

WAY 16

MediZap – Terminal Sterilizer by E-Beam | X-Ray Irradiation Built for Compounding

Combining expertise and advanced tech, we elevate sterile compounding for 503A and 503B pharmacies. Our solutions enhance safety and effectiveness in custom sterile drugs, addressing FDA shortages for hospitals and patients.

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Founded: 2015

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Company Background

MediZap is transforming the compounding industry by addressing the critical need for sterility assurance in compounded sterile drug products. Recognizing the limitations of traditional aseptic filtration, we are pioneering the use of E-Beam and X-Ray terminal sterilization to achieve the highest possible Sterility Assurance Level (SAL). We aim to elevate safety standards and ensure compliance with USP 797 and cGMP guidelines.

Product Overview

With locations in California and Texas, we offer E-Beam and X-Ray terminal sterilization services certified to ISO 13485 and ISO 11137 standards. We are FDA-registered and hold DEA registration for Schedules II-V, providing a robust and reliable sterilization solution. Our DualBeam™ processing system boasts a 99% uptime, guaranteeing swift turnaround times, including standard two-day, rush one-day, and even same-day options. Our dedicated capacity ensures flexibility for manufacturers without requiring advance reservations. Standard formats include IV bags, pre-filled syringes, vials, and syringe push, supporting safe, timely care.

Features & Options

- **Superior Sterility Assurance:** E-Beam and X-Ray technology provide a remarkable SAL of 10^{-6} , surpassing autoclaving's SAL of 10^{-3} , significantly reducing contamination risk. This level of assurance is vital for safeguarding patient health and minimizing healthcare-associated infections — a top priority for hospital systems.
- **Reduce Human Error:** Compared to aseptic processes that rely on environmental and human factors, this process reduces contamination risks. It extends drug beyond-use dates, ensuring the stability and availability of critical medications.
- **Enhanced Drug Quality:** Unlike heat-based sterilization methods, E-Beam and X-Ray are gentler on reducing potency degradation associated with autoclaving. This ensures that compounded drugs retain their efficacy and stability, which is crucial for optimal therapeutic outcomes.
- **Operational Efficiency:** Our services provide unparalleled speed, flexibility, and responsiveness, which is essential for hospitals that need timely medication access, especially during drug shortages or urgent patient needs.

- **Environmental Responsibility:** Our technology aligns with sustainability initiatives by eliminating radioactive materials such as Cobalt-60, commonly used in gamma sterilization, thereby supporting hospitals' environmental goals.
- **Advanced Sterilization Expertise:** We offer a dedicated solution to achieve the highest sterility standards, with expertise in validating sterilization processes according to ISO 11137 guidelines. This commitment is crucial for regulatory compliance and ensures the safety and efficacy of compounded drugs in healthcare settings.
- **Streamlined Packaging Solutions:** Understanding the challenges hospitals face with packaging, we provide pre-validated primary and secondary packaging options explicitly designed for E-Beam and X-Ray sterilization. This eliminates the need for costly, time-consuming sourcing and validation studies, allowing hospitals to focus on operational efficiencies.
- **Compliance Support:** We help hospital systems navigate regulatory complexities with a team of experts guiding compliance with USP, cGMP, and ISO standards. We also provide best practice documentation to ensure compounded drug production meets the highest quality and safety benchmarks, maintaining impeccable document control.

Additional Resources

Our resource center is a comprehensive knowledge hub, offering Zap+Learn webinars, articles, video library, and white papers.

Affiliations

As a proud sponsor of the Alliance for Pharmacy Compounding (APC), we are committed to promoting and protecting the practice of pharmacy compounding. We actively support APC's efforts to address drug shortages and advocate for access to compounding, including lobbying activities on Capitol Hill. We are also a member of the Outsourcing Facilities Association (OFA), representing FDA-registered 503B outsourcing facilities. OFA works with industry partners, government agencies, and healthcare providers to ensure access to safe, effective compounded medications.

Trade Shows/Meetings Attended

MediZap participates in various trade shows, such as the ASHP Mid-Year Clinical Conference, American Academy of Anti-Aging Medicine (A4M), and Parenteral Drug Association (PDA) events, to showcase our innovative solutions and expand our market presence. We partner with Complete Group Services (CGS), the first and only GSO dedicated to compounding and manufacturing pharmaceutical products.

Ordering Information

Contact a MediZap sales representative at customerservice@medizap.co.