



GIBRALTAR

STERILIZATION SERVICES

Division of Gibraltar Laboratories



The Gibraltar **SteriKit**[®]
Ready to use vials, seals & stoppers

Why The Gibraltar SteriKit[®] is 100% The Right Choice:

- Vials, stoppers and seals certified in-house as sterile, pyrogen and particulate free.
- Manufactured and packaged in cGMP ISO clean rooms.
- Final assembly performed under ISO Class 5 conditions.
- Reliable delivery time.
- Full analytical service to support development from pre-clinical R&D through commercial manufacturing and sterilization.
- Gibraltar does not compete with Contract Manufacturing Organizations (CMOs).
- No order is too small.
- Processing vials in house is not optimal. Repurpose space to increase production.

APPLICATIONS

- Aseptic fill of injectable liquids
- Vaccine companies
- Biopharmaceutical companies
- 503B Compounding pharmacies
- Small batch sizes
- Orphan drugs
- Personalized medicines
- Clinical trials
- Technical batches
- Diagnostics

BENEFITS

- Offered in a variety of sizes (2 – 50 cc vials – Clear or Amber)
- Customizable
- Saves time, space and money
- Shorter lead times (on stock)
- Easy to use disposable packaging
- Certified in-house
- No ETO residual or trembling during transport.
- Made in the USA

LEAVE IT TO THE PROS

Particulate problems? ETO residual? Endotoxin problems? Lengthy lead times and high outsourcing costs? Autoclave issues? Wasting time, space and money? At Gibraltar Laboratories, Division of Sterilization Services; ***we heard you.***

Don't waste time, space and money washing, depyrogenating, sterilizing and certifying vials, seals and stoppers. We want you to use that time, space and money to do what you do best – accelerate your manufacturing process. Whether it be a diagnostic, injectable drug or an implant, Gibraltar is here to help. Through our world class sterilization services, Gibraltar offers pyrogen free, particulate free and sterile vials, seals and stoppers that are ready to be inserted directly into your manufacturing facility.

Our facilities are modern and our processes are validated and compliant as per cGMP standards. Our packaging is easy to use, clean, disposable and prevents vial trembling during shipping. The clear final packaging also allows for visual inspection of the vials before use.



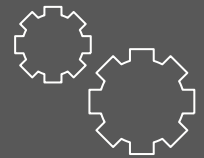
The Gibraltar SteriKit[®]

Quality Standards

- Backed by Gibraltar Laboratories, the award winning, 46 year old 2015 ISPE nominated Facility of the Year.
- Every SteriKit[®] is certified by Gibraltar Laboratories sterile, pyrogen and particulate free (USP <71>, <85> & <788>, respectively).
- These quality attributes for the product are important for patient safety.

EXCEPTIONAL PROCESSING

- Type I borosilicate glass vials are USP WFI washed, aseptically repackaged in a 316 SS tray and USP dry heat depyrogenated.
- The stoppers and seals are USP WFI washed, aseptically repackaged and cGMP moist heat steam sterilized.
- Following sterilization, the components are assembled, vacuum packed and heat sealed in a pre-sterilized LDPE bag under ISO Class 5 conditions.



CUSTOM ORDERS

Call us about sizes, colors, kit quantities & more!

Take control and accelerate your manufacturing cycle with the **Gibraltar Advantage[®]**:

Sterile vacuum packaging, shorter lead times and more customizable solutions.



VISIT OUR WEBSITE

www.gibraltarlabsinc.com



Your Trusted Partner in Quality

The Gibraltar SteriKit[®] is a ready-to-use kit that combines sterile, pyrogen and particulate-free vials, stoppers, and seals in sterile vacuum-sealed, disposable packaging. The SteriKit[®] is highly-customizable and scalable to meet your specific needs ranging from small, one-off R&D projects to large clinical and commercial manufacturing. Since development and manufacturing demands vary by client, product and application; the SteriKit[®] provides a robust platform that can help reduce variability and minimize risk to your products, patients, and reputation. It just makes good business sense.

Gibraltar is uniquely positioned to provide superior quality, product, and customer support. Unlike some of our competitors, we are not a Contract Manufacturing Organization (CMO) nor do we rely on a single source for our kit components. This eliminates the potential for competition with our clients and allows us to utilize multiple vendors to ensure uninterrupted supply of the SteriKit[®] while maintaining the highest standards of quality, reliability, and turn-around time.

In response to scientific expectations of both regulators and industry to design effective means to assure product quality, we have invested heavily in the SteriKit[®] as well as equipped our full-service cGMP contract laboratories with the most updated technology. Our focus on science and risk is part of the Gibraltar Advantage[®], as we offer both routine product testing and assist clients with development, manufacture, validation, and testing of sterile products from pre-clinical R&D through commercial manufacturing.



We believe that our client's success is our success. Take control and accelerate your manufacturing with the **Gibraltar SteriKit[®]**.

STERILIZATION ◦ MICROBIOLOGY ◦ MEDICAL DEVICE ◦ CHEMISTRY ◦ CONSULTING

Whatever your need, Gibraltar Laboratories is here to help. We offer full analytical testing support to help contract manufacturers market and release their products safely and timely.

Our sterilization services division specializes in the sterilization of air-over pressure steam sterilization that conforms to bioburden-based sterilization cycle parameters.

We also sterilize manufacturing equipment used in aseptic processing, along with:

- Glassware
 - vials, flasks, etc.
- Stainless steel components
 - cutters, mesh, grinders, etc.
- Instruments
- Surgical Tools
- Medical Devices
- Medical Equipment

Our methods for sterilization include:

- Moist Heat Steam Sterilization
- Dry Heat Sterilization
- Liquid Chemical Sterilization

We develop and validate our sterilization services on a case-by-case basis, achieving a probability of a non-sterile unit (PNSU) and a sterility assurance level (SAL) of 10^{-6} .

Gibraltar offers expertise in the sterilization of complex orthopedic medical trays in hospital wrap or rigid containers, tested under minimum and maximum load conditions.



Learn more

About the **Gibraltar Advantage**[®]:

Visit us at:

www.gibraltarlabsinc.com

Or give us a call at:

877.315.5847

And ask us how the **Gibraltar SteriKit**[®] can save you **time, space and money.**

SteriKit[®] Specifications

All SteriKits[®] come validated with a 2-year shelf life and conform to EP2.9.19-Test 1B and USP <788> for particulates, EP2.6.14 and USP <85> for bacterial endotoxins and EP2.6.1 and USP <71> for sterility testing.

	Particulate Matter	Endotoxin/Sterility
Vials	≤ 3000 of ≥ 10µm ≤ 300 of ≥ 25 µm	NMT 0.005 EU/mL / Sterile
Stoppers		
Seals	N/A	Sterile



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