# The Influence of HPMC Viscosity and %HPC Content as FRC Parameter on the Release of Highly Soluble Drug from Hydrophilic Matrix Tablets

**Himankar Baishya*, Zhou Yangxing, Wangshengmin and Lin Shao Hui**

Department of Formulation Development, Beijing Sciecure Pharmaceuticals Co., Ltd., Beijing, China 101301

***Corresponding author:** Himankar Baishya, Senior Director, Research and Development Department, Beijing Sciecure Pharmaceuticals Co., Ltd., North Shi Zhen in the North industrial area, Shunyi district, Beijing, China-101301, Tel: +861060447688/ 8356; E-mail: himankar@sciecure.com

## 1. Abstract

Extended-Release modified dosage forms of Niacin were prepared using Hypromellose as rate controlling polymer. Previous studies have shown that hypromellose viscosity, hydroxypropoxyl content (%HP) and particle size are important material attributes that may impact the performance of ER matrix tablets, depending on the drug solubility and formulations. The aim of this study was to further examine the influence of critical material attributes (CMA) of hypromellose on granular parameters viz., Compressibility index and particle size distribution and in vitro drug release profiles from extended release (ER) hydrophilic matrix tablets containing Niacin, as a soluble model drug. Quality by Design (QbD) samples of Hypromellose K15M and Hypromellose K100M was used as the rate controlling polymer, at various levels, and the impact on the performance of ER matrices investigated. A $2^2$ factorial design was used for evaluation**.** The evaluated QbD samples of HPMC K15M and K100M differ significantly in terms of viscosity and % HPC within the supplier specification range. However there were no significant differences observed in the granules parameter and drug release profile. It can be concluded that batch-to-batch variation in viscosity and % HPC of the same HPMC grade had no significant effect on the Critical quality attributes of the product.

Hence, it was not required to postulate specification limits for viscosity and % HPC during the development stage. However, this conclusion cannot be generalized, because it is different for different tablet compositions.

**2. Keywords:** Functionality-related characteristics (FRC); Hydroxypropyl methylcellulose (HPMC); Apparent viscosity; Degree of substitution for Hydroxypropyl content; Dissolution testing