Case Study: Aptar CSP Technologies & Vaxxas Nanopatch™

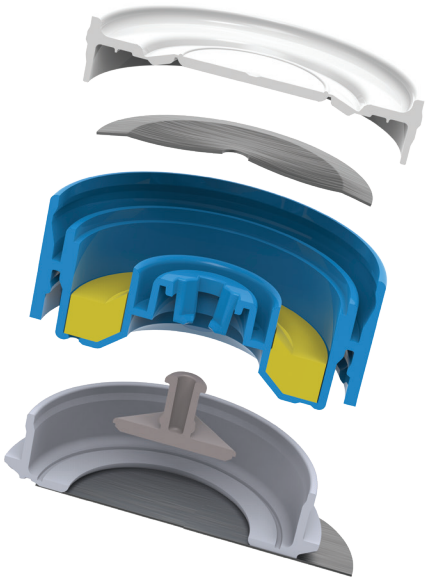
Delivering a material difference to MAP technology

Executive Summary

Aptar CSP Technologies is a material science specialist delivering innovative, highly-engineered, active packaging and device solutions that protect products and extend shelf life. Aptar CSP Technologies offers unique experience and expertise in relative humidity (RH) management to provide elevated, minimized or buffered environments, within a package and/or a drug delivery device, utilizing its 3-Phase Activ-Polymer™ technology.

Microarray patches (MAPs) are a game-changing drug delivery methodology for a wide range of treatments, including immunization programs in low income countries. These countries rely mostly on vaccine storage and transportation at 2-8°C and trained healthcare workers to administer injectable vaccines. MAPs offer clear advantages including increased vaccine thermo-stability, reduced packaging volume, ease of delivery, safer administration and disposal—possibly even by volunteers or inadequately trained health workers.

As part of Vaxxas' development of its proprietary Nanopatch™ MAPs technology, the organization employed the specialist services of Aptar CSP Technologies to develop their applicator design to achieve and maintain a target RH, by seamlessly incorporating an optimized Activ-Polymer™ desiccant into the design, to ensure the efficacy of the vaccine, and be capable of high volume and aseptic production.



Your product, actively protected™

Aptar
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MAP services employed

Device design, development and engineering; process development; test method development

Objectives

- Maintain low humidity within the device, throughout life; by delivering a robust combination of low moisture ingress, superior seal and closure integrity - all with active moisture management (see Figure 1)
- Develop a design optimized for high volume, mass production within an aseptic environment
- Attain the appropriate functional in-use performance

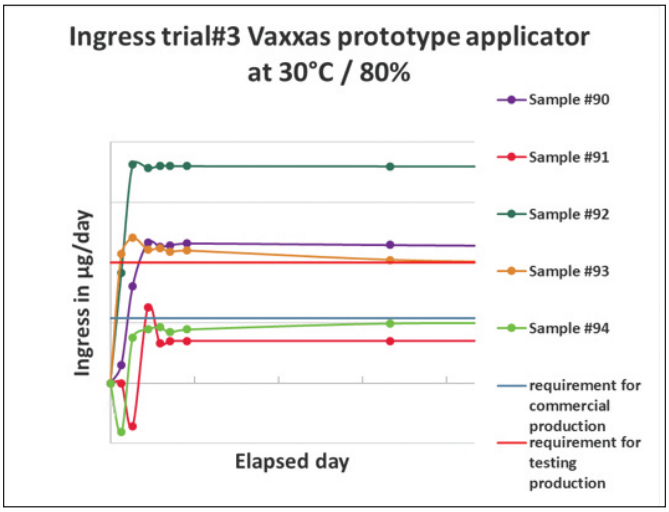

Figure 1

Challenges

There are several challenges associated with developing MAP technologies – primarily around their sensitivity to moisture. As a result, many MAPs require some form of desiccant technology applied to them. Without this control, there is a risk that the stability of the API will be compromised.

Many devices must be fit for manufacturing in an aseptic environment, which requires very low levels of particulates within the device. In this case, the challenge was to deliver assembled units within an ISO7 Clean room environment to support human use clinical trials.

Solution

- A delivery device that the OEM and end-users want, with the desiccant and low moisture design that the MAP required
  - Low humidity was achieved and maintained by integrating Activ-Polymer™ material into existing components and moisture tight sealing into the design
  - The appropriate actuation force was achieved using a bespoke designed spring assembly
- Theoretical modeling and experimental method development and testing, as well as rapid prototyping

Benefits

- MAP technology can be developed for a wide use of applications – with vaccines currently one of several focus areas
- Aptar CSP Technologies employed its ***Xcelerate*** Development Services to expedite time to market for the client
- Test methods and studies were employed to characterize the device and verify desiccant performance
- What was developed was a low moisture ingress assembly with an optimized Activ-Polymer™ desiccant capacity and integration into the device
  - Achieving and maintaining target moisture levels
  - Enabling small scale production for development and stability work
- Final device is suitable for aseptic production

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Photo courtesy of Vaxxas, Inc.