

Critical Environment Products and Services



For over two decades, EP Scientific products and services have defined clean for environmental sampling containers and services. Our proprietary cleaning methods ensure that the only thing in our containers is what you add.

EP Scientific Products are distributed by:

Greyhound Chromatography and Allied Chemicals

6 Kelvin Park, Birkenhead, Merseyside CH41 1LT United Kingdom

Tel: (+44) 0 151 649 4000 Fax: (+44) 0 151 649 4001

Email: sales@greyhoundchrom.com

www.greyhoundchrom.com



Custom Cleaning Services

We have the flexibility to meet your cleaning requirements, whether your cleaning needs are for high volumes or smaller quantities. We have the capability to clean clear/amber glass or plastic containers, as well as closures or other component parts.

Send us your containers and closures, or purchase from our extensive line of standard and custom products. We can process containers from 100 μ L to 20L. All cleaning services and packaging can be done in our certified class 100/10 cleanroom with full traceability and GMP compliance.

Silanization Services

Our line of ready-to-use silanized vials, culture tubes and autosampler inserts, save valuable time and minimize costs when performing quantitative analysis or storing materials.

Applications:

- Trace organic analysis
- Storage of materials prone to adhering to glass
- Extraction glassware

Siliconization Service

Siliconized products are physically coated with a medical-grade silicone emulsion to prevent sample material from reacting with the glass container.

Applications:

- Proteins
- Assays of blood serum
- Pharmacological assays of therapeutic drugs



Silanization – how do we do it?

A methylsilylating agent is introduced by vapor phase deposition onto the surface of the disposable glassware. The silylating agent reacts with active groups on the surface of the glass effectively tying up these sites so they are less reactive. This treatment inhibits materials from adhering onto the surface of the container, allowing for maximum recovery of trace analyte.



Depyrogenated Glass/ Depyrogenation Service

EP Scientific provides glass vials and other containers that have been specially prepared to meet endotoxin levels of less than 0.06 EU/mL. A variety of sizes are available. Depyrogenated vials and containers may also be requested with additional certifications.

EP Scientific can depyrogenate any glass as a service. The process uses dry heat at 250 degrees Celsius for a minimum of two and one half-hours. Cleaning and packaging is performed inside a Class 100 cleanroom.

Applications:

- Non-parenteral uses such as water sampling and testing of endotoxins.
- Storage of packaging of terminally sterilized articles.
- Storage of lab reagents and media

