

Trends in Excipient Demand

Pharma manufacturers are seeking out innovative excipients that address bioequivalence development and solubility challenges, while enhancing formulation

By Nigel Walker, Managing Director, That's Nice LLC/Nice Insight

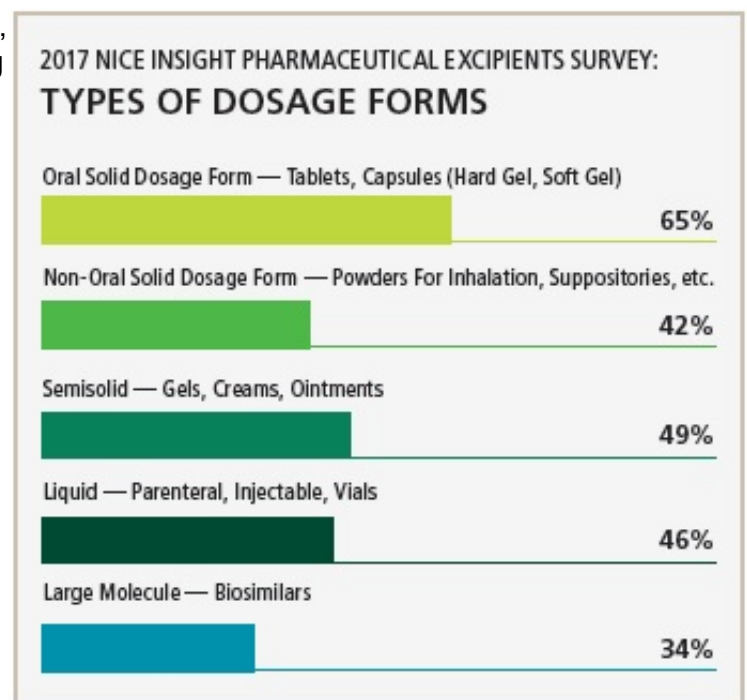
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Excipients play a key role in helping pharmaceutical manufacturers serve patients better through improved compliance and efficacy of treatment. They also help reduce developmental costs and provide opportunities to differentiate products through new modes of drug delivery.

Experts identify several trends driving excipient demand: solubility and bioavailability challenges, as well as the desire to increase the lifecycle of a drug, improve manufacturing efficiency and address the growing bioequivalence market.

Development of new treatments for chronic diseases, increased access to medication through generic drug production, increased research and development spending, growing competition, and new technologies are driving these trends, says Bosh Chattopadhyay, business director, BASF Pharma Solutions. As a result, he says there is a desire to:

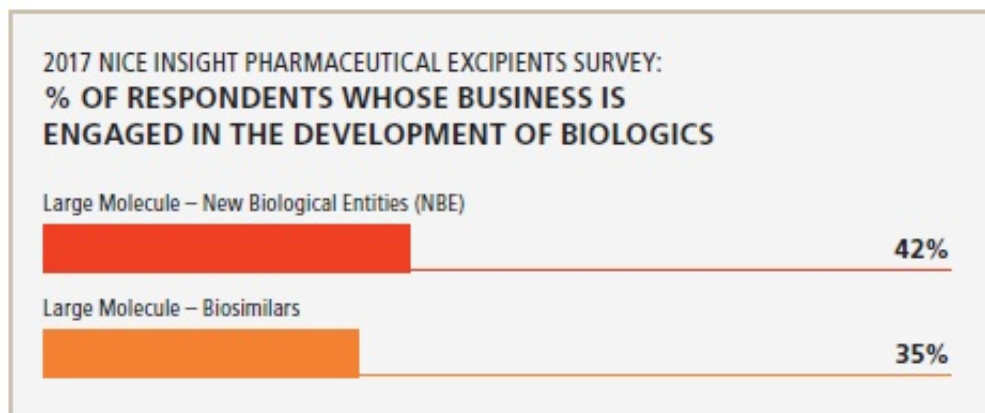
- Provide access to new treatments and improve the efficacy of new chemical entities (NCEs), which are typically less soluble;
- Address specific needs for pediatrics and geriatrics – taste masking, ease to swallow, alternative dosage forms (orally disintegrating tablets);
- Improve compliance – controlled release to reduce frequency of administration and extend duration;
- Provide different product options – alternative routes of delivery/dosage forms;
- Improve ease-of-use – no need to take with food / water, no need for refrigeration, lower risk of overdose due to consumption of alcoholic beverages; and
- Improve production technologies and realize more efficient and effective processing.



