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**Estimation of the critical quality attributes for hydroxypropyl methylcellulose  
with near-infrared spectroscopy and chemometrics**

Qingli Guo<sup>a</sup>, Lei Nie<sup>b</sup>, Lian Li<sup>a</sup>, Hengchang Zang<sup>a,\*</sup>

<sup>a</sup>School of Pharmaceutical Sciences and National Glycoengineering Research Center,  
Shandong University, Wenhuxi Road 44, Jinan, 250012, China

<sup>b</sup>School of Pharmaceutical Sciences, Shandong University, Wenhuxi Road 44, Jinan,  
250012, China

**Abstract**

With the implementation of quality by design (QbD), critical attributes of raw material (drug substance and excipients) are of significantly importance in pharmaceutical manufacturing process. It is desirable for the quality control of critical material attributes (CMAs) of excipients to ensure the quality of end product. This paper explored the feasibility of an at-line method for the quantitative analysis of hydroxypropoxy group in hydroxypropyl methylcellulose (HPMC) with near infrared spectroscopy (NIRS). Hydroxypropoxy group content can be seen as a CMA of HPMC for quality control. The partial least squares (PLS) model was built with 61 samples including 47 samples as calibration set, 14 samples as validation set by sample set partitioning based on joint  $x$ - $y$  distances (SPXY) method. Multiplicative scattering correction (MSC) combined with Savitzky-Golay (SG) smoothing with first derivative was used as the appropriate pretreatment method. Three variable selection methods including interval partial least-squares (iPLS), competitive adaptive reweighted Sampling (CARS), and the combination of the two methods (iPLS-CARS) were performed for optimizing the model. The results indicated that NIRS could predict rapidly and effectively the content of hydroxypropoxy group in HPMC. NIRS could be a potential method for the quality control of CMAs.

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\*Corresponding author. Address: School of Pharmaceutical Sciences, Shandong University, China. Tel./fax: +86 531 88380268.  
E-mail address: zanghcw@126.com (H. Zang).

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