

Tekni-Plex coextruded barrier structures enable commercialization of emerging drug therapies

Multilayer flexible film for sterile liquid reservoirs relies on tie resins to optimize the extractables and leachables profile

Tekni-Plex products:

Tekniflex® PTA series—LDPE/PCTFE (Aclar®) and Tekniflex® CTA series—COC/PCTFE. Both are multilayer coextrusions with high moisture barrier properties.

Problem

With an increasing number of liquid (injectable) pharmaceutical therapies in development, drug companies are constantly on the lookout for packaging and device pairings that will improve the quality of patient care and drug efficacy. Oftentimes these specialty pharmaceuticals target therapies for cancer, autoimmune disease, diabetes, etc. The objective is to put more convenience in patient hands (via wearable devices) in order to minimize doctor office and hospital visits and improve therapeutic impact.

One such pharmaceutical company knew that there was a problem finding the right structure from which

to construct its primary package. The ideal material of choice is a high barrier flexible film that is converted into a pouch or other drug reservoir type. These structures require protection against moisture loss and provide barrier against API's and/or excipients, to deliver desired drug stability (as long as two years). Typically, multilayer films have poor extractables/leachables performance.

Another driver is the desire to improve how devices work. For example, some devices rely on a glass reservoir that require a plunger movement to empty. Flexible reservoirs collapse on their own, requiring little pump pressure to do so. The latter approach has the potential to further miniaturize drug delivery systems, which are preferred by patients.

Cause

Traditional multilayer film solutions rely on reactive two-component adhesive laminations to “connect” the

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Low extractables & leachables



Easy film conversion



Successful stability tests

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various layers together. These adhesives may cause a high amount of “short chain reactive molecules” to leach into the drug, affecting both safety and efficacy. The pharmaceutical company knew it had to find a film supplier that had multilayer coextrusion capability. Further, the company needed to have an R&D group that could work hand-in-hand with its scientists to develop the right structure and take part in a long journey through validation.



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Solution

Tekni-Plex produces its multilayer coextrusions in an ISO 7 cleanroom which enables the company to create structures that offer the stability required by liquid drugs. The multilayer process does not rely on adhesives, but rather on tie resins with large polymer chains, minimizing extractables and leachables. Additionally, its development team focuses on delivering custom solutions and its pilot line capabilities provide quick turnaround of film prototypes. Moreover, Tekni-Plex specializes in using additive-free pharmacopoeia resins for the inner and outer layers in direct contact with the products.

Benefit

The pharmaceutical company is now in the final stage of validation. Using film options from Tekni-Plex, it has been able to demonstrate low extractables, easy conversion of the film into fluid reservoirs and successful stability tests.

Further, the pharmaceutical company benefits from Tekni-Plex’s ISO 15378 certification, the application standard for the design, manufacture and supply of primary packaging materials for medicinal products.

For additional information, please visit:
www.tekni-plex.com/healthcarepackaging