HEALTH

Not all carbomers are created equal

Carbopol® Polymers: How one pharma company stays ahead of the competition in safety and compliance

Ensuring safety in a competitive global market

To compete in a globalized pharmaceutical market, companies are under ever greater pressure to ensure that their products are competitive on cost, while ensuring optimum quality and compliance with the strictest global safety regulations. For some companies, a workaround to reconcile these conflicting goals can seem to be using a low-cost carbomer excipient in their drug formulation.

However, not all carbomers are created equal, as Kedar Chikhalikar, Head of R&D, South Asia & Middle East at Lubrizol Life Science Health explains:

> Some carbomers available on the global market are made using solvents categorized as Class 1 toxic solvents. Under USP 467 (ICH Q3C) guidelines these do not comply with stringent international safety regulations, which means that any product found containing these materials may not be eligible for sale in global markets.

As one pharma developer discovered when reformulating its widely used oral suspension product, it is not always clear which low-cost carbomers are safe to use, and which are not. In fact, these lower quality carbomers can prove costly in the medium term, especially when considering the potential risks associated with regulatory non-compliance.

Lubrizol Life Science demonstrated the value of Carbopol® polymers as a high-quality, non-toxic, compliant carbomer. Working together, the two businesses ensured the product stood out from competitors in terms of quality and product performance while also maintaining safety and regulatory compliance.

The challenge

As a champion of pharmaceutical product quality, safety and compliance, Lubrizol regularly explores the market to identify potential issues with established drug products and to support the companies behind them to enhance and improve their formulations.

During one of these exercises, we identified that one Asia-based pharmaceutical company's oral suspension product had been unknowingly manufactured using a sub-standard carbomer that contained significant amounts of 1,2 dichloroethane - a Class 1 residual solvent, continues Chikhalikar.

This solvent identified is not safe for use, as it is carcinogenic. It poses a potential threat to the wellbeing of patients. To make matters worse and contrary to the requirement of pharmacopoeia monograph compliance, the carbomer manufacturer did not disclose the presence of the class 1 solvent.

To continue selling the product globally, the pharmaceutical company had to reformulate its product with safe ingredients. Lubrizol approached the company to collaborate in finding an effective solution quickly, ensuring compliance as well as the maintenance of product quality.

The solution

Lubrizol's team of experts worked closely with the pharma company to reformulate the oral suspension product. Lubrizol scientists provided quantifiable proof of the presence of class 1 solvent - 1, 2 Dichloroethane in the inferior quality carbomer. Solvent levels in the excipient far exceeding the ICH limit of five ppm.

Because the carbomer excipient acts as a suspending agent within the drug formulation, it is vital to the drug's success. It prevents the active pharmaceutical ingredient (API) from settling at the bottom of the container, ensuring a uniform dose for the patient every time they administer the medication.

The formulation experts at Lubrizol recommended the use of a suitable grade of Carbopol® polymer, as the ideal solution to achieve the required suspension profile for maximum product quality while ensuring optimum regulatory compliance.

The benefits of Carbopol®

Carbopol® polymers are and have been the oldest and most pioneering, having been present in the pharmaceutical market for several decades. Created as the first commercial carbomers over 50 years ago, Carbopol® polymers are well known for their versatility and used extensively in pharma products for many reasons:

- Made using safe, non-toxic solvents that comply with USP 467 (ICH Q3C) guidelines.
- Offer formulation flexibility, making them ideal for use with a variety of pharmaceutical active ingredients for topical, mucosal and oral delivery.
- Provide optimum bio-adhesion, taste-masking and good binding characteristics.
- Offer a consistent release profile compared with competing carbomers, enabling controlled release of any API.

> Carbopol® was the ideal solution for this particular challenge, balancing both the quality and the regulatory compliance needs of the oral suspension. As well as offering the pharma company peace of mind that its product was made with compliant, non-toxic materials, Carbopol® provided the perfect suspension profile to ensure the uniform distribution of API throughout the product, for dosage consistency. - Mr. Kedar Chikhalikar, Head R & D, South Asia & Middle East, Lubrizol Life Science Health

The result

The reformulation project has now been completed and the new and improved oral suspension product is now on the market. It is as successful as ever, entering more international markets than ever before.

Not only is this thanks to Lubrizol's expert reformulation support, but thanks also to the ongoing technical and regulatory assistance it provides to the company. Lubrizol's technical support team is always on hand to provide documentation support for the company to submit to regulatory agencies when needed, providing them with the crucial supporting evidence to demonstrate the quality and safety of the product.

> We've fostered a true collaboration with our customer, providing them not just with documentation, but with guidance to fully understand the behaviour and the value of Carbopol® polymers to the product," says Mr. Chikhalikar. "With this insight, our customer has the information it needs to effectively demonstrate to regulatory authorities that their product meets global regulatory standards.

Looking ahead

Given the success of this project, it is no surprise that the company is exploring the potential use of Carbopol polymers across other areas of its product line.

> Mr. Chikhalikar concluded: We're looking forward to working with similar global pharmaceutical companies, supporting them to further expand in the global marketplace by offering formulation solutions that are differentiated and safe.

To find out more about how LLS Health can take your next project into clinical or commercial manufacturing, contact us today.

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