

**SECTION 23192**  
**SPECIFICATION FOR**  
**SANITARY CARTRIDGE FILTERS**

**PART 1        GENERAL**

**1.01    GENERAL REQUIREMENTS**

- A.    Refer to the Contract Documents for Terms and Conditions, warranty requirements, and other commercial instructions and information.

**1.02    SUMMARY**

A.    Work Included:

1.    Seller shall design, fabricate, test, inspect, clean, package, and deliver Sanitary Cartridge Filters in accordance with this Specification and the attached data sheet(s).
2.    Each Sanitary Cartridge Filter furnished shall include, but not be limited to, the following components as indicated on the data sheet(s):
  - a.    Filter element(s), when specified on the data sheet(s).
  - b.    Filter housing with inlet, outlet, vent, gauge port (for T-style housings only), and drain connection (for in-line type housings only).
  - c.    O-ring gaskets, as required.
  - d.    Clean -In -Place (CIP) cap, when specified on the data sheet(s).
  - e.    Jacketed filter housings, when specified on the data sheet(s)
3.    Where identified on the data sheet(s), Seller shall provide cart-mounted sanitary filters, with four (4) lockable non-sparking, non-marking type caster wheels, two (2) rigid and two (2) swivel wheels.
4.    Submittals and tagging as specified herein.

B.    Work Not Included:

1.    Refer to Section 23010 - Specification for General Requirements for Sanitary Mechanical Equipment.
2.    Utilities available.

**1.03    RELATED DOCUMENTS**

A.    Reference Specifications:

1.    Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.

B.    References:

1.    ANSI - American National Standards Institute.

2. ASME BPE - Bioprocessing Equipment Standard, 1997 & 2000 Addenda.
3. ASME B&PV - American Society of Mechanical Engineers - Boiler & Pressure Vessel Code.
4. ASTM - American Society for Testing and Materials.
5. AWS - American Welding Society.
6. CFR - Code of Federal Regulations.
7. cGMP/FDA - Current Good Manufacturing Practices of the Food and Drug Administration, United States Department of Health and Human Services (cGMP 21 CFR Part 210 & 211).
8. DIN - Duetches Industrie Normen, DIN 2743, DIN 2745 (if applicable).
9. EU Guidelines - European Commission's Working Party on "Control of Medicines and Inspection, Guide to Good Manufacturing Practices.
10. HIMA - Health Industries Manufacturing Association.
11. USP - United States Pharmacopoeia.
12. OSHA - Occupational Safety and Health Act.
13. State and local applicable codes.

C. Attachments:

1. Equipment data sheet(s).
2. Submittal Requirements Form.
3. Refer to purchasing documents for a specific list of attachments.

#### 1.04 SUBMITTALS

- A. Submittal requirements are as stipulated in Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.
- B. Seller to provide documentation as required by Submittal Requirements Form, Submittal Package Section A.

#### 1.05 QUALITY CONTROL

A. Source:

1. Refer to Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.
2. Seller to provide documentation as required by Submittal Requirements Form, Prior to FAT section B.
3. Inspection - General
  - a. Factory inspections are not expected.
4. Tests
  - a. A Certificate of Conformance shall be submitted for each filter element fabricated from each manufacturing lot, identifying the rating, element number, and the lot number. The certificate shall include the following documentation identifying the test methods and biological test organisms used for each manufacturing lot:
    - i The product meets the cGMP standards.