Sterilization Services

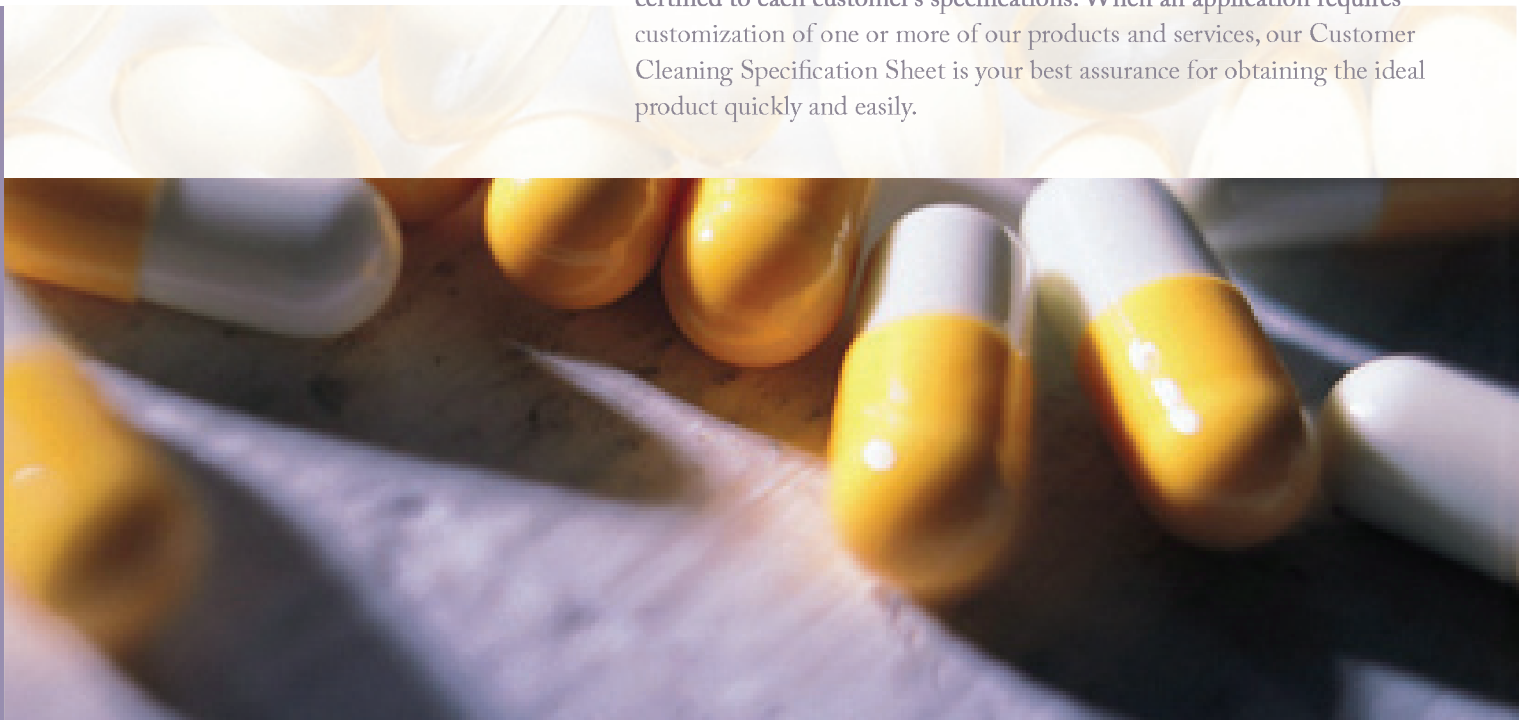
We offer a number of sterilization services to effectively destroy all viable forms of life, including bacterial spores to a sterility assurance level (SAL) of 10^6 . Services include gamma irradiation, dry-heat, autoclave or e-beam.

Applications:

- Injectable or parental drugs
- Lyophilization
- Final packaging prior to drug delivery
- Stability studies



Containers for Critical Environment applications are processed and certified to each customer's specifications. When an application requires customization of one or more of our products and services, our Customer Cleaning Specification Sheet is your best assurance for obtaining the ideal product quickly and easily.



Clean Process Containers

Low-Particle Containers

EP Scientific vials and containers are certified to contain fewer than 5 particles per milliliter larger than 0.5 microns. This exceeds the USP <788> specifications for particle content of containers. Cleaning and packaging is performed inside a Class 100 cleanroom. Class 100, double bagged glass bottles are assembled with low-shedding, polypropylene caps with chemically inert PTFE faced liners that do not contain adhesives.

- Storage and packaging of chemicals, reagents, powders etc.
- Excellent for preparation and storage of standards
- Double-bagged to ensure no contaminants are introduced to the clean room
- Off-line deionized water and chemical sampling for particle analysis
- Amber glass protects light-sensitive chemicals
- Ready for sterilization

To request a custom cleaning service, please fill in the custom cleaning specification sheet at the end of this document and fax to Greyhound Chromatography and Allied Chemicals on: **(+44) 0 151 649 4001**



The United States Pharmacopeia issued new guidelines in Method 643 making TOC analysis mandatory. The modification as published in the Fifth Supplement to the USP/NF 23 states that the glassware to be used must be “scrupulously cleaned of organic matter to reduce contamination”. Our TOC vials are prepared by a proprietary method to reduce background contamination to less than 10ppb TOC.



**Certificate of Analysis included
with all custom processes**

Clean Process Vials

Low Carbon (TOC) Vials

We offer low-level certified vials for Total Organic Carbon testing and sampling. Major TOC instrument manufacturers use and recommend our vials. We offer several sizes of containers including the popular 40mL autosampler vials cleaned, certified and ready to use. Each lot of vials is tested and certified to contribute no more than 10 ppb TOC as background. Certificate of Analysis included.

