

ULTRA LOW PARTICULATES

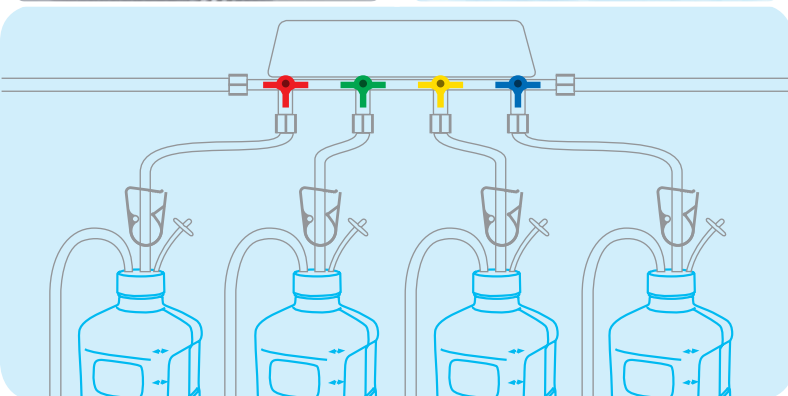
USP788 ✓
 EP 2.9.19 ✓
 JP 14th ed. part 1 sect. 24 ✓




SN20058622
 LOT 1000488
 EXP 25/01/17



PharmaTainer™
 Bottles and Carboys



125ML 20L



The new standard in single-use containers for storage and transport of vaccines, biopharmaceuticals, culture media and other biotech materials.

Clean, sterile & ready to use

Comprehensive validation file available

Medically approved resins
 Molded and capped in an **ISO CLASS 5 (class 100) environment**
 Certified by lot to meet USP788, EP and JP compendia standards for particulates in injectables
 Unrivalled **traceability** throughout production and during use
Precision, injection molded, flash and burr free neck finish
 PET PharmaTainers, **125ml to 20L** have excellent **gas barrier properties**
 PC PharmaTainers, **125ml to 20L** are ideal for **freezing applications**

DOUBLE SEAL CLOSURE SYSTEM



Precision molded closures and necks have robust threads that provide secure engagement between cap and bottle. Closures seal at two points; inside the neck and on the rim of the neck to provide a leak proof seal.

MANUFACTURED FROM 100% VIRGIN, MEDICALLY APPROVED, ANIMAL DERIVED COMPONENT FREE (ADCF) RESINS.

CERTIFIED TO MEET USP788 FOR PARTICULATE.

MOLDED AND CAPPED IN AN ISO CLASS 5 (CLASS 100) ENVIRONMENT.

PACKED IN AN ISO CLASS 7 (CLASS 10,000) CLEANROOM.

UNLINED, DOUBLE SEAL CLOSURE SYSTEM.

PRECISION, INJECTION MOLDED NECK IS FREE OF FLASH AND OTHER IMPERFECTIONS.

EACH CONTAINER IS PRINTED WITH A UNIQUE SERIAL NUMBER, BATCH NUMBER, EXPIRATION DATE AND MACHINE READABLE DATA MATRIX FOR UNRIVALLED TRACEABILITY.



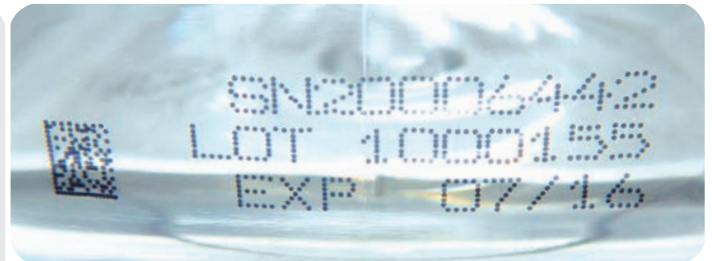
RAW MATERIALS

PharmaTainer™ products are manufactured from 100% virgin ADCF resins that are approved by our suppliers for medical applications and selected by Cella for their performance, clarity and biocompatibility.

Bottles and Carboys are manufactured from polyethylene terephthalate (PET) and polycarbonate (PC). Closures are manufactured from natural (non coloured) high density polyethylene (HDPE).

