

# PHARMA TAINER™ BRAND: Quality manufacturing of bioprocess containers

PharmaTainer is a trademark of Cellon SA, Bascharage, Luxembourg

**November 2013**



## **PharmaTainers are molded by Cellon in Luxembourg**

Cellon completed building it's molding facility in 2010

## **Cellon History**

Founded 1987

Located in Luxembourg

Distributing Roller Bottles, Biotainers and other cell culture items.

Manufacturing RollerCell 40 Automation

Serving Western Europe

Clients: GSK, Lonza, Merial, Sanofi Pasteur

**About Cellon SA**

## **Cellon Molding Facility**

Certified to ISO 19001:2008

Located in Luxembourg

Operational in 2011

Dedicated to single use, sterile products

## **Cellon Marketing**

Focused on biopharmaceutical manufacturing

Sells direct in Western Europe

**About Cellon SA**



**PharmaTainer Bottles – sizes 125 mL to 20 liters**

Available in polycarbonate or PET with HDPE closures

- Available in PC or PET with HDPE closures
- Sizes: 125 mL to 20 L, plus 75 mL stability tube in both materials
- All current styles have square footprint
- Double-seal closure seals at inside neck and at rim
- Black graduations, lot no, S/N

## PharmaTainer Bottles

## Available accessories:

- Ported closures (2, 3 & 4 ports)
- Custom tubing assemblies
- Torque fittings
- Filling bell

**PharmaTainer Bottles**



## PharmaTainer Molding Machines

Modern, HEPA filtered, clean environment





## Parts Molded in Class 100

Lot no, S/N printed and bottles capped in class 100



## Post-capping operations in Class 10,000

Physical inspection, printing graduations, vacuum packing



**Cellon molding facility warehouse**

Generally, bottles are molded by Extrusion Blow Molding (EBM) or a form of Injection Blow Molding.(IBM)

EBM containers are characterized by:

- Variable neck formation
- Variable wall thickness & weight
- Particulate from the molding process
- Inferior clarity

**Plastic Bottle Manufacturing**

PharmaTainers bottles are injection stretch blow molded (ISBM)

ISBM containers are characterized by:

- Perfect necks, no flash
- Uniform part-to-part wall & weight
- Smooth inner surface
- Superior clarity
- Process allows clean production

**Plastic Bottle Manufacturing**

ISO 9001-2008 Certified

TUV Rheinland, auditor

Product Certifications

Sterility: SAL  $10^{-6}$

Endotoxin: Negative by LAL

Particulate: Below USP 788 Standard

**Certifications**

Seal tested at -80°C (PC only)  
Drop tested at -80°C (PC only)  
USP VI, leachables, hemolysis  
No Animal Derived Components  
Full traceability  
Machine readable serial number  
Available validation documentation