- Off-line and gram sampling of high purity water
- 40mL vials fit most TOC instruments' autosamplers
- Low background is perfect for preparation and storage of standards
- Cleaning validation is simplified and costs are reduced by using the TOC method of testing

Sterile Empty Vials

Certified depyrogenated and sterile vials are available in sizes from 1mL to 100mL. Sterile vials are Type 1 borosilicate, assembled with butyl stoppers and aluminum seals. Sterilization is performed in a FDA licensed facility, practicing GMPs.

- Suitable for a number of uses where aseptic protocol is required
- Sterile Vials – clear finish, pyrogen tested with certificate of sterility

Customized analytical parameters may include special GC, GC/MS, ICP/MS, ICP, AA, GF-AA or other testing.



We supply the world's largest offering of clean containers that meet or exceed EPA and USP requirements.



Greyhound Chromatography Custom Cleaning Specification

Completion of this form is highly recommended to ensure proper service. Please return this sheet along with any additional special requirements to Greyhound Chromatography and Allied Chemicals: Fax: (+44) 0 151 649 4001 Tel: (+44) 0 151 649 4000

Company:..... Contact:.....
 Address:..... Telephone:.....
 Fax:.....
 Email:.....

Customer sending materials for service only Sales Rep.....Greyhound Provides Materials
 (Notice: All material will be processed and returned including manufacture defects. Multiple raw lots will require additional testing.)

Please Provide Container or Component Information

Manf. and Identification or EP Part # (if known)	Description (size, material, etc.)	Qty.

Use one sheet per item.

Process Required or Requested*

- | | | |
|---|--|--|
| <input type="checkbox"/> Dry Heat Depyrogenation, validated 3-log reduction | <input type="checkbox"/> Particulate cleaning | <input type="checkbox"/> WFI rinse (Containers < 250ml) |
| <input type="checkbox"/> Surface treatment (silanization) | <input type="checkbox"/> Irradiation (glass will discolor after irradiation) | <input type="checkbox"/> USP Purified Rinse (Containers > 250ml) |
| <input type="checkbox"/> Surface treatment (siliconization) | <input type="checkbox"/> Sterile Foil Wrap process | <input type="checkbox"/> Autoclave |
| <input type="checkbox"/> TOC process | <input type="checkbox"/> RNase & DNase Process | <input type="checkbox"/> Other..... |

Packaging Configurations

Cleanroom bags

- Individual unit Multi-unit
 Single Double

- Options: Autoclave bag (single, dbl., triple)
 Foil-wrap #..... Autoclave Wrap x 2

Other packaging configurations: (describe)

Clean polypropylene tray-pack:

- Shrink-wrapped with double bag; standard

Certification Requirements

- | | | | |
|--|--|--|--|
| <input type="checkbox"/> C of A, TOC | <input type="checkbox"/> C of A, Endotoxin | <input type="checkbox"/> C of A, Particles | <input type="checkbox"/> Selected testing by USP Methods |
| <input type="checkbox"/> Certificate of Processing | <input type="checkbox"/> Materials Cert. of Compliance (only if EP provides materials) | <input type="checkbox"/> C of A, RNase and DNase | |
| <input type="checkbox"/> C of Sterility/USP | | | |

Other Tests or special documentation LIST:

Please indicate shipping method required.....

Minimum lead-time for custom product is dependent upon quantity, analytical requirements, and availability of materials. Custom Cleaning Specification Sheet must be signed and dated. Failure to do so may cause your quote to be delayed. All information exchanged between 'Greyhound Chromatography' and the above 'Company' is considered confidential. Greyhound will not be responsible for failure by the customer to request any other requirements not included on this sheet.

Fax to Greyhound Chromatography and Allied Chemicals: (+44) 0 151 649 4001

Submitted by:..... Date:.....

* Some options may not be available for all sizes or container types.



Clean Room Process

	Irradiation	Sterile foil-wrap	Steam sterilization	Depyrogenation	Silanization	Siliconization
Injectable or parenteral drugs	●	●	●	●		
Lyophilization	●		●	●		
Final packaging prior to drug delivery	●		●	●		
Stability studies	●	●	●	●		
Clinical trials	●	●		●		
Proteins					●	●
Assays of blood serum					●	●
Pharmacological assays of therapeutic drugs					●	●

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