

P3-A[®] End Suction Centrifugal Pumps for Active Pharmaceutical Ingredients P3-A 003

Formulated by
3-A Sanitary Standards, Inc.
Pharmaceutical 3-A (P3-A) Steering Committee

It is the purpose of the Pharmaceutical 3-A (P3-A) Steering Committee in connection with the development of the P3-A Sanitary Standards Program to allow and encourage full freedom in inventive genius or new developments. Pumps and materials for use in Process Equipment and Systems used as product contact surfaces for pharmaceutical equipment and systems heretofore or hereafter developed, which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the manufacturer's opinion, are equivalent or better, may be substituted for the joint consideration of the P3-A Steering Committee and 3-A Sanitary Standards, Inc. at any time. The P3-A Sanitary Standards and P3-A Accepted Practices provide sanitary/hygienic criteria applicable to equipment and systems used to produce and package active pharmaceutical ingredient(s). Standard English is the official language of P3-A Standards and P3-A Accepted Practices.

A SCOPE

A1 These standards cover the sanitary design requirements of mechanically sealed end-suction centrifugal pumps, conforming to ANSI/ASME B73.1, pertinent to active pharmaceutical ingredient (API) manufacturing *in order to maintain product integrity*.

A2 In order to conform to these P3-A Standards, mechanically sealed end-suction centrifugal pumps shall comply with the following design, materials, and fabrication criteria. (Refer to Appendix D (Non-normative) for a typical diagram of a pump and a seal.)

B NORMATIVE REFERENCES

21 CFR 175 Subpart C¹, Substances for Use as Components of Coatings.

21 CFR 177 Subpart B¹, Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces.

21 CFR 177 Subpart C¹, Substances for Use Only as Components of Articles Intended for Repeated Use.

ASME B46.1 Surface Texture (Surface Roughness, Waviness, and Lay).

ANSI/ASME B73.1 Specification for Horizontal End Suction Centrifugal Pumps for Chemical Process.

P3-A-001 Standard Terminology Relating to Equipment Used in the Manufacture of Active Pharmaceutical Ingredients.

P3-A-002 Sanitary/Hygienic Standards for Materials for Use in Process Equipment and Systems.

C MATERIALS

C1 Equipment will wear and undergo changes from like-new condition. Selection of materials, finishes, and fabrication methods shall be based upon understanding of the environment of intended use. The owner/user shall accordingly be responsible for the final selection of materials of construction and surface finishes and associated rationales with regard to product safety, strength, identity, quality, and purity.

C2 Metals

C2.1 Metal product contact surfaces shall be specified by the user from among the metals listed in P3-A-002. Metals shall be suitable for all phase of the process, including cleaning and steaming.

¹For sale by the Superintendent of Documents, U.S.

Government Printing Office, Washington, D.C. 20402 (202) 783-3238.

C3 Surface Modification Materials

C3.1 Surface modification materials that become a part of the parent material on product contact surfaces shall comply with the appropriate provisions of one or more of the following:

- 21 CFR 175 Subpart C,
- 21 CFR 177 Subpart B, or
- 21 CFR 177 Subpart C.

C3.2. No surface finishing compound containing any animal extract shall be used to generate the required surface finish.

C4 Nonmetals

C4.1 Elastomer and elastomer-like materials and plastic materials shall be specified by the end user from among the materials meeting the requirements of P3-A-002, and, in their intended use shall be non-toxic and non-absorbent. Materials shall be suitable for all process phases, including clean in place (CIP) and steam in place (SIP).

C4.2 Elastomer and elastomer-like materials and plastic materials having product contact surfaces shall retain their surface and conformational characteristics.

C4.3 Materials having certain inherent functional purposes required for specific applications, such as seals, carbons, and/or ceramic materials may be used. Carbon and/or ceramic materials shall be inert. These materials must meet the requirements of C2 or be generally recognized as safe (GRAS) by the FDA.

C4.4 Lubricants intended for use during assembly shall meet the requirements of P3-A 002, paragraph C8.

D DESIGN**D1 Surfaces**

D1.1 All as cast pump casings and impeller surfaces shall be acceptable unless otherwise specified by the customer. Special surface finishes shall be clearly specified by the user on the attached Pump Data Sheet, Appendix A, if required.

D1.2 All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant by a user specified coating system. Nonproduct contact surfaces shall

have a smooth finish, free of pockets and crevices, and be readily cleanable and those surfaces to be coated shall be effectively prepared for coating.

D2 Permanent Joints

D2.1 All permanent joints in metallic product contact surfaces shall be continuous, full penetrating welds. Welded areas on product contact surfaces shall be a maximum of 63 μ in Ra (1.6 μ m Ra) finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices.

D2.2 Casing drain connection, if specified, shall have a full penetration weld ground flush on the product contact surface. Product contact surfaces should have a maximum surface roughness of 63 μ in Ra (1.6 μ m Ra) finish and be free of imperfections such as pits, folds, and crevices.

D2.3 Press, shrink, and slip fits shall not be used on product contact parts.

