



domnick hunter
PROCESS DIVISION

Certificate of Conformance

Pharmaceutical Grade HIGH FLOW TETPOR II

We hereby certify that HIGH FLOW TETPOR II pharmaceutical grade filters:

Code-Number: ZHFT

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:

Filtration Medium	:	expanded PTFE
Upstream Support	:	expanded polypropylene
Upstream Support	:	non-woven polypropylene
Downstream Support	:	expanded polypropylene
Inner Support Core	:	Polypropylene
Outer Protection Cage	:	Heat stabilised Polypropylene
End Caps	:	Heat stabilised Polypropylene with integral polysulfone support ring (T-Code)
Standard 'O'-Rings	:	Silicone

Technical Specifications

Max. Differential Pressure	:	In direction of flow (outside to in) 3,5 bar (50 psig) at 142°C (288°F)
Max. Operating Temperature	:	60°C (140°F)
Note: HF Tetpor II cartridges can be used as WFI vents in heated housings if changed on a 4-6 monthly basis !		
Sterilisation	:	in situ steam sterilised for up to 225 cycles at 142°C (288°F)
Integrity Testing	:	All cartridges are integrity tested prior to despatch by the pressure decay and aerosol challenge test methods. Values are for cartridges wetted with 60/40 IPA/Water

Signature

-Product Manager-

DateNov 2009.....

For and on behalf of:
domnick hunter ltd.
PROCESS DIVISION

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