

REFERENCE LIST PHARMACEUTICAL INDUSTRY

GlaxoSmithKline Plc

Maidenhead, UK Slough, UK Stevenage, UK Irvine, UK Carrigaline, Ireland Port Fairy, Australia Singapore



Sandwich, UK Ringaskiddy, Ireland Singapore

Sigma-Aldrich Co

Arklow, Ireland

Novartis

Grimsby, UK Cork, Ireland Basel, Switzerland Singapore

Aesica Pharmaceuticals Ltd

Cramlington, UK Queensborough, UK

Lonza

Visp, Switzerland

<u>Sanofi</u>

Essex, UK Frankfurt, Germany Singapore, Malaysia















Amazon Filters operates a well-established Quality System, which is accredited to BS EN ISO 9001:2008 with full design and manufacturing approval. Amazon Filters is also accredited to BS EN ISO 14001:2004 for its Environmental Management System.

Amazon Filters products 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.

Samples of polymeric materials used in the cartridge filters listed below have been tested by an independent laboratory and were shown to meet all the requirements of current USP Class VI-121°C Plastics Tests

Amazon Filters' cartridge 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 Amazon Filters 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.

The following lists example applications where Amazon products are in use extensively at specific Pharmaceutical sites worldwide.

Client	Site	Product Types Used	Application
Pfizer	Sandwich, UK	SupaPore Halar 16LPG	Solvent filtration (particulate free)
		SupaMesh 05SS 06CV Ceramic	Multi-purpose filter High temperature and aggressive solvent transfer
Pfizer	Cork, Ireland	SupaSpun Nylon 04NN SupaPore PPG 16PPG 06CV Ceramic	Solvent filtration (particulate free) High temperature and aggressive
			solvent transfer
GlaxoSmithKline	Irvine, UK	SupaPore TP 16TPB	Sterile inlet air, fermenters
		SupaPleat II 03PP	Particulate filtration for product and process streams
		SupaPore VP 16VPB	Sterile filtration, liquid process

GlaxoSmithKline	Port Fairy,	SupaCarb CP	API product purification
	Australia	06CP005	(decolourisation)
GlaxoSmithKline	Stevenage, UK	SupaSpun 04PP SupaPore PPG 16PPG SupaSpun Nylon 04NN	Various Kilo and Pilot plant liquid applications
GlaxoSmithKline	Worthing, UK	SupaSpun Nylon 04NN	Toluene transfer filters
GlaxoSmithKline /Boots	Maidenhead, UK	SupaPore TP 16TPB	Sterile Venting
		SupaPore PPG 16PPG	Mouthwash and toothpaste product filtration
MSD	Le Vallee, France Ballydine, Ireland Hoddesdon, UK	SupaPore TP 16TPB SupaPore PPG 16PPG SupaPleat II 03PP	Particulate removal from various products and process streams
		SupaCarb CP 06CP005	Decolourisation of acetone
Aesica	Cramlington & Queensborough, UK	SupaPore PPG 16PPG SupaSpun Nylon 04NN DuoLine 19PP Bag filters	Toluene transfer filters
Lonza	Visp, Switzerland	SupaPore TP 16TPB	Sterile air, Fermenter Off-gas
Novartis	Cork, Ireland Grimsby, UK	SupaPore TP 16TPB SupaPore VP 16VPB SupaSpun Nylon	Particulate removal from various products and process streams
	Singapore	04NN SupaSpun Nylon	
	Basel, Switzerland	04NN SupaPore PPG 16PPG	
Bristol-Myers Squibb	Swords, Ireland	SupaPore TP 16TPG	Solvent filtration (particulate free)
Eli Lilly	Cork, Ireland	SupaPore TP 16TPG SupaPore TT 16TT	Solvent filtration (particulate free)