



domnick hunter
PROCESS DIVISION

Certificate of Conformance

Pharmaceutical Grade HIGH FLOW BIO-X Filters

We hereby certify that HIGH FLOW BIO-X pharmaceutical grade filters:

Code-Number: ZCHB-BT ; Lot-No.:

Conform with the requirements for non fibre releasing filters as laid down in the United States Food and Drug Administration Regulations 21 CFR 211.72 and 210.3(b), (6).

The filters also meet the domnick hunter quality control and assurance standards:

Material of Construction:

Active Filtration Medium	:	PTFE impregnated microfibre
Upstream Support	:	Polypropylene
Downstream Support	:	Polypropylene
Core and Sleeve	:	Heat stabilised Polypropylene
End Caps	:	Heat stabilised Polypropylen
Filtration Area	:	0,38 m ²

Technical Specifications

Voids Volume	:	94%
Max. Differential Pressure	:	In direction of flow 3,5 bar (50 psig) at 70°C (158°F)
Max. Operating Temperature	:	70°C (158°F)
Sterilisation	:	In situ steamsterilisation or autoclavable up to 142°C (288°F) for a maximum of 120 cycles
Biological Safety	:	Conforms to current USP 23 Plastic Class VI at 121°C and BS 5736 safety standards.
Validation	:	By bacterial challenge levels of 10 ¹² Brevundimonas diminuta and MS-2 Coliphage

Signature
- Product Manager-

Date : April 2008

For and on behalf of:
domnick hunter gmbh
PROCESS DIVISION

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