## **Other Testing & Features**

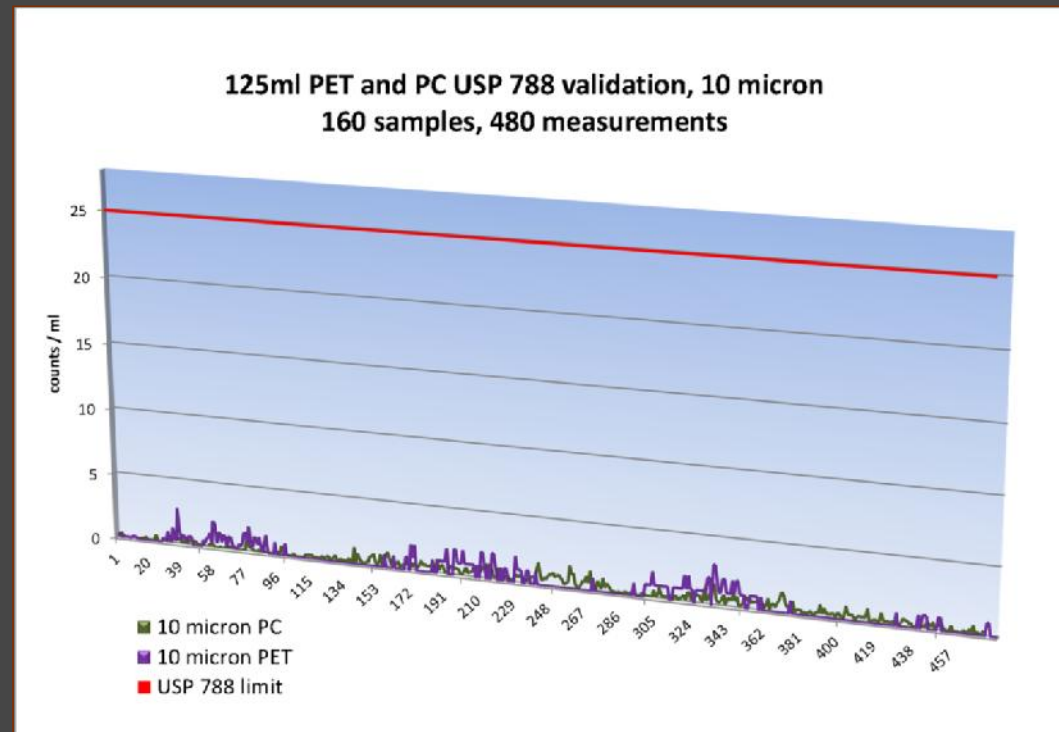


## USP <788> Certified

- Particulate below standards of USP788, EP2.9.19 and JP 14th edition, part 1 Section 24.
- Lot tested by light obscuration method
- The following examples are from the smallest and largest container sizes.

## Particulate Testing

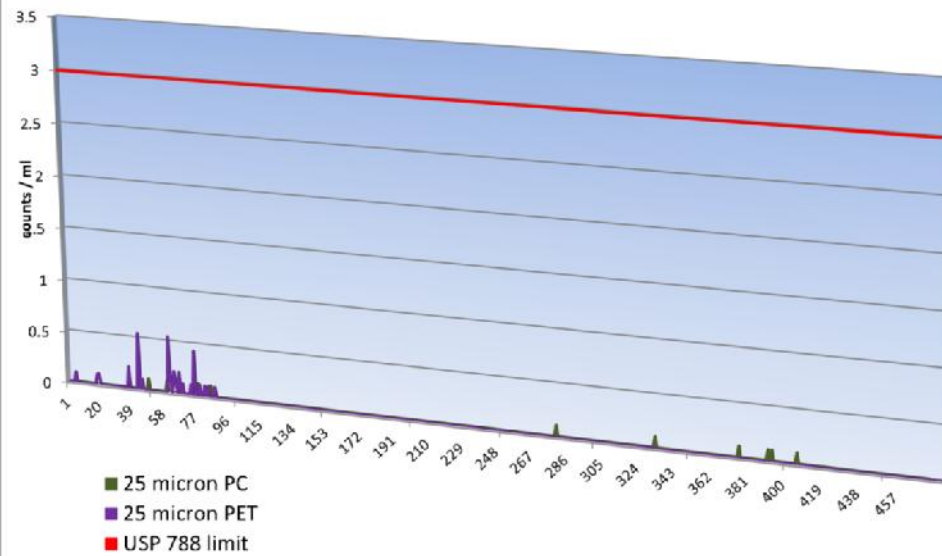




## Particulate Testing

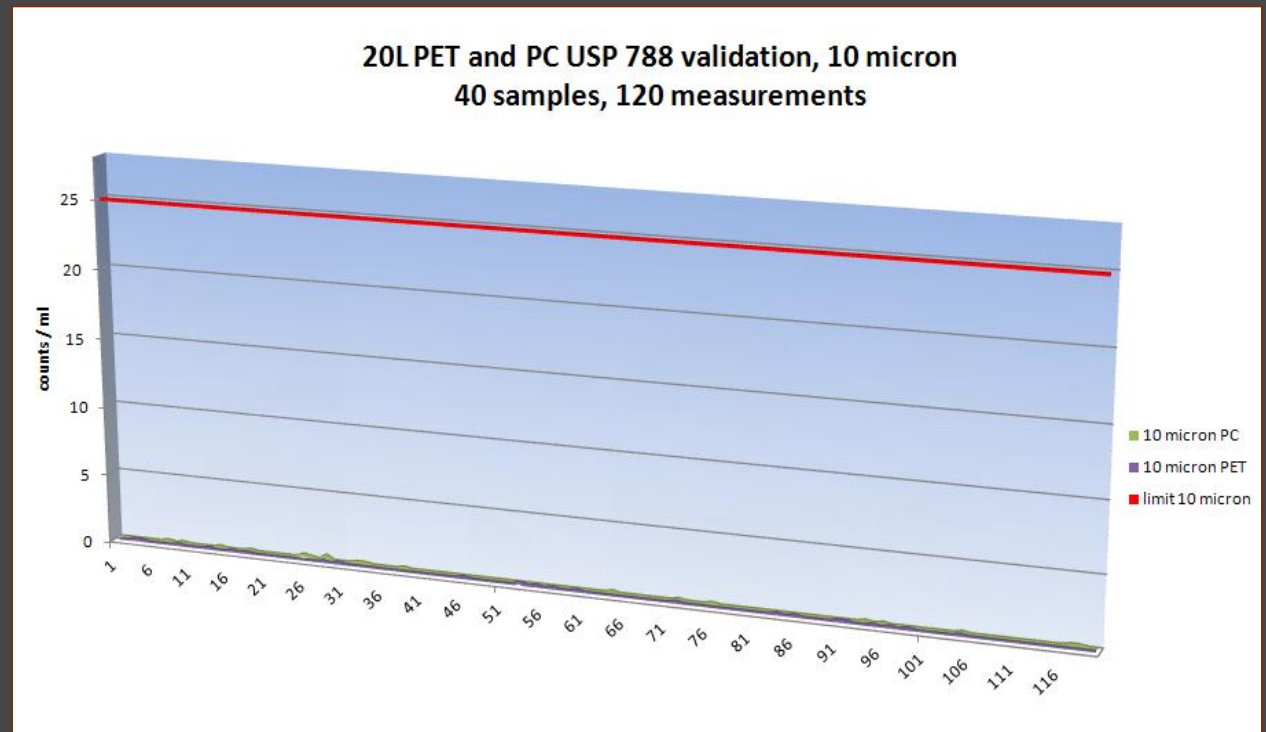
125 mL – 160 samples – 10  $\mu\text{m}$  – Red line is USP <788> standard

