Make it better.

IMPROVING THE STABILITY OF HYGROSCOPIC PRODUCTS THROUGH PACKAGING

Blister packs remain a popular packaging type for solid oral dosage formulations. However, when it comes to packaging of oxygen-reactive and hygroscopic pharmaceutical products, blisters provide inadequate protection from environmental factors; therefore, other measures are required. When a leading pharmaceutical company approached us for a secure packaging solution for their oxygen-sensitive product, we recommended blister packaging using nitrogen enhanced purging (NEP) to maximize product stability.

In the pharmaceutical industry, blister packaging is frequently preferred because of its convenience, high patient compliance, and cost-effectiveness. Their unique design allows blister packs to offer individual unit-dose compartments, along with tamper-evident features that ensure product security. However, blister packaging of oxygen-reactive and hygroscopic products needs special consideration. Although high-barrier thermoform film and aluminum foil blisters can provide a certain degree of protection against unwanted moisture and oxygen ingress, this may not offer complete protection against headspace moisture, gases, and impurities especially for moisture and oxygen-sensitive formulations. In such cases, NEP is a desirable method to increase the shelf-life of a product inside a blister pack. The NEP system is designed for easy-to-use single-point purging of air from the blister cavities, replacing it with dry nitrogen. That is why, when our client wanted to pack an air-sensitive product into blisters, ACG helped them by providing a NEP system on their B MAX packaging machine.

Client Profile

The client has been a top-ten pharmaceutical company in India for the past 15 years, with a comprehensive portfolio of 750+ brands covering all the major therapeutic areas. In addition to being ranked no. 1 for anti-infective agents in India for more than 10 years, this company has a strong presence in the gastrointestinal, pain management, and vitamins/ minerals/nutrients areas.
The client produces high-quality generic drugs, active pharmaceutical ingredients, and nutraceuticals for marketing in India and over 50 other countries.

Challenge

The client approached us to provide them with a retrofit solution that would enable packaging of a highly oxygen-reactive and hygroscopic product from clavulanate and amines family using the B MAX blister packaging machine, which was already in operation at their site.

ACG Solution

Our team of expert designers and engineers worked on a system to add dry nitrogen into the blister cavities, thus flushing out moist air. The B MAX machine was provided with a NEP unit attachment, which injected dry nitrogen into the blister pack before sealing. This unit comprised a nitrogen cylinder/reservoir with gauges and a regulator attached to the nitrogen chamber. Depending on the requirements, the nitrogen pressure can be adjusted (0.1 - 4.5 bar) and the gas can be blown into the cavities to flush out air and replace it with the required amount of dry nitrogen.

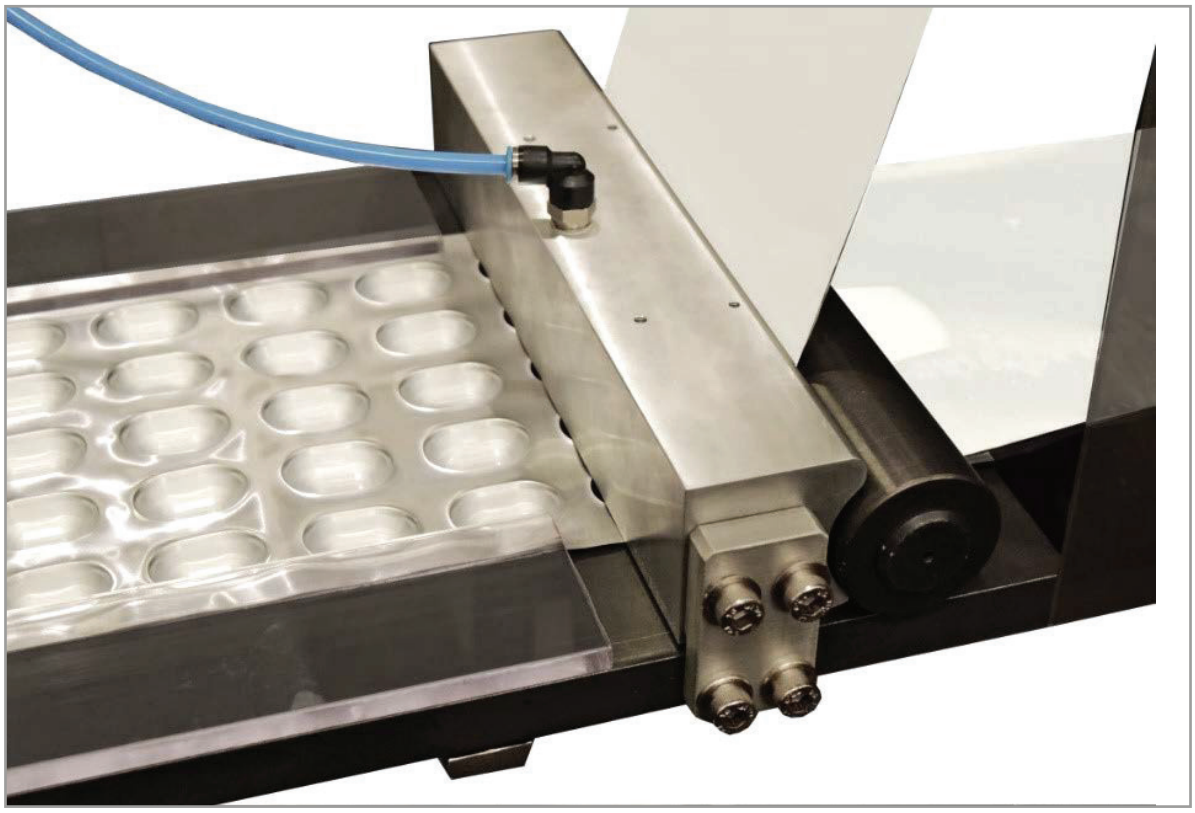

Figure 1: NEP unit before blister pack sealing

The NEP system is designed for easy-to-use single-point infusion of fresh nitrogen into the blister cavities, thereby completely removing air from the area.

Result

The addition of NEP enhanced the capability of the machine to facilitate packaging of oxygen-reactive products into blister packs. A destructive test was performed to check the level of oxygen using an oxygen monitoring kit; no trace of oxygen was detected in the packed blister. This ensured the purity of the pharmaceutical product and extended its shelf-life.

> **“Always getting the support from the ACG whenever we call them”**
>
> - Mr. Lalit Amru, Plant Head, Ajanta Pharma