APPLICATION BRIEF 22133

Testing a diverse range of pharmaceutical excipients by HPLC

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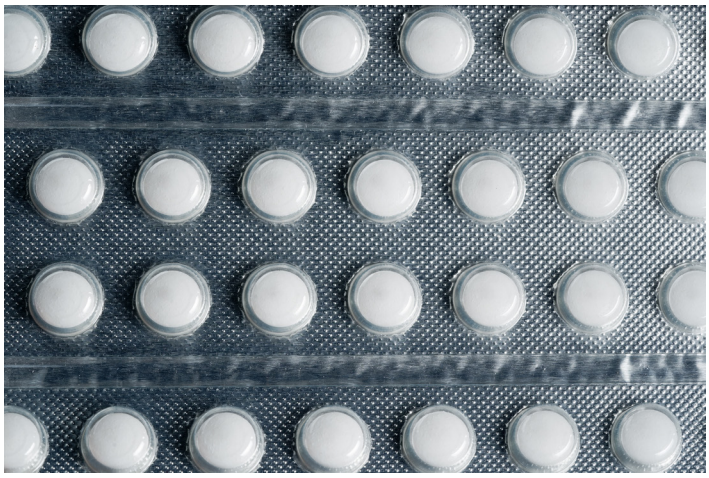
Introduction

Pharmaceutical excipients are substances other than the pharmacologically active drug or product which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form. These excipients can be used to increase the bulk or enhance the performance of the formulation, or as binders, colorants, preservatives, and disintegrants. Excipients consist of a wide range of substances. They can be plant based, mineral based, synthetic, or a combination, with differing chemical structures, making them challenging to analyze.



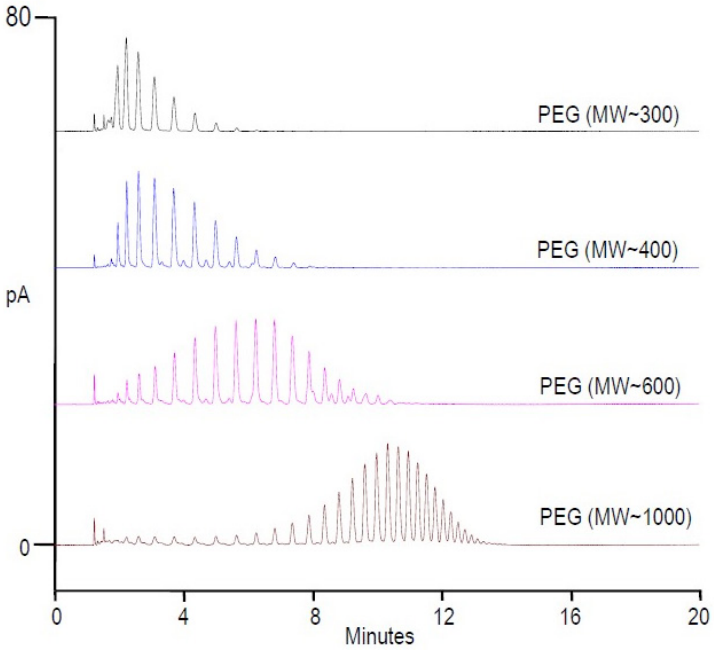
Excipients are blended with the Active Pharmaceutical Ingredients (APIs) to create tablets, capsules or other forms of pharmaceuticals. Both APIs and excipients have impurities. These impurities may affect the quality of the excipient or may enhance their interaction with the API.

The following examples demonstrate how a range of excipients can be successfully separated and analyzed using Thermo Scientific™ HPLC columns.

Polyethylene glycol

Polyethylene glycol (PEG) is a chemically inert, amphiphilic polymer used as an excipient in many pharmaceuticals for decades (i.e., PEGylation).[1] It is used as an inactive ingredient in the pharmaceutical industry as a solvent, plasticizer, surfactant, ointments, suppository base, and tablet and capsule lubricant. PEG has low toxicity with systemic absorption less than 0.5%.[2]

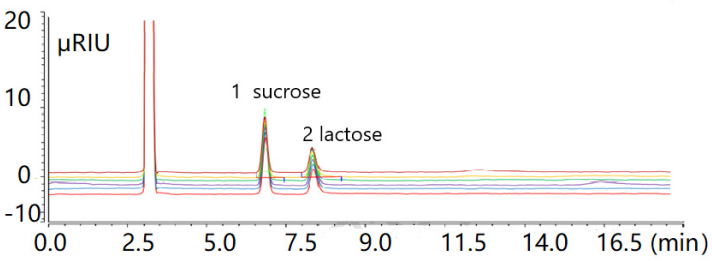
PEGylation occurs when PEGs are attached to various protein medications, allowing for greater solubility for certain drugs.



