Sartan Drugs Have Been Deemed in Shortage by the FDA

The US Food and Drug Administration (FDA) is warning that there is a shortage of drugs that is used by millions to treat high blood pressure. The drugs known as ARBs, or angiotensin II receptor blockers, contain valsartan, or sartan. However, the FDA also believes that other similar products will start to fall into a shortage soon.

N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) are Class 2A carcinogens that have been found to be present as impurities in several different generic drug substances and drug products. NDMA is highly toxic and is a known carcinogen in lab animals, and along with NDEA has been classified as a probable human carcinogen. Accurate identification and quantification of these impurities is essential to assure quality and safety of the drug substance and drug product.

Valsartan and other related sartan medicines are used to treat patients with hypertension (high blood pressure), and those with heart failure or who have had a recent heart attack. Sartans work by blocking the action of angiotensin II, a hormone that constricts blood vessels and causes blood pressure to rise.

The FDA issued a recall for several drug products containing Valsartan, due to the potential presence of the impurities NDMA and NDEA. The European Medicines Agency (EMA) also acted quickly to ban the importation of Sartans from certain manufacturers in China and India after these impurities were found to be present. All this attention has also resulted in additional products being voluntary recalled by the manufacturers for drug products containing other sartans (Irbesartan and Lorsartan).
NDMA and NDEA are not expected impurities and are believed to have been introduced into the drug products because of the specific sequence of manufacturing steps and chemical reactions used to make the drug substance; the specific source of these impurities is still under investigation.

To learn more about the analysis of NDMA and NDEA in sartan drugs and drug products check out our technical application below. Our scientists conducted the analysis by GC-MS on a Zebron ZB-624PLUS. Click the following link or the image below: http://bit.ly/2UdhqhG
Sartan Drugs Have Been Deemed in Shortage by the FDA

to check out “Biosimilars, Generic Drugs, and the Pharmaceutical Industry.”

Biosimilars, Generic Drugs, and the Pharmaceutical Industry

Share with friends and coworkers:

- Click to email this to a friend (Opens in new window)
- Click to share on Twitter (Opens in new window)
- Click to share on Facebook (Opens in new window)
- Click to share on Pinterest (Opens in new window)
- Click to share on LinkedIn (Opens in new window)
- Click to share on Tumblr (Opens in new window)
- Click to share on Reddit (Opens in new window)