- ii The manufactured lot, which the filter element is from, has been sampled, tested and released by the manufacturer's quality control department.
    - iii The filter element meets the requirements as specified herein.
  - b. All test instruments shall be factory calibrated before testing. Calibration of test instruments shall be NIST traceable or to another recognized standard, meeting the requirements of NIST.
  - c. The following tests shall be conducted for each filter lot:
    - i Materials Toxicity: Filter elements shall be non-pyrogenic per USP Bacterial Endotoxin Test and USP pyrogen test, non-toxic per USP toxicity test for plastics and USP mouse safety test, and non-mutagenic per Ames Mutagenic Assay.
    - ii The filter elements shall be provided with documentation that a sample from the same lot as the filter provided, passed a destructive bacterial challenge test in accordance with ASTM methodology.
    - iii Bacterial Retention: 0.2 micron rated filters shall retain *Brevundimonas diminuta* tested in accordance with ASTM methodology at a level of  $10^7/\text{cm}^2$ . 0.45 micron rated filters shall retain *Serratia Marcescens* tested in accordance with ASTM methodology at a minimum challenge level of  $10^7/\text{cm}^2$ .
    - iv Integrity Tests: The filters shall be provided with integrity test results to ensure filter integrity. The results shall detail the filter integrity test method and clearly identify the filter element.
    - v The following tests shall be conducted on an audit basis:
      - i Toxicity: Element shall be non-toxic per the current USP General (Mouse) Safety Test.
      - ii Gravimetric Extractable: The amount of non-volatile extractable shall be equal to or less than 20 mg per 10 inch filter element after 24 hours in deionized water at controlled room temperature.
      - iii Multiple Steam Cycles: Integrity shall be maintained after 150 steam cycles of 30 minutes at  $145^\circ\text{C}$ .

#### B. Site

1. Refer to Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.
2. Equipment will be subject to reinspection, at the jobsite, for damage during shipment.
3. Any field changes required to meet this specification shall be implemented, recorded, and all documentation updated and resubmitted to the Buyer at no cost to the Buyer.

### 1.06 DELIVERY, STORAGE, HANDLING

- A. Refer to Section 23010 - Specification for General Requirements for Sanitary Mechanical Equipment.

- B. Seller to provide documentation as required by Submittal Requirements Form, Final Documentation Package Section C.

#### 1.07 CLEANING, PACKAGING, AND TAGGING

- A. Refer to Section 23010 - Specification for General Requirements for Sanitary Mechanical Equipment.
- B. In addition to the information in Section 23010, the nameplate shall include the following:
  - 1. Equipment tag number.
  - 2. Housing Design Pressure.
  - 3. Housing Design Temperature.
  - 4. Housing Material of Construction.

#### 1.08 OPTIONS

- A. Seller shall provide separate costs for options as identified on the data sheet(s).

### PART 2 PRODUCT

#### 2.01 PERFORMANCE CRITERIA

- A. The filters shall perform in accordance with the requirements contained within this Specification and the attached data sheet(s).
- B. Filter performance shall be in full compliance and capable of being validated in accordance with the cGMP's.
- C. All filter ratings specified are absolute ratings, referring to the largest hard spherical particle, which will pass through the filter under the specified conditions.
- D. The filter housing, gaskets and o-rings shall be capable of being repeatedly steam sterilized in-situ.
- E. The liquid filter elements, housings, gaskets and o-rings shall be capable of being sanitized with CIP solution, if specified on the data sheet(s).
- F. All vent and gas filter elements shall be hydrophobic.
- G. All liquid filter elements shall be hydrophilic and shall be uniformly wettable when exposed to water or any other specified liquid.
- H. All filters shall be sized based on the flow rate and coincident pressure drop as indicated on the data sheet(s). All vent filters shall be sized on the most demanding draw requirement due to either vacuum after steam-in-place (SIP), process fill rate or process draw rate.

- I. Where applicable, the filter housings and O-ring gaskets shall be capable of being repeatedly steam sterilized in either direction of flow or autoclaved. The vent filter elements shall be capable of consecutive non-continuous cycles of steam sterilization at the specified pressure and temperature. Seller to identify the estimated number of cycles on the data sheet(s).
- J. Seller shall recommend housing CIP procedure based on pharmaceutical application experience, unless specified otherwise on the data sheet(s).
- K. Where specified on the data sheet(s), filter with all components shall be capable of being cleaned with cleaning solution and hot water for injection.
- L. In the event of conflict between this specification and the data sheet(s), the data sheet requirements shall govern.

