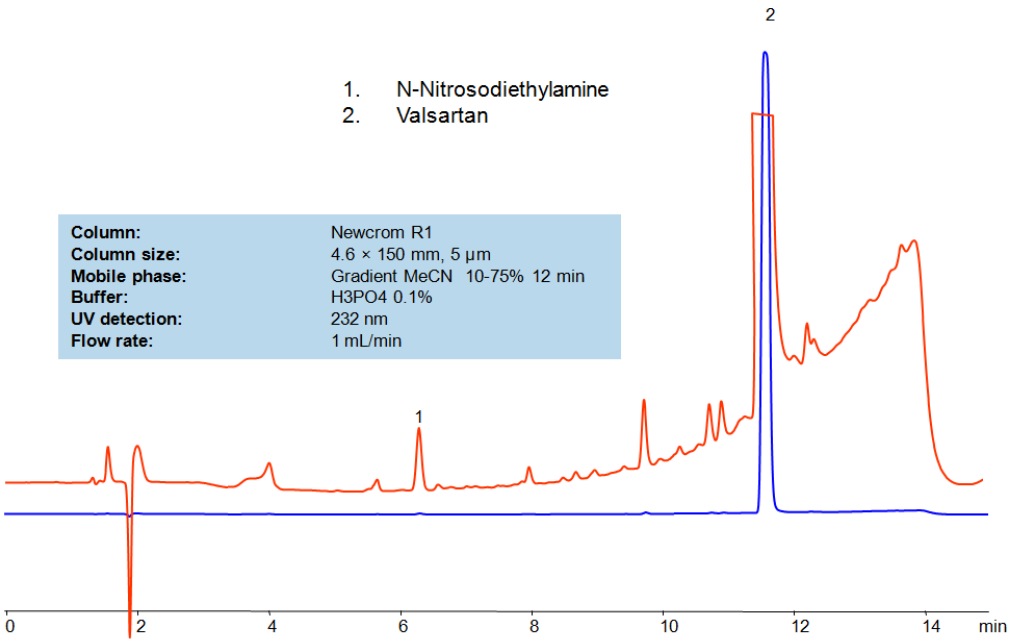
HPLC Method for Detection of NDEA in Valsartan Drug Substance



High Performance Liquid Chromatography (HPLC) Method for Analysis of Valsartan , N-Nitrosodiethylamine

Valsartan products are used to treat high blood pressure and congestive heart failure. On July 13, 2018, FDA announced a recall of valsartan tablets because of the potential for certain products to contain an impurity, N-nitrosodimethylamine (NDMA). Nitrosamine impurities is classified as a probable human carcinogen and is believed to have been introduced into the finished products as a result of the manufacturing process of the drug substance.

SIELC developed simple and fast HPLC method to measure presence of NDEA in drug formulations. This UV based method allows to detect ppb level of the compound in solution. Simple mobile phase comprised of acetonitrile (MeCN) and water with detection at 232 nm using Newcrom R1 column can be used to detect both the API and the NDEA.

Method Parameters

Column	Newcrom R1, 4.6 x 150 mm, 5 µm, 100 Å, dual ended
Mobile Phase	Gradient MeCN – 10-75%, 12 min
Buffer	H3PO4- 0.1%
Flow Rate	1.0 mL/min
Detection	UV, 232 nm

Quelle: https://sielc.com/hplc-method-for-detection-of-ndma-in-valsartan-drug-substance