125ml PET and PC USP 788 validation, 25 micron  
160 samples, 480 measurements



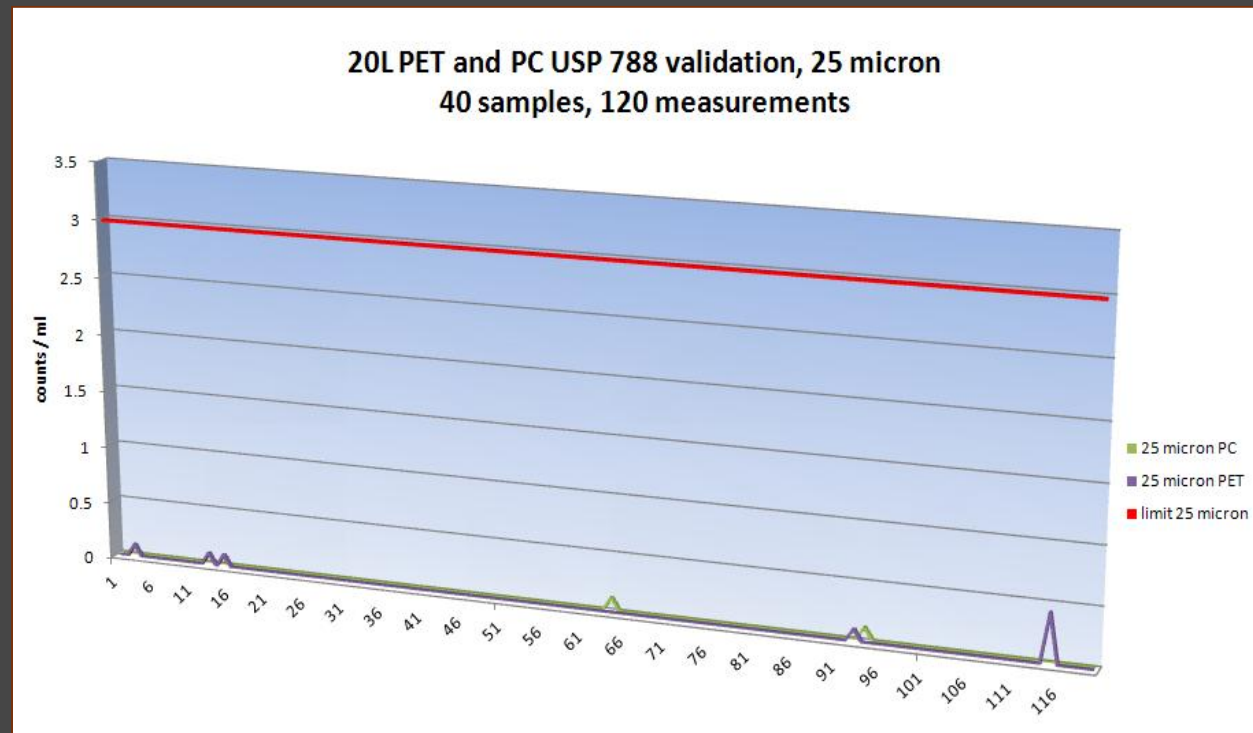
## Particulate Testing

125 mL – 160 samples – 25  $\mu$ m – Red line is USP <788> standard



## Particulate Testing

20 L – 40 samples – 10  $\mu\text{m}$  – Red line is USP <788> standard



## Particulate Testing

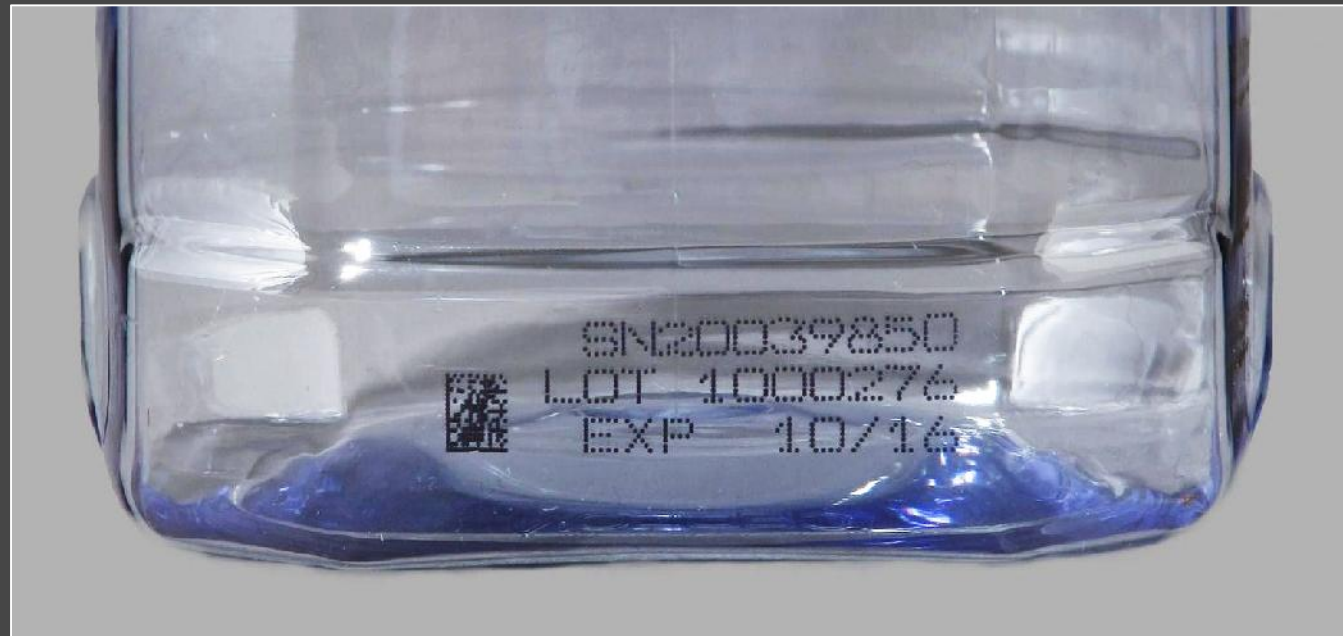
20 L – 40 samples – 25  $\mu$ m – Red line is USP <788> standard



On all levels of packaging:  
Description, cat. No., batch no.  
radiation dot, bar code & expiration  
date

On each container:  
Batch no., expiration. date, QR code  
QR code is a unique serial number  
Graduations accurate  $\pm 2\%$

**Labeling**



## On-Bottle Labeling

Use QR code to scan parts in and out of inventory

Resin identity & data sheets

Product specifications

Biocompatibility test reports

USP VI, leachables, hemolysis & more

Batch testing information

Endotoxin, sterility, seal, particulate

USP 788 test method

