Upcoming additions and changes to USP Standards

What is it?

- The United States Pharmacopeia (USP) has updated Chapters <87> and <88>.
  - USP <88> has been reduced in scope, removing the table classifying plastics I - VI (e.g. USP Class VI). Only one test remains, and it is not recommended. USP Class VI will no longer exist.
  - USP <87> has increased in scope, offering more options for biocompatibility testing to replace what has been removed from USP <88>.
- USP Chapter <665> is a new USP standard for leachable and extractable (L&E) studies for drug product and drug substance in multi-use and single-use manufacturing.
  - Limited to thermoplastics (excludes thermoset elastomers)
  - Not a pass-fail test like biological reactivity testing

Why is this happening?

- USP <88>: The primary driver is to reduce antiquated, insufficient and inhumane animal testing.
- USP <665>: Establishes a standard baseline for the qualification of multiuse and single-use plastic component extractables for risk assessment.
- Ensure product safety by demonstrating that materials contacting the product do not introduce harmful substances, using modern, scientifically advanced testing approaches.

What is replacing it – what is the "new USP class VI"?

- USP <88> is being scaled back to reduce reliance on animal testing while USP <87> now has additional in-vitro tests to take its place
- The ASME-BPE has approved updates to biocompatibility testing requirements, emphasizing in-vitro cytotoxicity (USP <87>) and eliminating the need for in-vivo (USP <88>) testing, unless justified by data.

When does this take place?

- The changes to USP Chapters <87> and <88> have been approved by USP. Effective December 1, 2026.
- The publication of USP Chapter <665> is approved by USP and is currently available. Effective May 1, 2026.

New Testing Expectations for Single-Use Technologies (SUTs) and elastomers (gaskets, seals, etc.)

- A risk-based approach to extractables testing, using USP <665> and USP <1665> as tools to comply with 21 CFR 211.65.
- For new components from December 2026, biocompatibility testing defaults to USP <87> or ISO 10993-5, with additional tests considered on a case-by-case basis.
- Extractables testing will follow USP <665>, though risk-based testing decisions may require further industry guidance.
- Legacy components launched before December 2026 can meet biocompatibility requirements through historical testing methods.

Impact(s) to you

- All specifications that reference USP Class IV specifications need to be updated by December 31st, 2026
- Begin to understand what is needed by your company to assess L&E and new biocompatibility requirements.

Helpful Links

- BPSA position statement (Single-Use)
- Biophorum position statement (Single-Use)
- ISPE: future of USP for plastics
- 21 CFR 211.65

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Nov 30th, 2026			
Tri-Clamp Gasket Specification Sheet			
For Compendial Water (WFI) Service			
Document Number	TCG-SPEC-001		
Effective Date	5/26/2026		
Prepared By	Engineering Department		
Approved By	Quality Assurance		
1. Scope			
This specification defines the material, dimensional, performance, and compliance requirements for ASME BPE (2026) tri-clamp gaskets used in hygienic process piping systems for compendial water applications.			
Note: ASME BPE compliance is required, ASME BPE certified with a certificatation number is preferred.			
2. Applicable Standards	ASME BPE (2024)	Bioprocessing Equipment Standard	
	USP <87> “Biological Reactivity Tests, In Vitro.”	In-vitro biocompatibility / cytotoxicity testing for plastics, elastomers, and other polymeric materials.	
	USP <88> “Biological Reactivity Tests, In Vivo.”	In-vivo biocompatibility testing (including systemic injection, intracutaneous, and implantation tests) for classification of plastics and polymeric materials.	
3. Material Specifications		**EPDM**	**PTFE**
	Color	Black	White
	Hardness	70 ±5 Shore A	55–65 Shore D
	Temp Range	-40°C to 150°C	-100°C to 260°C
4. Dimensional Specifications	As per ASME BPE (2025)		
5. Performance Requirements	Compression Set	≤ 25%	
	Tensile Strength	≥ 7 MPa	
	Elongation	≥ 150%	
	Surface Finish	Smooth, flash-free	
	Leak Integrity	Zero leakage at rated pressure	
	Pressure Rating	Up to 10 bar (150 psi) depending on application	
6. Surface Finish & Cleanliness	No visible cracks, voids, pits, or contamination		
	Free from mold release residue		
	Suitable for hygienic and sterile service		
	Individually packaged in clean environment when required		
7. Incoming inspection	Visual inspection		
	Dimensional verification		
	Material certification review		
8. Marking & Traceability	Each gasket batch shall include:		
	Material identification		
	Batch/lot number		
	Manufacturing date		
	Certificate of confirmance with ASME BPE Requirements as per Parts GR, DT and PM.		
	Statement of Compliance for the Absence of ADIs, Phthalates, Nitrosamines, and TSE/BSE-Derived Materials.		
	Certificate of confirmance for testing to USP <88> Class VI		
9. Packaging Requirements	Packaged in UV resistant plastic to NEMA4.		
10. Storage Conditions	Storage Temperature	10°C to 30°C	
	Humidity	< 70% RH	
	UV Exposure	Avoid direct sunlight	
	Shelf Life	EPDM: 10 years from date of manufacture PTFE: 8 years from date of manufacture	
14. Revision History	**Revision**	**Date**	**Description**
	A	5/26/2026	Initial Release

December 1st, 2026			
Tri-Clamp Gasket Specification Sheet			
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	Statement of Compliance for the Absence of ADIs, Phthalates, Nitrosamines, and TSE/BSE-Derived Materials.		
	Certificate of confirmance for testing to USP <88> Class VI (exp. Nov. 30, 2026) **OR** Certificate of Conformance with in vitro biocompatibility testing per USP <87> Cytotoxicity (or ISO 10993 5) **OR** Other USP <87> testing as defined by Owner/User risk assessment (see RA-2026-001)		
9. Packaging Requirements	Packaged in UV resistant plastic to NEMA4.		
10. Storage Conditions	Storage Temperature	10°C to 30°C	
	Humidity	< 70% RH	
	UV Exposure	Avoid direct sunlight	
	Shelf Life	EPDM: 10 years from date of manufacture PTFE: 8 years from date of manufacture	
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