

Printed (In alpha-numerical and bar-code form) on the outer packaging label.

Batch Number

Printed (in alpha-numerical form) on the outer packaging label.
These identifying numbers allow full product traceability back to raw material lot numbers.

Biological Safety

US FDA CFR Title 21 for Food Contact

All the materials used in the construction* of SupaGard 07 cartridge filters fulfil the requirements on materials used for articles intended to come into contact with food as described in CFR Title 21, as well as the appropriate European guidelines.

USP Class VI Plastic Test

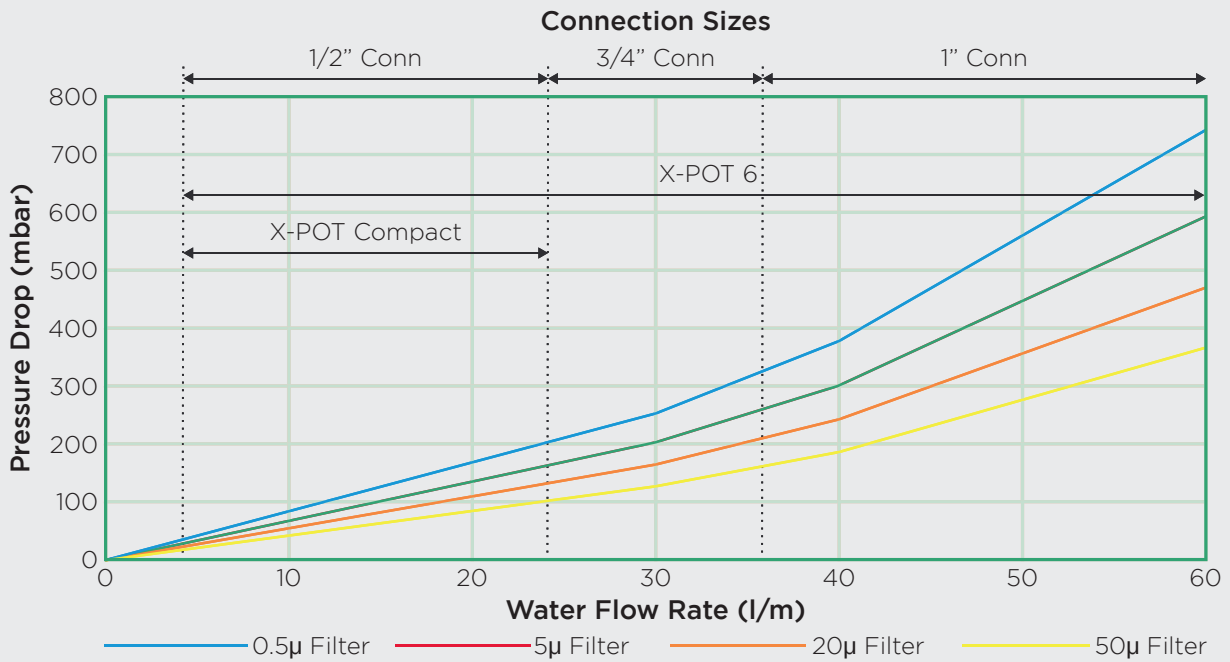
Samples of the components of VEXO® Filters SupaGard 07 cartridge filters have been tested by an independent laboratory and were shown to meet all the requirements of current USP Class VI-121°C Plastics Test.

Extractable

As part of the validation process for VEXO® Filters SupaGard 07 cartridge filters, cartridge samples have been tested for extractable, and the levels in aqueous extracts were typically below the current USP limits defined for Water for Injection.

VEXO® Filter SupaGard 07 typically exhibit low levels of non-volatile residues.

Flow DP of X-POT Compact & 6 Cartridge Filters Including Magnet Grate



NOTE - Choice of X-POT is dependent upon system working pressure and system volume.
 Dirty filter state can be estimated by multiplying the clean filter state by a factor of 2.