**White Paper: Evaluation of hydrogen as a carrier gas in the analysis of residual solvents in pharmaceuticals by HS-GC-MS**

**Introduction**

Residual solvents and organic volatile impurities (OVIs) in pharmaceuticals can result from the manufacturing process of the active pharmaceutical ingredients (API) and the final product. The level of residual solvents can also be affected by the packaging, storage and transportation of pharmaceutical products. All drug substances, excipients and drug products must be monitored and controlled for safety, their effect on crystalline form, solubility and stability1.

One of the most common methods used is the United States Pharmacopeia (USP) Method <467> which closely follows the International Conference on Harmonisation (ICH) Q3C guideline Q3C (R6) on impurities: guideline for residual solvents2. Residual solvents have been classified by the ICH into three main classes based on their risk:

* Class 1: solvents are considered hazardous and should be avoided in the manufacturing process due to toxicity or environmental impact.
* Class 2: solvents should be limited in their use due to potential toxicity.
* Class 3: solvents are considered less toxic and pose a lower risk to human health.

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