

ONE DAY SYMPOSIUM

DISSOLUTION SCIENCE & TECHNOLOGY

DATE: 12TH DECEMBER 2024

TIME: 9:30AM TO 5:30PM

VENUE: PRESTIGE INSTITUTE OF MANAGEMENT & RESEARCH, INDORE

AGENDA

Time	Торіс	Speaker
09.15-10.00	Inauguration	
10.00-10.20	Intro to SPDS & AIPAC	Dr L.Ramaswamy Founder & National Convenor, AIPAC Founder & Secretary General, SPDS Founder & Chairman, Sotax India
10.20-11.00	Why dissolution is so important? How it got evolved? Current Regulatory scenario & concerns.	Vijay Kshirsagar Founder President SPDS Director- TRAC Pharma Consulting, Mumbai, India
11.00-11.30	Tea Break/Stall visits/Net working	
Session I: Chair - Mr Vijay Kshirsagar		
11.30-12.00	Dissolution Chapter & Diff Types of Dissolution Apparatus as per IP including Type IV, an emerging tool .	Suhas Yewale Asso. Director- Techno Commercial, SOTAX India, Mumbai
12.00-12.35	Development of Discriminatory Dissolution Methods	Dr Rupesh Kelaskar VP, FDC Limited
12.35-13.10	Validation/Verification of Dissolution Methods	Sudhir Tomar DGM, ARD, Sun Pharma
13.10-13.30	Question & Answers related to above presentations	Chair & all the above speakers
13.30-14.30	Lunch Break Stall Visits/Net working/Live demo of USP 4	
Session II: Chair - Dr Subhash Pande		
14.30-15.10	Investigation of OOS results obtained during dissolution testing	Rajendra Dadhich Sr. VP, CQA-IPCA
15.10-15.50	Development of dissolution method for nano formulations	Dr Padma Devarajan President SPDS, Dean-Research & Innovation and Professor in Pharmacy, Institute of Chemical Technology, Mumbai
15.50-16.10	Common Deviations noticed during dissolution testing/methodology & limits	Sonalika Parashar Sr. Director - QA & Micro, Cipla
16.10-16.30	Question & Answers related to above presentations	Chair & all the above speakers
16.30-17.10	Panel Discussion / Q&A What care needs to be taken during dissolution testing? Common Flaws?	Moderator: Dr Rajiv Desai & Panellists
17.10-17.30	Tea Break/Stall visits/ Net working	



Vijay Kshirsagar

Vijay is an accomplished Quality, Regulatory & Analytical professional with > 38 yrs of rich experience of working for reputed Indian, MNC Pharma firms & later 11 years as a Global Pharma Consultant. His last stint was with Unichem as EVP responsible for CQA, Regulatory & Analytical Research. Later he formed his own Pharma consulting company called TRAC & also continued as Advisor for Unichem for 11 years. Prior to Unichem he worked for Ranbaxy, Sun, Tata-Merind, IPCA, German Remedies, Lupin & Duphar Interfran in various senior positions.



Suhas Yewale

30 Years of experience in Analytical R&D for Generic Pharma Companies like Sandoz, Glenmark, Famy Care and Par Formulations at Senior Management positions. Maharashtra State FDA Approved Chemist in "Chemicals and Instruments. Trustee & Scientific committee member of "Society For Pharmaceutical Dissolution Science (SPDS)". Currently associated with SOTAX India as "Associate Director Techno Commercial" and responsible for the USP IV application and training.



Dr Rupesh Kelaskar

Dr Rupesh is currently Vice President-Corporate QC & AR&D for both formulations & API for FDC Limited, Mumbai. He has rich and well diversified experience of over 25 years with Apotex, IVAX etc apart from FDC. Rupesh has contributed earlier too in SPDS events to spread the knowledge related to dissolution science.



Sudhir Tomar

Sudhir is currently DGM-Analytical at Sun Pharma, Gurgaon. He has > 16 years of working for companies like Ranbaxy and Sun Pharma. He is well versed with Chemical/Instrumental & Microbiological analysis apart of analytical method development & validation.



Dr Subhash Pande

Dr Subhash is a seasoned Pharma Professional with > 30 Years of Corporate experience in Strategic Pharma and Leadership roles, achieving organisational goals and objectives through superlative problem solving approach within cGMP compliance framework. He handled corporate roles like SVP-Corporate Quality for Zydus Cadila. He has also headed Quality function of Ranbaxy & Lupin.



Rajendra Dadhich

Rajendra is SVP -Corporate Quality at IPCA Laboratories, Mumbai. He is responsible for overall Quality into product, system and culture. He has a rich, well diversified experience of around 40 years, working for reputed companies like Wockhardt, Ranbaxy, Fulford, Ponds apart from IPCA.



Dr Padma Devarajan

Dr (Ms) Padma V. Devarajan is Professor in Pharmacy and ex-Head, Department of Pharmaceutical Sciences and Technology at the Institute of Chemical Technology, Mumbai, India. She is a member on the Board of Governors of ICT and Coordinator of the world Bank TEQIP programme and M.Tech Pharmaceutical Biotechnology. Her research interests include colloidal carriers for targeted delivery in cancer and infectious diseases, Veterinary Drug delivery, Bioenhancement strategies, Mucosal DDS and QbD in drug development. And, she is Current President of SPDS.



Sonalika Parashar

Sonalika is currently Sr. Director - QA & Micro (Cluster Head) at Cipla, Pithampur. She has over 23 years experience of working for reputed companies like Cipla, Ranbaxy, Glenmark, Plethico & IPCA. She has a good blend of technical skills in injectable, microbiology, QA, QC, QMS in OSD, MDI, DPI, Nasal, Liquid orals, FFS and Injectable in Regulated plants.



Dr Rajiv Desai

Dr Rajeev is former EVP-Global Quality Head of Lupin Laboratories and currently he is Senior Advisor to Indian Pharmaceutical Alliance. Experience of over 38 years in the pharmaceutical industry. Worked at top pharma multinational companies of the world. Including Alembic, Mylan, DRL, Piramal, Novartis etc. Contributed substantially in areas of Quality Management, Basic Research, Process Development, Analytical development, and Regulatory Affairs.



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See differences between formulations that apparatus 1 and 2 won't show



SOTAX CE 7smart USP apparatus 4

The Flow Through dissolution method is approved for use and accepted by the FDA and USP fo a wide range of formulations and applications including:

Small Volume Dissolution • IVIVC Studies • XR/MR Solid Dose • APIs, Powders, Granules Injectable Suspensions • Poorly Soluble Compounds • Soft Gels • Suppositories • Implants Stents • Drug Coated Medical Devices • Liposomes • Microspheres • Nanoparticles

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