Analytical Method Validation (AMV) of Paracetamol Honey Suspension

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Introduction: Paracetamol (PCM) suspension that is available in the market is formulated with high sugar content and more than 7 excipients to stabilise and to mask the bitter taste of PCM suspension. This oral suspension is indicated to alleviate minor ailments and fever, especially in a paediatric patient and elderly patient which having difficulty in swallowing. However, the high sugar content of PCM suspension may lead to a lot of health problems and make it PCM suspension no longer suitable is for the long term. Therefore, the formulated PCM honey suspension could be treated as an alternative approach instead of existing commercial one. Methods: The usage of honey for replacing the sucrose and sorbitol in PCM suspension is the main concern of this study. Results: In these contexts, the accurate and specific instrument which is High-Performance Liquid Chromatography (HPLC) can be used to validate PCM honey suspension based on the requirement stated under ICH Q2 (R1). Conclusions: Thus, it could be concluded that the proposed analytical method could be a precise and specific one to be used in accordance with the purpose of validation of PCM honey suspension.

KEYWORDS: PCM honey suspension; HPLC; Analytical Method Validation (AMV)