

## Trace level determination of t-butyl alcohol and t-butyl chloride by GC in dolasetron mesylate

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We herein report the trace level determination of t-butyl alcohol and t-butyl chloride by GC of dolasetron mesylate using a DB-502 column. This method was developed based on an oven programming approach using a nitrogen gas as the mobile phase. The detection limit for the t-butyl alcohol and t-butyl chloride using our developed method was 1.5 ppm. The quantification limit for the t-butyl alcohol and t-butyl chloride using our developed method was 4.5 ppm respectively. Our method is also compatible with the GC-MS (mass spectrometry) technique using helium gas mobile phase instead of nitrogen gas. The successful separation of t-butyl alcohol and t-butyl chloride were confirmed by determination of their corresponding specific molecular masses. We expect that our method will be applicable for the trace level determination of t-butyl alcohol and t-butyl chloride during the control of manufacturing processes, and for use in rapid analysis for quality control in the pharmaceutical industry. Finally, this method was validated according to the International Council on Harmonization Validation Guidelines Q2 (R1).

Keywords: GC, DB-502, t-butyl alcohol, t-butyl chloride, GC-MS.