Sterility validation

**Documentation**

## ISO9001-2008 Certificate

### -80°C Performance Tests

- Freezing
- Seal integrity
- Drop test from 1.1 meters

Ambient seal integrity tests

Gas permeability data

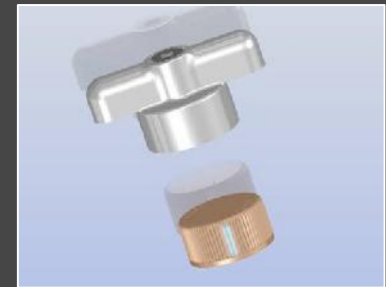
Torque recommendations

**Documentation**





Aseptic transfer systems  
Sampling systems  
Ported closures  
Filling bells  
Capping chucks



**Accessories**

**PharmaTainer™ Bottles & Carboys**  
Are distributed in the U.S., Canada and Puerto Rico by



8207 118th Avenue ♦ Largo, FL 33773

☎ 1-727-437-7777 ✉ [info@biofluidfocus.com](mailto:info@biofluidfocus.com)

🌐 [www.biofluidfocus.com](http://www.biofluidfocus.com)

**Contact**

## **Biofluid Focus - Jon West**

2011 – Founded Biofluid Focus

PharmaTainer Master Distributor

Biotech Distributor for Savillex

2007 – Consultant for Savillex

1998 – Product Manager , Nalge Nunc

Biotainers, Nalgene Carboys, Tanks

1994 – Introduced Biotainer product line

**History**