

Analysis of Residual Free Polyethylene Glycol and Additives Contained in Biopharmaceuticals Using a Charged Aerosol Detector

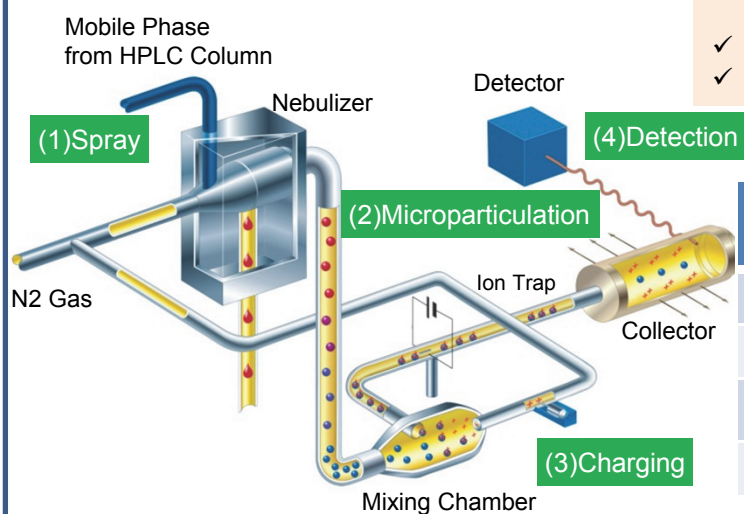
C-5

The charged aerosol detector (CAD) can detect the compounds that have no absorption on ultraviolet rays. Since the sensitivity of the detector depends on the weight concentration of the analyte concerned, the detected peak responses can be directly compared among different compounds. Using CAD, we analyzed residual free polyethylene glycol (PEG) and additive polysorbate, monitoring of which is needed in the development of modified biopharmaceuticals.

Mechanism and Feature of Charged Aerosol Detector (CAD)

As a detector of high-performance liquid chromatography...

- ✓ Compounds without any absorption on ultraviolet rays can be detected.
- ✓ The sensitivity does not depend on the chemical structure of analyte compounds.
- ✓ More sensitive than RI¹⁾ and ELSD²⁾
- ✓ Gradient elution is applicable.



Comparison among detectors

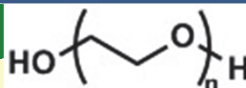
	Sensitivity (g)	Selectivity	Dynamic range	Gradient elution
CAD	10 ⁻⁹	No	10 ⁴	Applicable
RI ¹⁾	10 ⁻⁷	No	10 ³	N/A
ELSD ²⁾	10 ⁻⁸	No	10 ³	N/A
UV	10 ⁻¹¹	Yes	10 ⁴	N/A

- 1) Refractive Index Detector
2) Evaporative Light Scattering Detector

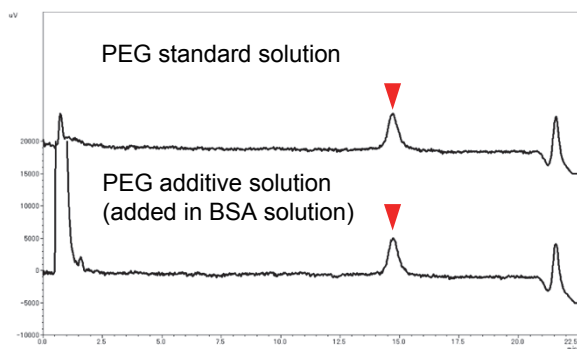
Reference: CHROMATOGRAPHY, Vol 32, 161 (2011), JIS K 0124.

Application Data

Polyethylene glycol (PEG)

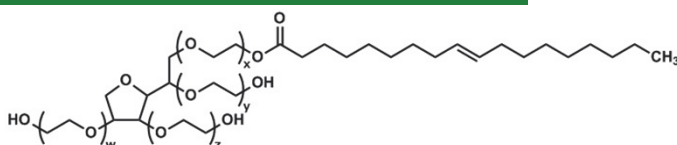


- PEG is bound to biopharmaceuticals for decreasing immunogenicity and improving pharmacokinetics.
- PEG is bound to liposome surface for improving the stability of liposome preparations.
- Free (unbound) PEG should be monitored in the stability testing

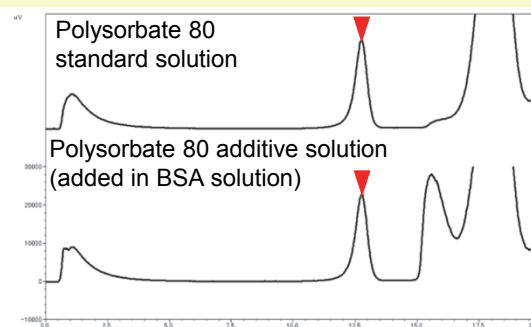


Chromatograms of PEG standard solution and PEG additive solution.

Polysorbate 80



- Polysorbate 80 is a typical nonionic surfactant.
- Polysorbate 80 is added to biopharmaceuticals as the stabilizer to prevent proteins from aggregating.
- Polysorbate 80 is also used as a solubilizer or emulsifier for insoluble drug substances.



Chromatograms of Polysorbate 80 standard solution and Polysorbate 80 additive solution.