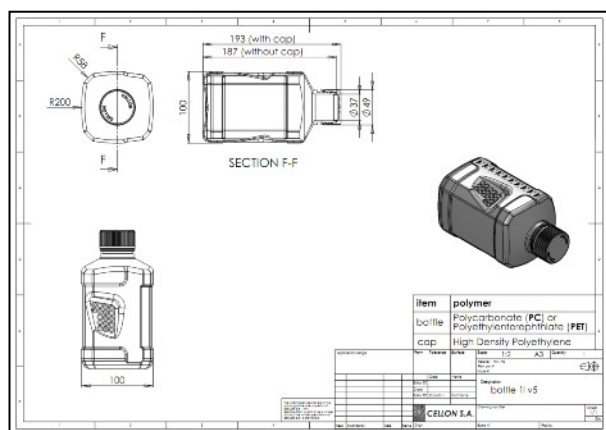


PharmaTainer™ FAQ

PharmaTainer™ Validation Information

<http://biofluidfocus.com/>



You are concerned about biocompatibility and other container quality issues, The manufacturer has developed a validation file to assist prospective users of PharmaTainer products. The complete validation file is available under a confidentiality agreement.

If you wish to initiate the CDA process, please notify your dealer or drop a note to info@biofluidfocus.com.

What's In The File

1. General Information
 - 1.1. Product Literature
 - 1.2. ISO 9001-2008 certificate
 - 1.3. Production Overview
2. Specifications (for each container size/material)
 - 2.1. Specification Sheets
 - 2.2. Part Drawings
 - 2.3. Certificate of Compliance (example)
 - 2.4. Batch testing (endotoxin, particulate.)
 - 2.5. Packing scheme
3. Resin Information for PET, PC, HDPE
 - 3.1. Resin manufacturer's data sheet
 - 3.2. Resin manufacturer's biocompatibility statement, tests specified by the United States Pharmacopoeia or described by ISO 10993

What's In The File continued:

- 3.3. Cellon's method of resin identity confirmation & examples
- 3.4. Material Safety Data Sheets
- 3.5. Resin manufacturer's statements regarding freedom from animal derived components (BSE/TSE)
- 3.6. Resin manufacturer's statement with respect to RoHS/ELV/REACH-SVHC/CPSIA/Packaging
- 4. Testing of Finished Product
 - 4.1. Biocompatibility testing reports, post sterilization
 - 4.1.1. USP VI
 - 4.1.2. In vitro cytotoxicity (MEM)
 - 4.1.3. Indirect hemolysis
 - 4.1.4. Leachable study, (aqueous & 20% ethanol)
 - 4.1.5. Bioburden and sterility validation
 - 4.1.6. Endotoxin (batch testing)
 - 4.1.7. Particulate (batch testing to USP <788>)
- 5. Additional information available separately
 - 5.1. Seal integrity testing (ambient)
 - 5.2. Seal integrity testing at -80° C (PC)
 - 5.3. 1.1M Drop test at -80° C (PC carboys)
 - 5.4. Gas transmission
 - 5.5. Recommended torque values
 - 5.6. Chemical resistance information
 - 5.7. Business continuity plan (table of contents)



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Manufactured by Cellon SA, Bascharage, Luxembourg
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