Column	Thermo Scientific™ Acclaim™ Surfactant Plus, 3 µm
Dimensions	3.0 × 100 mm
Mobile phase	A: Water (0.1% TFA)
	B: Acetonitrile (0.1% TFA)
Gradient conditions	2–20% B, 20 min linear gradient
Temperature	30 °C
Flow rate	0.6 mL/min
Injection volume	2 µL
Detector	Electrospray detector
Sample	PEG (300), PEG (400), PEG (600), PEG (1000)
Instrument	Thermo Scientific™ UltiMate™ 3000 system

Lactose and sucrose

Lactose is widely used as a filler or filler-binder in the manufacture of pharmaceutical tablets and capsules. The general properties of lactose that contribute to its popularity as an excipient are its: cost, availability, bland taste, low hygroscopcity, compatibility with active ingredients, excellent physical and chemical stability and water solubility. The most common form of lactose used in pharmaceutical formulation is crystalline a-lactose monohydrate. This form is available in a range of milled and sifted pharmaceutical grades differing in physical properties, such as flowability, bulk density, and particle size distribution.[3]



Column	Thermo Scientific™ Hypersil™ APS-2, 5 µm
Dimensions	4.6 × 250 mm
Mobile phase	Acetonitrile / Water (30:70)
Temperature	40 °C
Flow rate	1.0 mL/min
Injection volume	10 µL
Detector	Refractive index (RI) detector
Sample	Peak 1 sucrose, Peak 2 lactose
Instrument	UltiMate 3000 system

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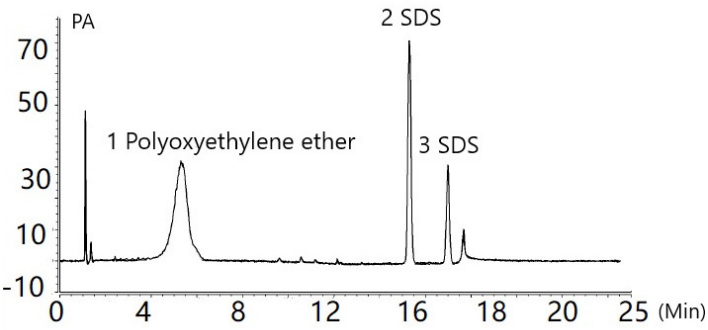
Defoamers: Polyoxyethylene ether

Polyether defoamers have been used in some countries in the pharmaceutical industry because they are non-toxic, odorless, non-irritating and easy to disperse in water.[4] The combination of xylose and polyoxyethylene ether has been found to provide a particularly interesting excipient base for pharmaceuticals.



Column	Acclaim Surfactant Plus, 3 µm
Dimensions	3.0 × 150 mm
Mobile phase	A: 20 mmol/L NH_4Ac
	B: Acetonitrile
Gradient conditions	30–85% B, 10 min linear gradient
Temperature	30 °C
Flow rate	0.6 mL/min
Injection volume	10 µL
Detector	Electrospray detector
Sample	1. Polyoxyethylene ether
	2. SDS
	3. SDS
Instrument	UltiMate 3000 system

For more examples of excipient separations, download the applications notebook:
HPLC-Charged Aerosol Detection for Excipients

References

1. https://www.pharmaexcipients.com/parenteral-excipients/polyethylene-glycol-peg-exposure-in-parenteral-therapies-for-the-pediatric-population/
2. https://www.drugs.com/inactive/polyethylene-glycol-177.html
3. https://drug-dev.com/lactose-in-pharmaceutical-applications/
4. https://www.zilibon.com/newShow_681.html

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