All raw materials are supported by drug master files held by the FDA. All raw materials meet the following requirements.

TRACEABILITY



Each container is printed with a unique serial number, lot number, expiration date and machine readable data matrix to provide unrivalled traceability through the production process at Cella and during use at your facility.

	PET	PC	HDPE
Approved for medical use	Yes	Yes	Yes
USP Class VI	Yes	Yes	Yes
In vitro cytotoxicity test	Yes	Yes	Yes
Drug master file	DMF15205	DMF1562	DMF1646
ADCF*	Yes	Yes	Yes

*Animal derived component-free

Resin identity is confirmed by (FTIR) Fourier transform infrared spectroscopy analysis for all resin lots prior to release into the manufacturing process.

CERTIFIED TO MEET USP788 STANDARDS FOR PARTICULATE

Every batch of PharmaTainers is tested using liquid particle count technology and certified to meet USP788, EP 2.9.19 and JP 14th edition part 1 section 24 criteria for particulate in injectable liquids i.e.

Liquid particle count limits, USP788, EP, and JP Compendia

Particle size	≥10 µm	≥25 µm
Container working volume >100ml	25/ml	3/ml

MANUFACTURING



PharmaTainer™ bottles are manufactured in our state-of-the-art facility dedicated to the production of sterile single use products for use in biotech industries. Single-use containers eliminate cross over contamination from failure to clean in reusable containers, and also eliminate the possibility of contaminants that may be present when non-sterile, general purpose products and sterile disposable products are manufactured in the same facility.

Production is by an injection blow molding process that produces bottles with a precision, flash-free, burr-free neck, eliminating the primary cause of seal failure.

Uniform bottle walls provide strong, freezer safe and break resistant containers. An extensive, ongoing quality control program ensures uniformity of production and conformity to our exacting manufacturing specifications.

Molding and capping operations are performed in a ISO Class 5 (Class 100) environment minimising the possibility of particulate, bioburden or endotoxin inside the container. Caps are applied mechanically, with a consistent torque to ensure a seal between the cap and container.

Bottles and carboys are printed with clear, easy to read black graduations, accurate to +/- 2%.

VALIDATION DOCUMENTATION

The PharmaTainer product line is supported by a comprehensive validation file available on CD from Cellon. Please contact us at sales@cellon.lu to receive your copy

PACKAGING



PharmaTainer™ products are packed in an ISO Class 7 (Class 10,000) clean room to minimise the impact of particulate from packaging in your controlled environments. Products are shipped in cartons with 3 layers of internal packaging to aid delivery into your clean room manufacturing areas. The innermost packing layer is vacuum sealed to provide assurance of an intact sterility barrier. The second bag is heat sealed and the third bag (carton liner) is folded and tape closed. Clear labelling of all levels of packaging simplifies your inventory control and enhances traceability throughout your processes

MANUFACTURING PRODUCTION RECORDS



Comprehensive production records are collated and maintained for each PharmaTainer™ production lot, including raw material certificates, FTIR scan test results, machine and operator details for all production stages, QC records, sterility and endotoxin test certification. Samples of all raw material lots and final product lots are retained for future reference if required

STERILITY



PharmaTainer™ product family sterility certification is based on a VD_{max}^{25} sterilisation study performed according to "ISO11137-2:2007, VD_{max}^{25} sterilisation of health care products- radiation-part 2", which demonstrates that a 25kGy irradiation dose achieves a sterility assurance level (SAL) of 10⁻⁶.

Ongoing sterility assurance is maintained by bioburden assessments on every product batch and quarterly VD_{max}^{25} dose audit studies.

ENDOTOXIN



Endotoxin testing is carried out as part of product release criteria for each manufacturing lot. The test is carried out by an independent laboratory by means of a validated assay method using a 5% rinse volume and a detection limit of 0.001EU/ml that complies with current USP and EP bacterial endotoxin test (BET) methodologies. The tests demonstrate no detectable endotoxin.

QUALITY SYSTEM, PRODUCT CERTIFICATION, CUSTOMER AUDITS

Cellon business operations and manufacturing processes conform to ISO 9001: 2008. There is a formal change notification policy to provide advance notice in the event of a necessary product change.