D3 Coatings

D3.1 Coatings shall meet the requirements of P3-A-002.

D4 Cleaning Verification

D4.1 Centrifugal pumps that are to be cleaned in place shall be designed so that the product contact surfaces of the pump are accessible and removable for cleaning verification or validation.

D5 Draining

D5.1 All product contact surfaces shall be drainable without pump disassembly or removal.

D6 Seals and Seal Chambers

D6.1 The primary product mechanical end face seal (seal) shall be sanitary in design with all product contact parts demountable and accessible for inspection and cleaning.

Refer to Appendix D (Non-normative) for an example diagram of a conforming seal design.

D6.2 Metal bellows seals, split seals, and packing shall not be used. Seals that use set screws on product contact surfaces shall not be allowed.

- D6.3 Seals utilizing single spring designs that reside on the product side of the seal may only be used if manual cleaning methods, requiring pump disassembly, are utilized.
- D6.4 Seals shall be capable of momentary dry running. Details of such occurrences shall be specified by the end user.
- D6.5 In liquid lubricated seal arrangements the buffer/barrier fluid used in dual seal arrangements shall be provided by the owner/user. The design of the outboard sealing chamber as applicable, piping circuit, and reservoir shall allow for the ability to drain and change the buffer/barrier fluid in order to reduce particulates, prevent degradation of the fluid lubricating properties, and manage biological degradation of some buffer/barrier fluids as necessary.
- D6.6 Seal chambers shall be a tapered bore design that will allow for complete draining of the pumped product in an assembled state. Seal chambers shall not contain threaded connections on product contact surfaces.
- D6.7 Seal chambers and/or gland plates shall be designed such that the seal chamber and piping system, if supplied, is self-venting during start-up and operation.
- D6.8 Seal chambers shall not contain throat bushings.
- D6.9 Seal chambers shall be provided by the pump or seal manufacturer.
- D6.10 All product contact surfaces in the seal chamber and gland plate shall be as cast or machined. Machined surfaces should have a maximum surface roughness of 63 μ in Ra (1.6 μ m Ra). Specific surface finishes other than that stated above shall be specified on the data sheet (Appendix A).
- D7 Gaskets and O-rings**
- D7.1 Gaskets and O-ring retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except those for standard O-rings smaller than 1/4 in. (6.35 mm), and those provided for in Table 1.
- D7.2 Gaskets and O-rings, when used within the pump, shall be self positioning. Mating surfaces shall be within 1/32 inch.
- D8 Radii**
- D8.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/8 in. (3.18 mm) except that:
- D8.1.1 Smaller radii may be used on gasket pilot diameters. In no case shall such radii be less than 1/32 in. (0.794 mm).
- D8.1.2 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Table 1.

TABLE 1 - Groove Radii Dimensions for Standard O-Rings

O-Ring Cross Section, Nominal (AS 568 ²)	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1 ³)	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.388 mm)

² The document establishing these standard dimensions is Aerospace Standard (AS) 568, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086 (412-776-4970).

³ The document establishing these standard dimensions is ISO 3601-1: 1988 (E), published by the International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland (41-22-734-1240).

D9 Threads

- D9.1 There shall be no exposed threads on product contact surfaces.
- D9.2 Shaft threads shall be enclosed and sealed from product by means of an O-ring, gasket, or similar type seal.

D10 Steam, Water, or Chemical Treatment Provisions

- D10.1 Pumps designed to be used in a processing system to be sterilized or otherwise treated using steam, water, or chemicals shall comply with the following:
- D10.1.1 Where steam or other sterilizing medium is used, the connection(s) on the pump(s) shall be such that the medium lines can be securely fastened to the pump(s).
- D10.1.2 In a processing system to be treated using steam or water and operated at a temperature of 250°F (121°C) or higher, all pumps shall be designed and constructed such that they can be (1) treated by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) for a minimum time duration of 30 minutes, and (2) operated at the temperature required for processing. Other conditions may be used when demonstrated to be effective.

- D10.1.3 In a processing system to be treated by chemical means, all pumps shall be capable of sustaining vacuum while idle.

- D10.2 Any conditions to which the pumps will be subjected during such treatment(s) shall be specified by the Owner of the Pump Data Sheet (Appendix A) and Seal Data Sheet (Appendix B).

D11 Pump Design

- D11.1 The pump package shall include the pump, seal reservoirs, motor, coupling, coupling guard, and mechanical seal mounted on a common bedplate unless otherwise noted on the Pump Data Sheet (Appendix A).
- D11.2 Closed and semi-closed type impellers shall not be used.
- D11.3 All pump casings shall include 150# or 300# ANSI flanges as noted on the Pump Data Sheet (Appendix A). A minimum ½ inch (12.7 mm) welded ground flush casing drain shall be supplied if noted on the pump data sheet (Appendix A). No other connections shall be allowed unless noted on the Pump Data Sheet (Appendix A).
- D11.1.4 Guards required by a safety standard that will not permit accessibility for cleaning and inspection shall be designed to be readily removable.