

STRUCTURE DETERMINATION OF IMPURITY IN MEMANTINE HYDROCHLORIDE BY ANALYTICAL TECHNIQUES

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ABSTRACT

Impurity related to the synthesis of pharmaceutical ingredient Memantine hydrochloride bulk drug was detected by GC and was subjected to GCMS for identification. The proposed impurity was prepared synthetically and was injected on GC for comparison of retention time with that of the unknown impurity in Memantine. The GCMS spectra of synthetically made impurity and that of process related impurity in the Memantine hydrochloride were found to be the similar. The postulated structure was unambiguously confirmed with the help of NMR and IR analysis. Based on GCMS, NMR and IR data the structure of the impurity was proposed to be 1,3-diacetamido-5,7-dimethyl Tricyclo decane (Diacetamido impurity). This impurity which was elucidated was not found to be previously reported in any synthetic or analytical literature pertaining to Memantine hydrochloride.

KEYWORDS: Memantine Hydrochloride, Impurity, GC, GCMS, NMR, IR Structural Elucidation