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Considerations for
Sterile Filtration of
Biologic Drugs ...
An inhalation spray

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drug product consists of the formulation and the container closure system. The formulations are typically aqueous based and, by definition, do not contain any propellant.

Drug Products
Development &
Contract Manufacturing

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This guidance replaces the 1987 Industry Guideline on Sterile Drug Products Produced by Aseptic Processing (Aseptic Processing Guideline). This revision updates and clarifies the 1987 guidance.

Formulating Biologic
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Fill/Finish ...

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Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including

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Products

solutions, suspensions, ophthalmics and freeze dried products.

Manufacturing

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Similarly, ICH Q8a (r2) advises manufacturers, "For those products intended to be sterile, an appropriate method of sterilization for the drug product and primary

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packaging material should be chosen and the choice justified" .

Manufacturing

7 Sterile Products:

Formulation,

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The main factors that must be considered from the outset when developing formulations for biologic drug substances that require

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sterile filtration include, according to Yunsong (Frank) Li, director of process development at Catalent Biologics, the product's chemical and physical stability under various stress conditions (e.g., thermal, mechanical, photostability) during product manufacturing, storage, shipping, and administration;

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Biologics
compatibility with the
materials used during
sterile fill ...

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For combination device-
drug products,
formulations must be
tailored to achieve
specific attributes
related to both the
device and drug

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Products, like stability during targeted shelf life, compatibility with the primary packaging, viscosity and similar parameters, plus other aspects of drug administration relative to the specific medical device.

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Quality teaches the
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ophthalmics and freeze
dried products.

Packaging

Sterile drug products :
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experience, specifically
in the area of sterile
parenteral
manufacturing. Mr.
Jarman's areas of focus
have included aseptic

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filling operations for both vial and syringe products, suspension filling, lyophilized product manufacturing, formulation activities, equipment and component preparation, and capping operations.

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Research (CDER)

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of Regulatory Affairs
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(ORA) September 2004

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CordenPharma's state-of-the-art formulation facilities are equipped to manufacture solid dose and parenteral formulations. The broad spectrum of capabilities

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allows formulations of highly potents, oncologicals, cephalosporins, penicillins, and hormones or hormone blockers. Handling of sterile powder-filled...

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experience in the
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forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products.

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ophthalmics and freeze

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dried products.

Sterile Products:

Advances and Challenges in Formulation ...

Successful sterile filtration requires a drug product formulation with an appropriate viscosity and compatibility with the contact surfaces and shear stresses involved

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in pumping the fluid.

Single-use technology is widely used in sterile fill/finish operations today, reducing the turnover time and cross-contamination risk.

Sterile Drug Products:
Formulation, Packaging

...

Sterilization methods in
sterile product
manufacturing The

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entire field of discipline of sterile product science and technology is based on the ability to render finished dosage forms sterile. Sterility is defined theoretically as the complete absence of microbial life.

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