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Organic Volatile Impurities in Citicholine Sodium : A Robust Analytical Method Development and Validation by Head Space Gas Chromatography

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Abstract : The Active Pharmaceutical Ingredients (APIs) is an ingredient in a pharmaceutical drugs that is biologically active which are basically drug Substance and gives therapeutic benefit. These drug substances are used as bulk active in the manufacturing of medicines. There are process solvents which includes Methanol and Isopropylalcohol (IPA) which are basically Organic Volatile Impurities (OVI) used during the manufacturing process. It is very difficult to remove these solvents completely by the work-up process. It is mandatory for the pharmaceutical manufacturers to identify and qualify if any such impurities are present in APIs. To identify and control these solvents Gas Chromatography - Head Space (GC-HS) method was developed. The method was validated as per International conference on harmonization guidelines (ICH) & United States Pharmacopoeia (USP).

Key Words : Citicholine Sodium, OVI, Residual solvents, GC.

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