Lipid excipients from Stéarinerie Dubois

For oral dosage forms

There has always been a continual quest for improvement in pharmaceutical formulations, and this applies to all galenic forms we have today: tablets, capsules, liquids, emulsions, dispersions, and semi-solids. The market diversity of esters, in particular those available in the range of Stéarinerie Dubois for standard and innovative formulations, offers developers a wide range of possibilities.

In this article, ***Dr. Samer Joudeh, Head of the Pharmaceutical Division at Stéarinerie Dubois****, provides an overview of various lipid-based pharmaceutical excipients, such as fatty acids or fatty acid esters, and their use in oral lipid-based formulations (OLBF).*

Lipid excipients from Stéarinerie Dubois: Innovation & diversity

Esters are derivatives of carbonic acid, in which the hydrogen of the carbonic acid (-COOH) has been replaced by an alkyl group (-R). The functional group of the ester can thus be represented as -COOR. The number of possible combinations in the molecular structure is practically infinite since, depending on the fatty acid, there are countless differences in chain length, degree of saturation, presence of branches, and type and number of bound molecules (e.g. glycerin, other fatty acids, propylene glycol, polyglycerin, saccharose, etc.). This makes for a **broad range in terms** of the following parameters:

- Application areas for these excipients
- Range of the hydrophilic/lipophilic balance (HLB)
- Wetting behaviours & polarities
- Gel-forming properties
- Melting points, crystallinities, and porosities

Oral lipid-based formulations (OLBF) are the most commonly used drug delivery system (DDS) because they **improve the oral bioavailability** of poorly water-soluble pharmaceuticals by improving the dissolution of drugs in the gastrointestinal tract (GI tract) or the dwelling time in the stomach.

Lipid formulations are therefore **highly attractive**, but present a number of challenges in terms of their development. Often, developers are faced with problems like **masking tastes**, **improving shelf life and API stability, or controlling release**, in particular when processing many APIs, such as chloroquine, acetaminophen, metoprolol tartrate, ibuprofen, herbal extracts, diltiazem, diclofenac, bromhexine, antibiotics, n-acetylcysteine or mesalazine.

In order to meet this challenge, Stéarinerie Dubois offers a **wide and diverse range of effective excipients** that help to combine the chemistry, functionality, and behaviour of the excipient with those of your active ingredient (hydrophobicity, hydrophilicity, acidity, hygroscopy, polymorphism, instability, taste, ...). They have a **multitude of lipid excipients** with different melting points (27–85 °C) available, which allows the integration of many different technologies and methods that have been developed specifically for lipid formulations on an industrial scale:

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Lipid-based excipients from Dubois

Example products	Product segment	Example applications
Stellipress™, Stearic acid, Myristic acid, Palmitic acid	Fatty acids	Lubricants, Tabletting excipients, Coating excipients
Carnauba wax, beeswax alternatives	Waxes	Coating excipients, Matrixes, API protection
DUB PP, hard fats	Fully or partially hydrogenated vegetable oils and fats, Hydrogenated cocoglycerides	Matrixes
PEG 6 or 8 stearates	PEG fatty acid esters	Taste masking, controlled API release
Stelliesters™, oleic acid macroglycerides, caprylocaprate macroglycerides	Polyoxylglycerides	Solubilizers, Bioavailability enhancers
DUBCARE™, Glyceryl monostearate, Glycerol monooleate	Monoacylglycerides	Taste masking, controlled API release
Stelliesters, Glyceryl dibehenate, Glyceryl palmitostearate	Diacylglyceride	Taste masking, controlled API release
Stelliesters MCTs	Triglycerides of fatty acids	Solubilizers, vehicles, Bioavailability enhancers
Stelliesters SE	Fatty acid esters of saccharose	Surfactants, bioavailability enhancers, tabletting excipients

Clever chemistry that promotes an environmentally friendly future

All GMP excipients from **Stéarinerie Dubois** are developed and produced under strict quality control and under **careful selection** of the raw materials and supply chain. This **"Quality by Design"** approach reflects Dubois' efforts to enter into the era of **"green chemistry"**: chemistry that respects the environment and is conscious of its practices and its impact on the planet.

With its words, *"Our ingredients for a responsible future are the reflection of our sincere, pragmatic and long-term approach to sustainability,"* Stéarinerie Dubois states its aim to make a positive influence for people and the environment throughout the entire value added chain from the selection of raw materials, to the first production steps, to the marketing of the products.

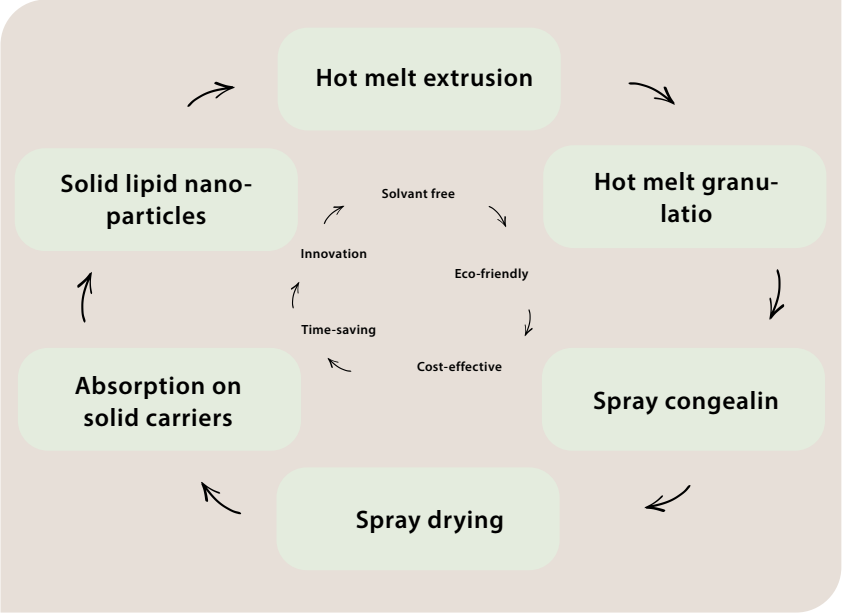

Figure 1 illustrates the "Quality by Design" approach

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