MonoSelect nPEC

Rapid Evaluation of Encapsulation Efficiency of Small Molecule Compounds in Nanoparticles!

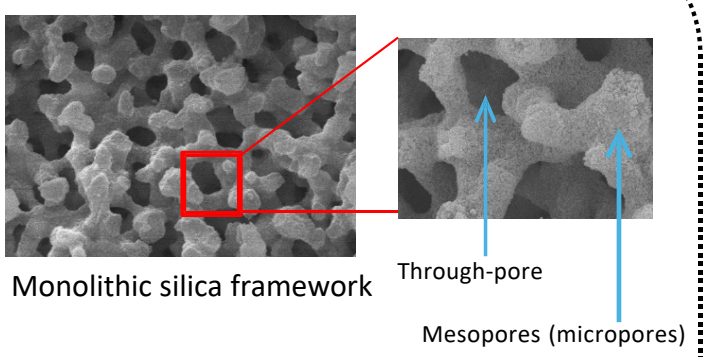
MonoSelect nPEC is a HPLC column capable of separating nanoparticles and free small-molecule compounds in a short time by Nanoparticle Exclusion Chromatography (nPEC) method* proposed by Prof. Kato and colleagues at Showa University.

In recent years' research and development of nanoparticle-based formulations (nanomedicine), such as liposomal formulations, has been increased. Evaluation of encapsulation efficiency (EE) is considered essential in quality control of nanomedicine, and it is required to determine encapsulated drugs and free drugs contained in the formulations. Until now, the technique of separating nanomedicine from free drug by ultracentrifugation has been mainly used. However, this method took more than 1 hour before the EE was finally calculated after sampling. Therefore it was difficult to use this method, particularly for in-process control (IPC) the manufacturing method develop of the drug product. Since the particle size of nanomedicine is as large as 100 nm, it has been difficult to analyze samples by direct injection into common particle-packed HPLC columns due to the problems of separations performance and durability. Therefore, in MonoSelect nPEC, monolithic silica which has large through-pore were selected as the substrate. We recommend to use MonoSelect nPEC as a new method for assessing the EE of small-molecule compounds in nanoparticles.

Feature

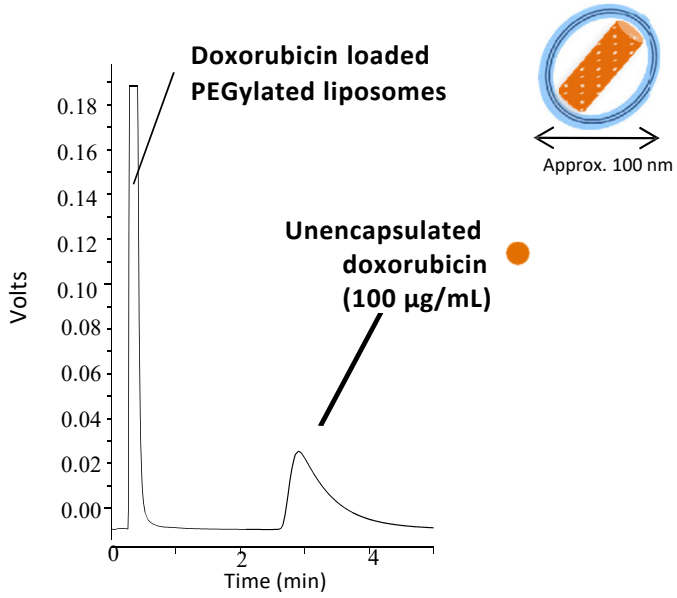
- Compared with the method using ultracentrifugation, EE can be measured in a shorter time, so it is also suitable for IPC in the investigation stage of the manufacturing method of the drug product.
- The process of dilution and preparing the supernatant can be omitted, thus reducing human errors.

■ Superiority of Monolithic Silica Columns



The presence of this through-pore allows nanoparticles as large as 100 nm to pass without clogging.
In addition, the presence of nm-order mesopores (micropores) within the silica framework enables efficient retention and separation of small-molecule compounds. For these reasons, monolithic silica are considered to be the best substrate for the analysis of nanomedicines.

■ A Representative Chromatogram



Conditions

Eluent	:A) 50 mM Na_2SO_4 in 20 mM Acetate Buffer (pH4.6) B) CH_3OH A/B = 95/5, v/v
Flow rate	1.0 mL/min
Column Temp.	: 30 ℃
Detection	: 254 nm
Injection	: 5 µL

【Specification】

Silica	: Highly pure monolithic silica
Through-pore size	: 1 µm
Meso-pore size	: 110 Å (11 nm)
Surface area	: 340 m^2/g
Bounded phase	: Hydrophilic polymer
Max. operating temp.	: 50 ℃
Max. operating pressure	: 40 MPa (400 bar)
pH range	: 2 -7.5

【Reference】

N. Itoh, *et.al.*, *J. Chromatogr. A,* **1484**, 34–40 (2017).
A. Kimoto, *et.al.*, *Chem. Pharm. Bull.,* **65**, 945–949 (2017).
E. Yamamoto, *et. al.*, *Int. J. Pharmaceut.,* **536**, 21-28 (2018).

Note 1) Since this product is shipped in a dry state, it is necessary to remove air after assembling the column.
Please refer to the accompanying instructions on how to operate for details.

MonoSelect nPEC set (Holder+Cartridge)

Description	I.D. (mm)	Length (mm)	Cat.No.
MonoSelect nPEC sets	3.0	50	5020-10816

Note 2) Two packing for cartridges are attached to the cartridge.
Note 3) The joint type is parker type (UP type).

MonoSelect nPEC Cartridge

Description	I.D. (mm)	Length (mm)	Cat.No.
MonoSelect nPEC Cartridge	3.0	50	5020-10817

Note 4) Two packing for cartridges are attached to the cartridge.

MonoSelect nPEC Cartridge

Description	Qty.	Cat.No.
MonoSelect nPEC Packing	6 pcs	5020-10880

※ This product is developed in collaboration with Dr. Kato, School of Pharmacy, Showa University, and Eisai Co., Ltd.

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