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Friday 6th November 2015

To Whom It May Concern,

The following information is to answer questions on the use of TETPOR PLUS at 120 °C.

Potential deformation:
The only true test of a filter's performance, regardless of exposure conditions, is a post use integrity test.

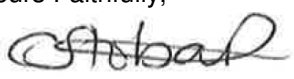
The melting point of the PTFE membrane used in TETPOR PLUS cartridges is > 300 °C. Therefore PTFE is very thermally stable at even 120 °C. The filter membrane should not open and close at different temperatures within the recommended operating limits, as PTFE exhibit plastics deformation, not elastic deformation. Therefore any damage to the filter would be detected by a post use integrity test failure.

Particulate shedding:
The validation guide for TETPOR PLUS states requirements for Cartridge Cleanliness and Biocompatibility:
TETPOR PLUS filters must meet stringent standards to be certified pharmaceutical (P) grade product by Parker domnick hunter.

- Conformance to the requirements for non-fibre releasing filters as laid down in the United States Food and Drug Administration Regulations 21CFR11.72 and 210.3(b), (6).
- Effluent quality following a purified water flush must also be met as determined by the following tests:
  - Test for oxidisable material per USP 23 Purified Water
  - Test for bacterial endotoxins using a gel clot LAL (Limulus Amoebocyte Lysate).
  - Test for particulates
  - Test for TOC (total organic carbon)
  - Test for conductivity
- All components conform to the Biological Safety Standards identified in USP<88> to Class VI-121°C levels.
- All filters must meet minimum defined integrity test values prior to despatch, defined from a correlation against an appropriate bacterial challenge.
- All filters are flushed with a high flux of purified water prior to despatch as a guarantee of product cleanliness.

One aspect of this is to confirm levels of potential contaminants that may be added to a process stream by the addition of the filter cartridge.

Yours Faithfully,



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