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Development and characterisation of process related impurity in Hydralazine Hydrochloride by some analytical technique

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ABSTRACT

The unknown impurity associated with the synthesis of Hydralazine hydrochloride bulk drug were detected by high performance liquid chromatography and were subjected to high resolution accurate liquid chromatography mass spectroscopy for identification. The proposed impurities were isolated from Hydralazine hydrochloride active pharmaceutical ingredient by preparative chromatographic method and were injected on HPLC for comparison of retention time with that of the unknown process related impurity in Hydralazine hydrochloride. The molecular ion peak of preparatively isolated impurity and that of unknown process related impurity in Hydralazine hydrochloride were compared for confirmation. The structure were determined and confirmed with the help of some analytical techniques. This impurity of Hydralazine hydrochloride is not been previously reported. A rapid Acquity H-class gradient method with runtime of 12.0 min was developed for Quantitation on Unisphere Cyno column and validated for parameters such as accuracy, precision, linearity and range, robustness. The LOD and LOQ of method were 0.081% and 0.0246% respectively.

Keywords: Acquity UPLC H-class, Hydralazine hydrochloride, HR/AM-LCMS, NMR.