Characterization of Doxorubicin Liposome Formulation by Novel In Vitro Release Test Methodology Using Column-Switching HPLC

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Purpose
To develop a novel in vitro release test methodology for liposome formulation using a column-switching HPLC system.

Methods
Doxorubicin (DXR) liposome formulation was used as a model. A DXR liposome formulation was dispersed into a release medium, and the dispersion fluid was injected directly at predetermined time points into the column-switching HPLC system. To evaluate the release profile, this system can be used for determining the released and encapsulated DXR in the liposome formulation separately.

Results
Comparison with a conventional in vitro release test methodology by dialysis revealed that the methodology developed by column-switching HPLC had no rate-limiting process of membrane permeation of drug, which is occasionally observed in dialysis method. In vitro release profiles of DXR liposome formulations were well characterized using the method developed by column-switching HPLC, and different in vitro release characteristics were revealed.

Conclusion
The developed method did not require a large amount of sample or complicated pretreatment. In addition, the developed column-switching HPLC system was applicable for characterization of the encapsulation profile of liposome formulations.