



Seminar On 'Impurity Profile: Drug Substance, Excipients and Drug Product'

**HOTEL RADISSON, MIDC CENTRAL ROAD, ANDHERI (EAST), MUMBAI
9.30 AM TO 5.00 PM TUESDAY, 23RD OCTOBER 2018**

SCHEDULE	TOPICS	SPEAKERS
9.00 am – 9.30am	Registration – Tea/Coffee	
Inaugural Session		
9.30 am -9.40am	Welcome Address (Facilitator) – Mr. Daara B. Patel , <i>Secretary-General, IDMA</i>	
9.40 am – 9.50 am	Setting the Tone	Mr. J. L. Sipahimalani , <i>Quality Management & Technical Committee, IDMA & APA</i>
9.50 am – 10.05 am	Keynote Speaker	Mr. P B N Prasad , <i>Deputy Drugs Controller, West Zone, CDSCO</i>
10.05 am – 10.20 am	Guest of Honour	Mr. O. S. Sadhwani , <i>Ex Joint Commissioner, FDA Maharashtra</i>
10.20 am – 10.40 am	Chief Guest	Dr. Sanjit Singh Lamba,** <i>Managing Director, Eisai Pharmaceuticals</i>
10.40 am – 10.50 am	Vote of Thanks	Mr. B R S Rao , <i>Chromochemie Laboratory Pvt. Ltd</i>
10.50 am – 11.05 am	Tea/ Coffee Break	
Technical Session – Facilitator Dr. Milind Joshi, <i>President, Global Regulatory Management, J. B. Chemicals & Pharmaceuticals Ltd.</i>		
11.05 am – 11.45 am	Forced Degradation and Impurity Profiling	Dr. P L Sahu , <i>Scientific Director, National Dope Testing Laboratory (NDTL)</i>
11.45 am – 12.45 pm	Impurity Standards & Characterization	Dr. Malladi Srinivas , <i>Chief Scientific Officer, Chromochemie Laboratory Pvt Ltd.</i> Dr. Sakthivel C , <i>Chromochemie Laboratory Pvt Ltd.</i>
12.45 pm – 1.45 pm	Networking Lunch	
1.45 pm - 2.25 pm	New Initiatives for Custom Synthesis for Impurities	Dr. Sanath Kumar Goud , <i>Associate Director, USP India (P) Ltd</i>
2.25 pm -3.05p m	Justification of Impurity Limits	Dr. Subramanian Iyer , <i>Head of OSD Quality – India R&D Mylan Pharmaceuticals Pvt. Ltd</i>
3.05 pm - 3.45 pm	Approaches and understanding of Genotoxic impurities in Drug Substance, Excipients and Drug Product	Mr. Rahul Gupta , <i>Vice President-Regulatory Affairs, USV Pvt. Ltd.</i>
3.45 pm – 4.00 pm	Tea/ Coffee Break	
4.00 pm – 4.40 pm	Current Challenges in Drug Product Impurity Profiles – Drug Excipients Interactions	Dr. Nandkumar Bhilare , <i>Director – Pharma Research Analytical, Lupin Ltd.</i>
4.40 pm – 5.15 pm	Panel Discussion Moderator : Ms. Meena Shah , <i>Consultant, Regulatory Affairs</i>	
5.15 pm – 5.25 pm	Summing up & Vote of Thanks	Dr. Milind Joshi , <i>President, Global Regulatory Management, J. B. Chemicals & Pharmaceuticals Ltd.</i>

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