## 2.02 DESIGN DETAILS

### A. General

- 1. The design and construction of the filters supplied under this Specification shall be the manufacturer's proven design for the pharmaceutical industry and in addition be in compliance with cGMPs.
- 2. Drain valves, if required, shall be Seller's standard sanitary, free draining type.
- 3. In the event of conflict between this specification and the data sheet(s), the data sheet requirements shall govern.
- 4. For additional general design requirements, also see Section 23010 - Specification for General Requirements for Sanitary Mechanical Equipment.

### B. Filter Elements

- 1. The filter element pore structures shall not vary with temperature, pressure and flow conditions. Filter elements shall not shed or unload as filter clogs and pressure increases. The filter elements shall be non-fiber releasing as defined in CGMP (CFR 21- Part 210.3 (b) (6)).
- 2. The 0.2 and 0.45 micron filter elements shall be membrane type.
- 3. The filter element shall be a single piece of thermoplastic construction. The filter cartridge end caps, and O-ring adapters shall be thermoplastic bonded. The multi-length elements shall be assembled by thermoplastic bonding of cartridges end to end.
- 4. The filter elements shall have locking tabs at the base for bayonet lock to prevent element from unseating unless specified otherwise on the data sheet(s).

### C. Filter Housing

1. All housings shall be designed and fabricated in accordance with ASME Boiler & Pressure Vessel Code, Section VIII Division I, Section II Material Specifications and Section IX Welding and Brazing Qualifications.
2. National Board (NB) registration and ASME Code U stamp shall be provided where applicable.
3. Filter housings shall be specified for design pressure and the corresponding design temperature.
4. The filter housings shall be capable of accepting sanitary style filter cartridges that utilize code 7 design filters with type 226 double O-ring sealing mechanism at the open filter end and a finned end cap at the blind end.
5. The filter housing closures shall utilize quick release mechanisms to facilitate easy filter element change outs.
6. All connections shall be a standard sanitary, Tri-clamp type design.
7. The filter housings shall be designed for positive, complete gravity drainage of fluid.
8. The nozzle configuration of all filters shall be indicated on the data sheet(s).

D. Materials of Construction

1. Materials of construction for the filter assemblies shall be as specified on the data sheet(s).
2. All gasket materials in potential product contact must be approved by Buyer. Gasket materials shall be steam resistant. Seller to furnish manufacturer's data on gasket material being furnished.
3. Only ASME approved materials shall be used for tubing and pressure-containing parts. Materials of construction for major components shall be as specified herein. Prior approval by the Buyer will be required if materials other than those specified are to be used. Materials not specified (other than for product-wetted parts) shall be Seller's standard for the application.
4. The Seller shall indicate on review drawings the ASME material specification and grade number furnished for all ASME materials. For non-ASME materials, materials shall be specified by ASTM or other standard designations.
5. Chloride, asbestos or asbestos bearing materials are not permitted. Seller shall provide written certification that all materials are asbestos and chloride free.
6. Bolts and nuts shall be stainless steel material.

E. Carts (if specified on the data sheet(s))

1. Carts for portable liquid filters shall be provided with push handle bar. Construction of carts shall be sanitary in all aspects and legs shall be square tubes with welds ground smooth, finished to the same external finish as for filter housing requirements.
2. Seller shall provide lockable non-marking casters, which can be autoclaved. Casters shall be sized to handle twice the total load of the filter full of liquid.

## 2.03 WELDING

- A. Refer to Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.

#### 2.04 SURFACE FINISH

- A. Refer to Section 23010 – Specification for General Requirements for Sanitary Mechanical Equipment.
- B. Seller to indicate passivation procedures, which are to be executed.
- C. Refer to data sheet(s) for additional surface finish requirements.

**END OF SECTION**