To cap it all

While the use of two-piece capsules in dry powder inhalers is well-established, the move from gelatin to hydroxypropyl methylcellulose is ongoing. *World Pharmaceutical Frontiers* talks to **Qualicaps**' Fernando Díez, to learn how his company is spearheading the movement through its groundbreaking, plant-derived Quali-V capsules.

Patented in the 19th century, two-piece capsules have played a prominent part in the pharmaceutical sector. For much of that period, gelatin capsules – which contain filings such as active pharmaceutical ingredients (API) and excipients – were classed as the market standard; however, in recent years, there has been a paradigm shift, with hydroxypropyl methylcellulose (HPMC) capsules rising to the fore, particularly in the field of dry powder inhaler (DPI) applications, which are used to treat pulmonary and systemic diseases.

The switch has come on the back of substantial pharmaceutical research revealing that while gelatin – a protein derived from animals – allows for an overall decent powder release from the capsule shell, it also has the potential to become chemically unstable and carries the risk of transmissible spongiform encephalopathy – a group of neurodegenerative conditions.

Subsequently, HPMC, which is known for its chemical inactivity, lack of crosslinking and low moisture content – not to mention excellent microbiological qualities – has emerged as the market's most viable alternative.

HPMC development

Developed by Qualicaps – a global supplier of two-piece capsules, equipment and technology to the pharmaceutical and health and nutrition sectors – Quali-V is the industry's leading plant-derived HPMC capsule to be specifically designed for use in DPIs.

"We first launched the design for HPMC capsules for inhalation in 2006,"explains Fernando Díez, Qualicaps' business development manager. "The main advantages over gelatin relate to mechanical properties – it is much easier for the film to be penetrated by pins and blades, unlike gelatin capsules, which have been proven to show signs of brittleness in the puncture process.

"Another benefit is its aerosolisation properties – the fine particle fraction of the API is higher when using Quali-V with fewer shell particles generated in use."

In developing HPMC products, Qualicaps makes use of a state-of-the-art capsule R&D department, located in Osaka, Japan. Furthermore, the group has a vast global network of pharmaceutical researchers and academics to help it foster further innovative solutions.

"We try to collaborate with R&D centres as much as we can," says Díez. "We are in contact with them on a continuous basis in order to promote our own products, as well as to help scientists in coordinating the capsules with the dosage form. This is just the first step – when a R&D centre decides to use our capsules, we always follow up on the project."

Roots of growth

While Qualicaps' roots can be traced back to Japan, where it was founded in 1965, the group today finds itself present across Asia, Europe and the US. According to Díez, the latter has been earmarked as a particularly lucrative market as the group looks to bolster its global coverage.

"In terms of HPMC, we are seeing real demand in Europe," he says. "It has become our most important market for both manufacturing and sales [the group has offices in both Spain and Romania].

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"However, that's not to say that our interest there will come at the expense of other markets. In the future, I think we're set to see bigger reports come from the US, which could prove to be a very important area for us going forward."

With the proven pharmaceutical performance of Quali-V, Díez is sanguine that Qualicaps can consolidate and build on its already-favourable position, and continue to deliver a number of beneficial capsule solutions to the DPI marketplace.

"There are many possibilities," he says. "When it comes to using these capsules, I would say that there are two important advantages. The first is price – working with HPMC is always cheaper. Second, you can actually deliver more drugs at a higher quantity.

"Put the two together and you have an ideal platform for new inhalation drug development." ■

Further information
Qualicaps
www.qualicaps.com