Surfactants in Biopharmaceutical Development

Insights from our industry experts

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Chapter 3: Surfactants: (Polysorbates and Poloxamers) synthesis, characterisation, and degradation

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Can you tell us a bit about yourselves and your backgrounds?

I'm Sreejit, currently heading the Life Sciences R&D team for North America at Croda. I've been with the company for seven years, starting as a technology specialist in the Pharma R&D team. My background is in synthetic organic chemistry. Over the years, I've transitioned from new product development to leading the new product and applications team, and now to my current role overseeing pharma, crop, and seed R&D teams.

I am a Life Sciences Research Fellow at Croda. I've been with the company for many years and am currently responsible for developing external relationships and collaborations, from our customers through to universities and research institutes. Previously I started my career in analytical chemistry and have held numerous roles, including managing the analytical and pharmaceutical R&D teams for North America. I have broad experience in working in all of our three major platforms excipients, adjuvants and lipid delivery systems.

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Why are polysorbates and poloxamers important to the pharma industry?

These surfactants are critical for maintaining the stability and activity of active pharmaceutical ingredients. Their ability to keep the actives stable is a key factor in their importance to the industry. The quality and purity of these ingredients are also very important, as they directly influence the stability of biologic formulations, which has been addressed in the book.

From small molecule to biologic therapeutic formulations, polysorbates and poloxamers have a long history of safe, effective use in various pharmaceutical applications. They are crucial for everything, from downstream processing to final formulation, acting as emulsifiers and stabilizing agents in both small molecule formulations and biologic therapeutic formulations.

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What are some key highlights and findings from your chapter, that you believe are the most important for readers to understand and explore?

One key highlight is the detailed explanation of raw material selection, processing conditions, and isolation steps, which are crucial for the final quality of these surfactants. This understanding enables users with a better appreciation for the role of raw materials in formulation performance. The book also serves as an educational tool for any new formulator, especially in the biopharmaceutical industries, solving key challenges within the bio formulation space.

As an industry leader, our chapter aims to demonstrate how we’re able to understand and characterize these types of molecules which can give greater insight into how their composition can impact performance and stability. This helps in understanding their versatility and application.

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Why are polysorbates and poloxamers considered critical in stabilization and formulation of biologic drug products?

Aside from their known history of safe use, these molecules perform exceptionally well in maintaining stability. The industry's risk-averse nature also plays a role in their continued use. However, this doesn't limit the exploration of new materials to address existing challenges.

They work! They not only work very effectively across a wide range of molecular types and variants, they have a proven track record of safety and effectiveness, which is paramount in the pharmaceutical industry. Their established efficacy and safety profile makes them indispensable.

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Are there any important synthesis and characterization techniques readers should look forward to learning in your chapter?

Starting with synthesis, we emphasize the importance of raw material selection, quality, and the complex chemistry involved in synthesizing these surfactants. Readers will gain an appreciation for the unit operations involved in each step, as every step and choice contributes to the quality of the end product. Each step in the process affects the final product's quality, which we thoroughly discuss in our chapter, including how to assess and characterize the complex chemistry involved and establish confidence in batches

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Are there any important synthesis and characterization techniques readers should look forward to learning in your chapter?

There's a lot of misconceptions about how polysorbates are made and the different types of materials used, since it is not entirely intuitive. Our chapter covers advanced analytical techniques like LC-MS, NMR, and MALDI mass spectrometry, which allow us to fully characterize these materials. These techniques have proven to be highly useful in enabling us to characterise these products in detail which, combined with our understanding of their performance, has enabled us to develop effective working relationships with our customers in joint projects and enhancing their performance for particular applications.

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How does your chapter address the impact of surfactant purity on stability and efficacy?

As mentioned previously, the choice of raw materials, processing conditions, and the final material all contribute to the end purity and quality of polysorbates or poloxamers. Croda has their own proprietary process in place to further eliminate certain problematic impurities for end use formulations. We highlight in the chapter the different grades of materials available in the industry and how controlling those impurities play an important role in making stable and effective drug products.

In addition, Croda produces specific grades of polysorbate designed for injectable formulations, emphasizing the importance of purity. Educating customers on these aspects helps them successfully develop drug formulations from the start, saving time and costly resources in their development cycle

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What future research directions and trends in surfactant use do you see?

