Divi's Laboratories Limited

Date: 15th September, 2018

DECLARATION

Product : **Valsartan API**

Subject : **"N-Nitrosodimethylamine (NDMA) / N-Nitrosodiethylamine (NDEA) / Other Nitroso" impurities formation in VALSARTAN API**

Divi's Laboratories Limited has reviewed the filed process with USDMF (DMF No# 024797). From the review of the route and scheme of synthesis, it is confirmed that there is no risk for the formation of NDMA / NDEA / Other Nitroso impurities in Divi's route of synthesis. NDMA / NDEA / Other Nitroso impurities cannot be formed due to the following reasons:

1. Divi's is *not* using 'Sodium Nitrite' in the process.
2. The tetrazole formation step in Valsartan is carried out in *'Basic pH'* condition

Divi's has tested 3 batches of Valsartan samples by a suitable test method and the results reported for NDMA impurity are "Not detected".

Hence, we confirm that there is no possibility of for the formation/presence of NDMA / NDEA / Other Nitroso impurities in Valsartan API supplied by Divi's.

D. Pradyumna 15 September 2018

D. Pradyumna
Deputy General Manager – QA & RA
Divi's Laboratories Limited, Unit-2.

FACTORY : Unit-2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh-531 162, INDIA.
Ph. : +91-8922-248911, Fax : +91-8922-248922.
CORPORATE OFFICE : 1-72/23(P) / Divis / 303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad-500 032, Telangana, India. CIN : L24110TG1990PLC011854
Ph. : +91-40-23786300, 23786400, Fax : +91-40-23786460, E-mail : mail@divislaboratories.com, Website : www.divislaboratories.com