SOLUBILITY AND TARGETED DELIVERY

The solubility and permeability of many new chemical entities - which are very often highly potent - is a key issue for the development of new drug formulations. As a result, the industry is in urgent need of new approaches to drug development and tailored drug delivery. The 2017 Nice Insight Pharmaceutical Excipients Survey indicates that solubilizers - commonly used to improve the solubilization of hydrophobic substances and to increase bioavailability - experienced a 49 percent increased use over the last year among survey respondents.

“In oral drug delivery, we see an increasing interest in excipients and formulation techniques to enhance drug solubility and improve the bioavailability,” says Dr. Thomas Riermeier, vice president, Pharma Polymers & Services, Evonik Health Care. “The industry is adopting more innovative formulation technologies that appropriately target the improvement of the



transcellular and paracellular uptake of both small molecules and biologics requiring new types of excipients, like permeation/transfection enhancers, enzyme inhibitors and polymers with advanced functionalities.”

Riermeier says solid dispersions and solid solutions, combined with targeted drug delivery, are the future for oral drug delivery. “If you have a BCS class IV API with poor solubility and poor permeation, increasing the solubility alone may not solve all your problems, but delivering the now soluble drug to the right area of the GI tract may be able to boost bioavailability. Hence, methods for absorption window mapping gain importance in formulation development,” he says.

As an example, Riermeier says that Evonik’s functional polymer excipients, EUDRAGIT, can significantly increase bioavailability through delivering the active to the appropriate area of the GI tract where absorption is the highest or to the site of action where the active is needed.

Chattopadhyay says that leveraging the characteristics of excipients to modify the release profile of a drug can increase the lifecycle of that drug.

“In parenteral drug delivery, there is a greater focus on developing more advanced complex formulations such as liposomes and polymer-based microparticles, allowing for specific drug targeting or extended release, where a single injection can provide the dose for a week, a month or even longer,” says Riermeier.

BIOSIMILARS REQUIRE NEW EXCIPIENTS

Biosimilars are driving demand for excipients used to manufacture biologicals. In fact, the 2017 Nice Insight Pharmaceutical Excipients Survey also indicates that large-molecule (biosimilars) manufacturers represent a growing group of excipient purchasers. “Thus, excipients that can mitigate biological production risks and improve process yield are in high demand,” says Chattopadhyay.

The number of biological actives coming off patent will increase in the near future. Developing biosimilars is significantly more challenging than conventional small molecules as different physico-chemical properties and specific sensitivities to regular manufacturing parameters have to be handled, explains Riermeier.

“Biotechnology-based products require greater attention to stability in the dosage form as well as unique approaches to overcome biological barriers to target site delivery,” he says. “New types of excipients and innovative formulation and manufacturing technologies offer new opportunities to formulate these drugs with high bioavailability.”

MULTI-FUNCTIONAL EXCIPIENTS MAKE BETTER PILLS

As the number of difficult-to-develop compounds continues to rise, the industry is taking bolder steps in

evaluating non-conventional technologies for effective delivery to mitigate risks while enhancing the efficacy of drugs and bringing these compounds to the market much faster.

“Today, more than ever, pharmaceutical formulators are seeking ways to improve the manufacturing process and product quality through the use of multi-functional excipients,” says Chattopadhyay. “Multi-functional excipients play an important role in innovating delivery technologies and helping in-line extensions of marketed drugs.”

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