Polysorbates and Poloxamers are here to stay, but the industry is constantly exploring new materials to overcome existing limitations. Croda is at the forefront of this research as well. The only caveat being these are novel materials, where we work with the excipient manufacturer, the pharmaceutical customer, and the regulatory bodies to access, review and progress them. On average a novel excipient takes anywhere between 8-12 years to come to maturity and be used in market products.

We collaborate with customers to tailor existing materials to their needs within regulatory boundaries. At Croda, we have the skills to produce materials that are multi compendial compliant and, to a certain extent, capable of being customized for a specific formulation. While polysorbates remain the mainstay, Croda’s portfolio contains other materials to stabilize proteins and we are always looking at potential alternatives and improvements.

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What are the main takeaways you hope readers will gain from your chapter? How can they apply the knowledge?

Our chapter showcases Croda's expertise in this field, helping readers understand the critical role of these materials in applications, addressing key challenges and creating a broader awareness.

We hope readers gain a deeper understanding of the complexity and characterization of polysorbates. The chapter, as part of the book, provides comprehensive insights into polysorbates synthesis and use, fostering more in-depth technical conversations with customers. We are not just an excipient supplier- we share our knowledge and experience with customers to enable them to use Croda materials to develop stable formulations.

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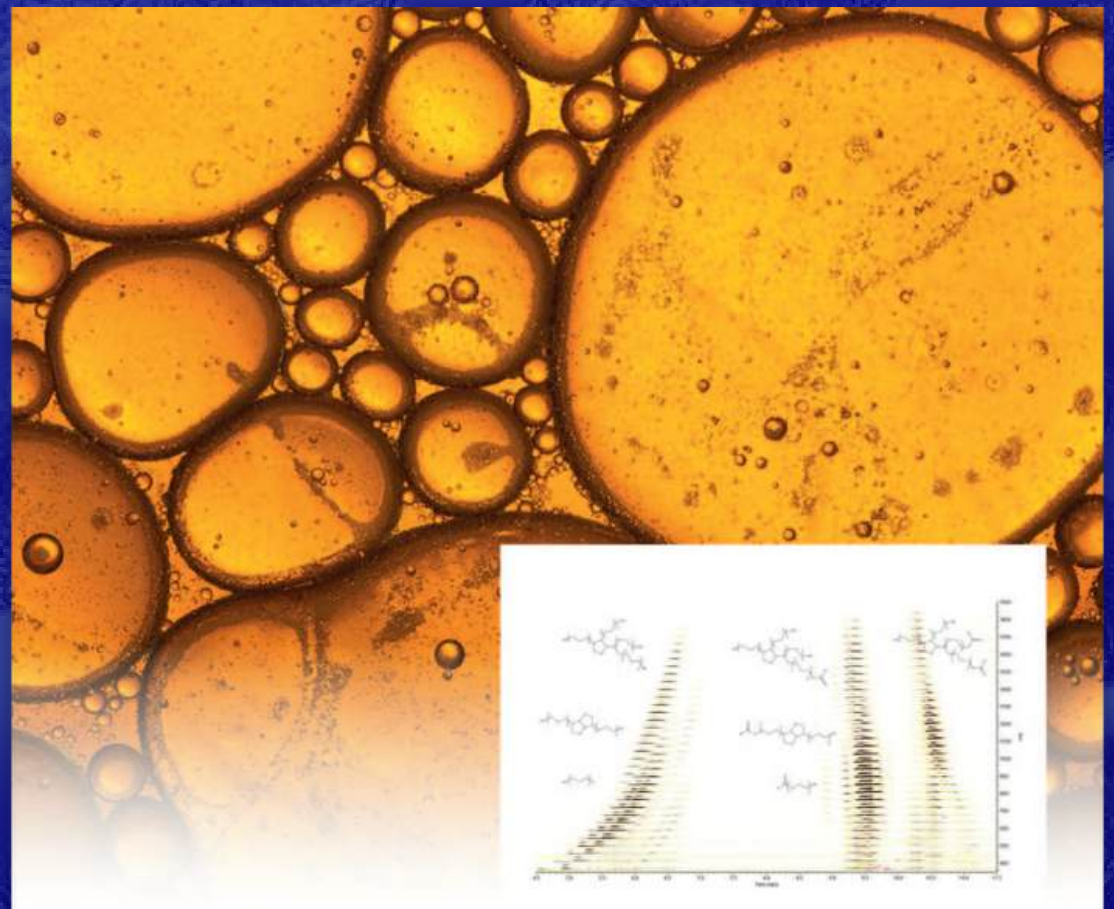

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