



Harman Finochem Limited

Recognized TRADING HOUSE

REGD. OFFICE: 107-A, VINAY BHAVYA COMPLEX, 159 A, C.S.T. ROAD, KALINA, SANTACRUZ (E.), MUMBAI 400 098. INDIA.

TEL.: (+91 22) 6733 0100 / 2652 8080. FAX: (+91 22) 2652 8285

Email : info@harmanfinochem.com

Website : www.harmanfinochem.com

Date: June 27, 2020

TSE/BSE STATEMENT

We **Harman Finochem Limited**, herewith confirm that our API **Metformin Hydrochloride** is manufactured at Plot No. A-100, A-100/1, A-100/2 & D-1, M.I.D.C. Industrial Area, Shendra, Aurangabad – 431 007, Maharashtra, India by using raw materials which are not of human or animal origin. No fermentation and cell culture steps are involved during production.

Furthermore, the above mentioned API is not contaminated by substances of animal origin or products produced from those, in the course of manufacture, storage and transportation.

On the basis of this statement our product meets the TSE/BSE requirements of Note for guidance 'TGA Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (TSEs), December 2004' and 'European Commission Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 rev.3, March 2011)' for details in relation to TSE/BSE., and our API is free from TSE/BSE contamination.

For **Harman Finochem Limited**,

{*See Electronic signature below*}

Rakesh Nunna

Junior Manager – Regulatory Affairs

Email: rakesh@harmanfinochem.com