

# WhitePaper

## Focus on eliminating formulation impurities drives introduction of new polysorbate products

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Eliminating impurities in drug formulations has always been a key focus for pharmaceutical manufacturers. The reason is simple—impurities can reduce the efficacy of active pharmaceutical ingredients (APIs) in formulations. In response to our customers' needs in this area, Avantor™ Performance Materials has provided a range of high-purity products to help manufacturers meet this challenge—solvents, sugars, buffering salts, chromatography media, denaturants and surfactants, among other offerings. Over the years, we've brought to market products that are more advanced and higher in purity, as the complexity of biopharmaceutical manufacturing increased and the tolerance of impurities in formulations declined dramatically. Among these products are several types of polysorbate excipients.

Today, pharmaceutical manufacturers are working with new APIs that are much more effective in formulations, but increasingly prone to stability issues and more sensitive to impurities. As a result, they're looking to their suppliers to find ways to reduce impurities and enhance API efficacy—and in response, we've introduced new versions of our polysorbate products, created with an advanced process to reduce impurities down to levels not previously achieved with traditionally produced polysorbates.

### New Super Refined® Polysorbates

Generally speaking, biopharmaceutical formulators turn to polysorbates for the benefits they provide in parenteral dosage applications (injectable, intravenous, subcutaneous), although these excipients are also used in solid and liquid dosage form products for their positive contribution to stability and API effectiveness.

Composed of fatty acid esters of polyoxyethylene sorbitan, polysorbates are surfactants which are amphiphilic and

non-ionic. The surface activity of polysorbates serves to stabilize proteins, by reducing the alteration or aggregation of proteins during manufacturing, distribution and storage. When formulated with poorly soluble drugs, polysorbates provide improvements in solubilization, and emulsions with polysorbates are widely recognized among formulators for enhanced stability. Avantor's high-purity J.T.Baker® brand polysorbate 20 and polysorbate 80 products have been used to address these issues, amid the variety of formulations and the growing presence of potentially sensitive APIs, for several years.

The new Super Refined®\*\* versions of polysorbate 20 and polysorbate 80 now in our product offering take this pursuit of greater formulation purity a step further. High-purity grade polysorbates already offer low levels of impurities to ensure high performance in formulations, but a proprietary flash chromatographic process used in making the Super Refined® versions has been shown to remove even more polar and oxidative impurities, such as peroxides and aldehydes. The decreased level of these impurities helps maintain API integrity and stability in formulations like parenteral drugs involving monoclonal antibodies or recombinant proteins (such as certain cancer drugs), and other formulations in suspension or emulsion dosage form.

With the introduction of the Super Refined® polysorbate products, we make it possible for customers to match the right level of purity to their specific API needs. This is especially relevant, for example, to makers of parenteral formulations and those involved in the growing biosimilars market in regions like Asia and India. (We also see our customers' pursuit of greater excipient purity extending beyond polysorbates, and we're preparing to offer other Super Refined® process excipient products in the next several months.)

## Quality Assurance is Key

As the need to reduce impurities in formulations continues to influence production decisions by manufacturers, quality assurance from suppliers becomes even more critical. Suppliers must be able to match their customers' emphasis on purity with an equal commitment to the quality of materials that they provide. Customers increasingly are choosing suppliers who can offer features like cGMP manufacturing and subdivision capabilities, FDA-inspected and ISO-certified facilities, nitrogen blanket packaging and rigorous multi-compendial requirements.

For example, Avantor's J.T.Baker® brand polysorbate products meet the requirements of the National Formulary (NF), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) or Japanese Pharmaceutical Excipients (JPE). Their vegetable-based composition serves to reduce endotoxins, peroxides and other impurities, which in turn improves oxidative stability and shelf life. And customers are able to choose among multiple packaging sizes to match the amount of polysorbate product they buy to their manufacturing processes more closely.

Increasingly, customers are looking to work with companies who see themselves more as partners than just suppliers. The foundation of that type of relationship is confidence in the quality of the products that they purchase and we provide.

## Enhancing Patient Welfare

Ultimately, our efforts and those of our pharmaceutical and biopharmaceutical formulator customers serve to fulfill the same goal—enhancing patient welfare. As suppliers, we contribute by understanding and anticipating our customers' needs, including the need for excipients that can further reduce the impurities that affect API efficacy. To meet the technological challenges involved in creating new and more effective formulations, manufacturers and suppliers will need to collaborate even more closely than they have in the past in order to facilitate the development of more effective drug therapies in the future.

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## About Avantor™ Performance Materials

Avantor Performance Materials manufactures and markets high-performance chemistries and materials around the world under several respected brand names, including the J.T.Baker®, Macron Fine Chemicals™, Rankem™, BeneSphere™, and POCH™ brands.

Avantor products are used in a wide range of industries. Our biomedical and life science solutions are used in pharmaceutical production, laboratory research for academic, industry and quality control, and in medical lab testing. Our electronics materials products are used in the manufacturing of semiconductors. Based in Center Valley, Pennsylvania (USA), Avantor is owned by an affiliate of New Mountain Capital, LLC.

For additional information please visit [www.avantormaterials.com](http://www.avantormaterials.com) or follow [www.twitter.com/avantor\\_news](http://www.twitter.com/avantor_news)

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