

Nitrosamine Impurity Assay with HPLC – Extended AppNote

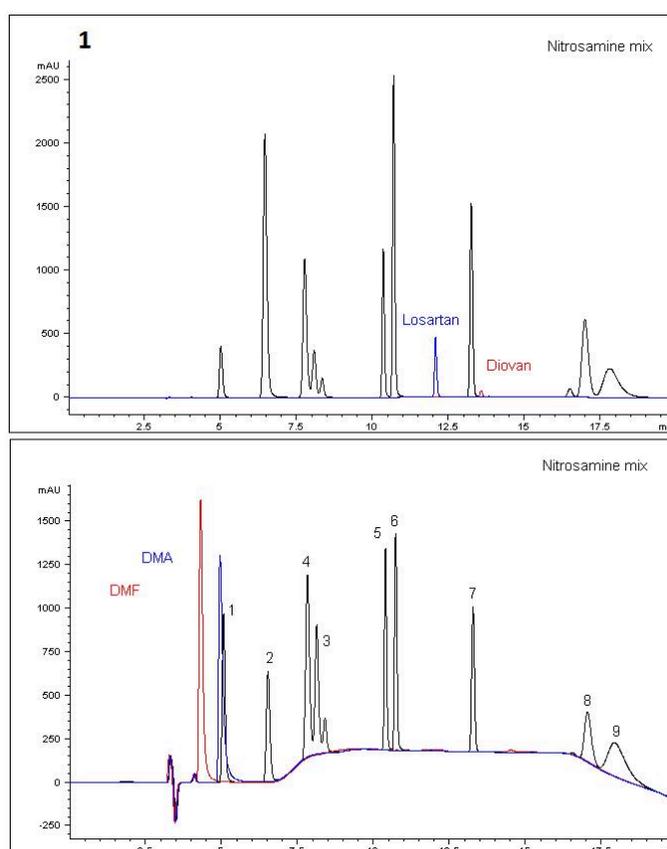
API or Impurity Assay Methods for Sartan Drugs

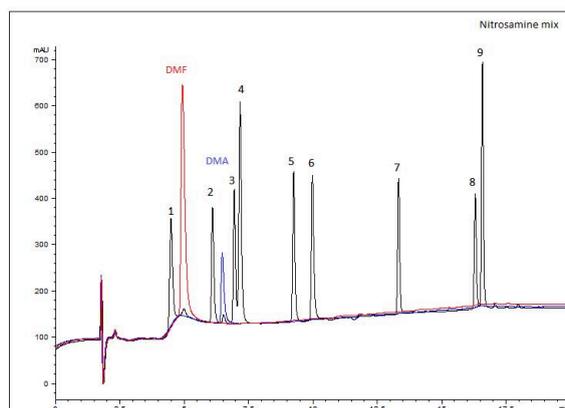
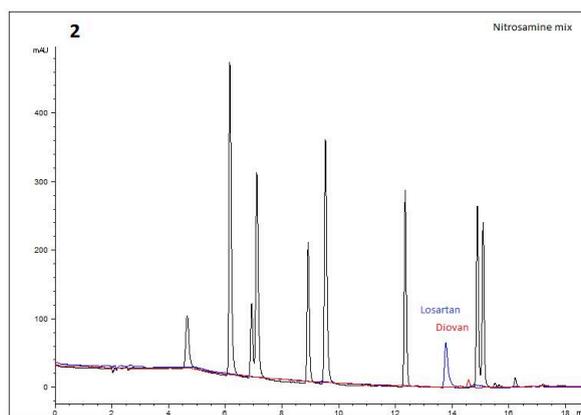
Nitrosamines are highly toxic and are suspected to be a human carcinogen. At high doses, some have been shown to be a hepatotoxin that causes liver fibrosis and cancer in several animal species. Due to the toxic nature of Nitrosamines, these compounds must be monitored using reliable Methods.

In this Extended AppNote, we present two HPLC Methods with UV detection for the simultaneous detection of nine Nitrosamine Impurities, two solvents used in the manufacturing processes, and several medications of importance. The nine Nitrosamine Impurities (NDMA, NMor, NMEA, NPyr, NDEA, NPip, NDPA, NDPA, NDPHA) are separated from other pharmaceutical compounds of interest. (Figure 1 and 2.)

Two solvents, Dimethylformamide (DMF) and Dimethylacetamide (DMA) are commonly used in manufacturing processes of Sartan drugs. Residual amounts of these solvents are important to detect in both raw processes and final drug products. Currently, no published data exists for separation of all nine Nitrosamine Impurities and solvents: DMF and DMA.

Click [Download File Below](#) for Full Study Conditions.





Peaks:

Peak Number	Abbreviation	Chemical name
1	NDMA	N-Nitrosodimethylamine
2	NMor	N-Nitrosomorpholine
3	NMEA	N-Nitrosomethylethylamine
4	Npyr	N-Nitrosopyrrolidine
5	NDEA	N-Nitrosodiethylamine
6	NPIP	N-Nitrosopiperidine
7	NDPA	N-Nitrosodi-n-propylamine
8	NDBA	N-Nitrosodi-n-butylamine
9	NDPHA	N-Nitrosodiphenylamine

Met hod Conditions:

Chromatogram 1: Cogent RP C18™, 3 um, 100 Å

Catalog No.: [68318-15P](#)

Chromatogram 2: Cogent Bidentate C18™, 4 um, 100 Å

Catalog No.: [40018-15P](#)

Dimensions: 4.6 x 150 (for both Columns)

Mobile Phase:

- A: DI water and 0.1% Formic Acid
- B: Acetonitrile + 0.1% Formic Acid

Injection vol.: 1 μ L

Detection: UV @ 254nm and 220 nm

Sample Preparation: Nitrosamine standard solution and Sartan Drug mixtures prepared as 1.0 mg/mL in Methanol

Note 1: *Angiotensin receptor blockers (ARBs) are a class of medicines that is used to treat high blood pressure (also known as hypertension). These ARBs work by blocking receptors that the hormone acts on, specifically AT1 receptors, which are found in the heart, blood vessels and kidneys. Blocking the action of angiotensin II helps to lower blood pressure and prevent damage to the heart and kidneys. These medicines typically have names that end in 'sartan'. Some of these sartan drug brands are valsartan, irbesartan, candesartan, losartan and olmesartan.*



Attachment Nitrosamine Impurity Assay with HPLC – AppNote [Download File](#)

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