

bottel

We offer
the solution!

bottelpack[®]

**ASEPTIC
SYSTEM**

*The Inventor of
«bottelpack»[®]
blow-fill seal-technique*



In past years the treatment of a variety of breathing disorders by the means of inhalation solutions has become a high priority.

It is observed that such disorders show a constant and important increase in numbers of patients.

Inhalation solutions are usually administered as a fine aqueous mist created by a nebulizer. Until recently a number of such nebulizer solutions were manufactured not to

be sterile but with a controlled microbial count limit. For this purpose a preservative is added to the solution, mostly Benzalkonium Chloride. This preservative, however, may cause the side effect bronchial constriction, possibly resulting in insufficient relief during an attack.

The FDA has published a proposal in which is stated that all inhalation solutions for nebulization should be sterile. It states that «contaminated inhalation solutions for nebulization are likely to

cause lung infections because the drug product is introduced directly into the lungs in a manner which at least partially bypasses the patient's natural defense mechanisms».

The solution to the aforementioned is an aseptic fill of a non-preserved solution into unit-dose containers. For more than 20 years the manufacture of such ampoules continues to be a speciality of the bottelpack-aseptic system.



bottelpack® 360 M

There is a direct relation between the advantages the blow-fill-seal technology offers and the increasing number of machines supplied to the most important manufacturers of such products.

More particularly, the industry decided to opt for the high-speed machines in our line-up. Both the machines 360M and the unique rotary high-speed 4010M offer a maximum of capacity with the well-known sterility assurance level of the BFS-technology.

A report of August 1998 published by «Allergy and Asthma Network, Mothers of Asthmatics, Inc». states: «It is recommended that nebulized solutions should be prepared under sterile conditions, formulated preservative-free, made available in unit-dose vials, and never be substituted with solutions containing Benzalkonium Chloride».



bottelpack® 4010 M

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