

Characterisation and quantitation of PEG-based polymeric excipients and impurities using UHPSFC-MS

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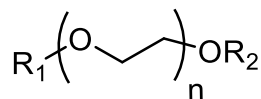
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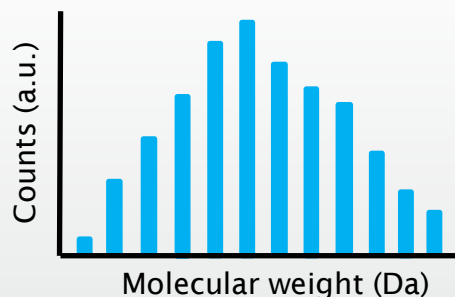
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Introduction

- Poly(ethylene) glycols (PEGs) are pharmaceutical excipients that aid drug delivery



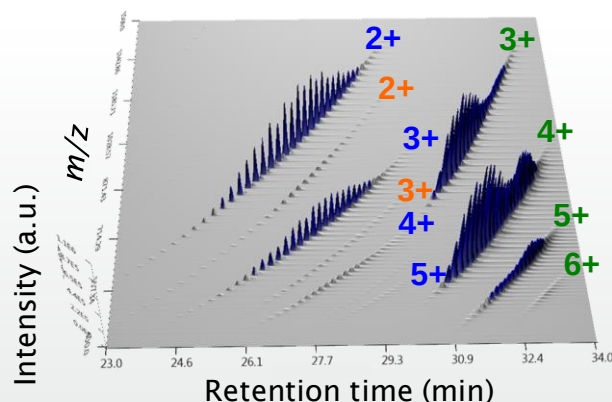
- Dispersity ($\mathcal{D}$) and impurities compromise the final formulation



- New methods developed using ultra-high performance supercritical fluid chromatography-mass spectrometry (UHPSFC-MS)

Characterisation

- UHPSFC separates PEGs based on:
 - the individual units (oligomers)
 - the end groups (R_1 , R_2)
- +ve ion electrospray ionisation produces multiply charged PEGs



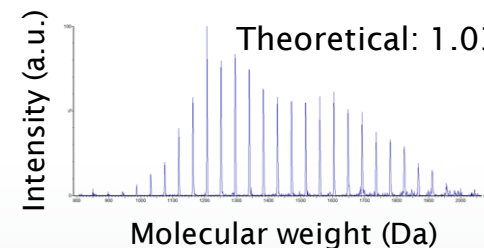
- Data visualisation using ion maps unlocks complexity
 - PEG 1: R_1 : CH_2COOH , R_2 : CH_3
 - PEG 2: R_1 : CH_2COOH , R_2 : CH_2COOH
 - Impurity revealed: R_1 : CH_3 , R_2 : H

Results

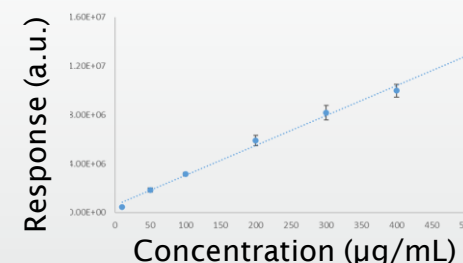
- Algorithm used to deconvolute the charge states to obtain:

-PEG 1450 $\mathcal{D}$: Calculated: 1.02

Theoretical: 1.03



- a calibration curve



Summary

- UHPSFC-MS is the technique of choice for characterisation and quantitation of PEG impurities