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Platform headspace gas chromatography method for high-throughput determination of residual solvents in pharmaceutical materials

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Abstract:

Static headspace capillary gas chromatography (HSGC) has been employed to monitor the level of residual solvents in the pharmaceutical materials. Most of the HSGC methods, however, consume significant amounts of diluents and require considerable amount of sample preparation time. Accordingly, a HSGC method featured with fast turnaround time, and minimal amount of solvent use has been developed for the quantitative analysis of 27 residual solvents frequently used in the development and manufacturing processes of pharmaceutical industry. This HSGC-FID method employs a commercially available fused silica capillary column, a split injection (40:1), and a programmed temperature ramp. It was qualified for specificity, accuracy, repeatability/precision, linearity, LOQ, solution stability, and robustness using two representative sample matrices. The standards, samples and spiked samples were demonstrated to be stable for at least 10 days at room temperature in sealed headspace vials with a recovery of $\geq 93\%$. The method was also shown to be robust, and its performance was not affected by small changes of carrier gas flow rate, initial oven temperature or the headspace oven temperature. In this new approach, the analytical sample was prepared by dissolving the sample into 1 mL of the diluent and the standard solution was prepared by diluting 1 mL of the custom-made stock into 9 mL of the diluent whereas the traditional approach requires liters of the diluent, making the new approach environmentally friendly, sustainable, economical, agile, error-proofing and thus appropriate for a variety of pharmaceutical applications

Biography:

Xun Guo has completed his PhD from Brown University and postdoctoral studies from Yale University Department of Chemical Biology. He is the senior scientist of Biogen Inc., a biopharmaceutical company. He has published more than 20 papers in reputed journals and has been serving as a reviewer for various journals in chemical and pharmaceutical space.

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