Each lot of PharmaTainer™ bottles is certified to meet our exacting production specifications.

Cellon welcomes the opportunity to showcase its manufacturing facility for customers who wish to conduct a plant tour or full production and process audit.

PORTED CAPS



A range of 2,3 and 4 ported caps with hose barbs suitable for use with silicone, thermo-elastomer and PVC tubing, specifically designed for use with the PharmaTainer™ range is available. Please contact us for details.

PRODUCT SPECIFICATIONS

PC PHARMATAINERS™

CATALOGUE NUMBER	SPECIFIED VOLUME	MAXIMUM VOLUME	BOTTLE MATERIAL	CLOSURE TYPE	BOTTLE DIMENSIONS H x W x D	CARTON DIMENSIONS MM	QTY PER PACK/CASE
200125-05	125ml	190ml	PC	49mm HDPE	95 x 58.8 x 58.2 mm	L620 x W340 x H270	5/100
200125-01	125ml	190ml	PC	49mm HDPE	95 x 58.8 x 58.2 mm	L520 x W285 x H530	1/48
200500-05	500ml	635ml	PC	49mm HDPE	152 x 83.2 x 83.2 mm	L530 x W450 x H380	5/60
200500-01	500ml	635ml	PC	49mm HDPE	152 x 83.2 x 83.2 mm	L520 x W285 x H530	1/36
201000-05	1,000ml	1,200ml	PC	49mm HDPE	187 x 101 x 101 mm	L358 x W548 x H448	5/30
201000-01	1,000ml	1,200ml	PC	49mm HDPE	187 x 101 x 101 mm	L520 x W285 x H530	1/24
202000-05	2,000ml	2,270ml	PC	49mm HDPE	240 x 120 x 120 mm	L630 x W515 x H300	5/20
202000-01	2,000ml	2,270ml	PC	49mm HDPE	240 x 120 x 120 mm	L520 x W285 x H530	1/14
205000-01	5,000ml	5,900ml	PC	70mm HDPE	322 x 168 x 168 mm	L590 x W400 x H350	1/6
210000-01	10,000ml	11,600ml	PC	70mm HDPE	395 x 212 x 212 mm	L458 x W248 x H458	1/2
220000-01	20,000ml	22,800ml	PC	70mm HDPE	500 x 256 x 256 mm	L590 x W330 x H570	1/2

PET PHARMATAINERS™

CATALOGUE NUMBER	SPECIFIED VOLUME	MAXIMUM VOLUME	BOTTLE MATERIAL	CLOSURE TYPE	BOTTLE DIMENSIONS H x W x D	CARTON DIMENSIONS MM	QTY PER PACK/CASE
100125-05	125ml	196ml	PET	49mm HDPE	95 x 58.8 x 58.2 mm	L620 x W340 x H270	5/100
100125-01	125ml	196ml	PET	49mm HDPE	95 x 58.8 x 58.2 mm	L520 x W285 x H530	1/48
100500-05	500ml	635ml	PET	49mm HDPE	152 x 83.2 x 83.2 mm	L530 x W450 x H380	5/60
100500-01	500ml	635ml	PET	49mm HDPE	152 x 83.2 x 83.2 mm	L520 x W285 x H530	1/36
101000-05	1,000ml	1,213ml	PET	49mm HDPE	187 x 101 x 101 mm	L358 x W548 x H448	5/30
101000-01	1,000ml	1,213ml	PET	49mm HDPE	187 x 101 x 101 mm	L520 x W285 x H530	1/24
102000-05	2,000ml	2,295ml	PET	49mm HDPE	240 x 120 x 120 mm	L630 x W515 x H300	5/20
102000-01	2,000ml	2,295ml	PET	49mm HDPE	240 x 120 x 120 mm	L520 x W285 x H530	1/14
105000-01	5,000ml	6,000ml	PET	70mm HDPE	322 x 168 x 168 mm	L590 x W400 x H350	1/6
110000-01	10,000ml	11,980ml	PET	70mm HDPE	395 x 212 x 212 mm	L458 x W248 x H458	1/2
120000-01	20,000ml	23,120ml	PET	70mm HDPE	500 x 256 x 256 mm	L590 x W330 x H570	1/2

