EUREKA

partner GBA GROUP

RESIDUAL SOLVENTS (OVI OR VOC) ANALYSIS

Residual solvent (RS) and organic volatile impurities (OVI) identification and quantification in pharmaceutical drug substances, excipients and products

Solvents used in the manufacture of active pharmaceutical ingredients (APIs) and excipients or in the formulation of drug products are often necessary. Control of residual solvents in the finished drug product is required by various regulatory agencies worldwide, as they provide no therapeutic benefit and may possibly be harmful.

There are many solvents that may be employed in the manufacture of pharmaceutical materials. ICH guideline Q3C (R5) and USP chapter <467> provide permissible daily exposure (PDE) for some of the commonly used solvents. USP <467> and Ph. Eur. 5.4 provide analytical methods for the analysis of the commonly used solvents. If a solvent other than those listed in the ICH Q3C (R5) or USP <467> is utilized in the manufacture of a pharmaceutical article then the onus falls on the drug product manufacturer to determine the acceptable PDE and establish a suitable analytical procedure for the control of that solvent. We provide expert determination and identification of residual solvents in pharmaceutical articles, helping customers to ensure the residual solvents have been reduced to acceptable levels in drug products, drug substances and excipients. Often it is prudent to ensure residual solvents are controlled for all excipients and the drug substance(s) in order to ensure that the finished product will meet the limits specified in ICH Q3C(R5) or USP <467> or the limit established by the drug product manufacturer for unique solvent(s).

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Our pharmaceutical analysis experts conduct residual solvent method validation which conforms to ICH Q2 (R1) guidelines on validation of analytical procedures. Bringing quality and safety to life, we offer Total Quality Assurance expertise to help you to meet and exceed quality, safety and regulatory standards. As a trusted provider of residual solvents determination from our network of GMP laboratories, we offer you extensive expertise for pharmaceutical impurity analysis, underpinned by with a broad range of analytical techniques to suit your particular needs.

As always, **Eureka** is here to support you not only with our **sampling, testing and inspection services,** but also with **expert advice on related topics.**

Please email us for all your upcoming requirements on testing as per above values.