

Technical Data Sheet

Product Name: Cryovial®

Catalogue No.: T301-X Series

This document replaces any previous version

1. Product Description:

➤ Assembled Internal Thread Cryogenic Vial with Silicone O-Ring Seal and Graduations:

- Sterile, Disposable Cryogenic Vial

➤ Available Options:

- T301-1 – CRYOVIAL® 1.2 ml self-standing
- T301-2 – CRYOVIAL® 2 ml self-standing
- T301-3 – CRYOVIAL® 2 ml round bottom
- T301-4 – CRYOVIAL® 4 ml round bottom
- T301-4A – CRYOVIAL® 4 ml self-standing
- T301-5 – CRYOVIAL® 5 ml round bottom

➤ Compatible with:

- Color Coding Cap Insert T312

2. Packaging:

- **Case:** 10 bags if 100 units / 1 000 units per case

3. Product Specifications:

➤ Material:

- Tube: Polypropylene
- Cap: Polypropylene
- O-Ring: Silicone

➤ Temperature Range: -196°C to +121°C

➤ Autoclavable: +121°C for up to 30 minutes

➤ Leak-proof: Tested in vacuum at 71.3cm Hg (95 kPa)

➤ Liquid Nitrogen (LN²) resistance: Gas phase of LN² only

➤ MEA: Product has passed MEA testing

4. Standards and Conformity:

- **Radiation & Dosage:** Sterilizer certifies a Gamma SAL of 10⁻³; between 6.5 kGy & 13.5 kGy
- **RN/DNase, DNA & PCR free:** Certified RNase, DNase, DNA & PCR Inhibitor Free
- **Pyrogen-Free:** Certified Acceptance Criteria per USP <85> Bacterial Endotoxins Test met [λ = 0.06 EU/mL; results < 0.06 EU/mL or < 21 EU/device]
- **FDA:** Resin conforms to FDA 21 CFR 177.1520
Silicone O-Ring conforms to FDA 21 CFR 177.2600
- **USP:** Plastic Conforms to USP Class VI
- **CE:** Product is CE Marked
- **CONEG / RoHS:** Suppliers certify resin and O-Ring are in conformity with CONEG / RoHS standards for heavy metals
- **REACH (SVHC):** Supplier certifies the resin is in conformity to REACH standards
- **EU Reg. 2019/1021 (POPs):** Supplier certifies the resin is in conformity with EU 2019/1021 (POP)
- **Toxic Substance Control Act:** Supplier certifies the resin is in conformity with US TSCA
- **PFAS:** Supplier certifies the resin as PFAS-Free
- **BSE/TSE:** Supplier certifies the resin as BSE/TSE-Free
- **Bisphenols:** Supplier certifies the resin as free from Bisphenols & their compounds

Technical Data Sheet

- **Phthalates:** Supplier certifies the resin as Phthalate Free
- **LATEX:** Supplier certifies the resin as Latex Free
- **Conflict Minerals Reporting:** Supplier certifies the resin is in conformity with CMR standards

5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Volume measurements
- Closure verification
- Leak proof testing in vacuum at 71.3cm Hg
- Gas phase of Liquid Nitrogen resistance

6. Traceability:

- **Lot No. Composition:** 8 or 9 digits
- **The lot number can be found in one or all of these locations:**
 1. On exterior case label
 2. On label inserted inside the master case
 3. On the inner bag

7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Avoid temperature variations and humidity
- Protect from any possible contamination
- Protect from any damage to the packaging which could compromise the product sterility

8. Recommended Use:

- Designed for storing biological material at temperatures as low as -196°C
- Not recommended in the liquid phase of LN². Disposables for single use only.
- Verify proper cap closure when using biohazard material and / or chemical reagents
- Follow chemical resistance chart recommendations
- For use in automated equipment, follow the equipment manufacturer's instructions
- Should be used only in the gas phase of Liquid Nitrogen (LN²)

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