MANISH KUMAR SHARMA, PhD

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SUMMARY

- 12 years of educational and research experience in pharmaceutical analytical research and development and co-authored 7 published, research publications and 3 submitted peer reviewed high impact research publications.
- Research in the field of corrosion and passivation of advanced metallic materials in various media
- Vast experience of generic pharmaceutical industry (ANDA-Abbreviated New Drug Application) to develop affordable and bioequivalent generic drugs.
- Experience on HPLC, UPLC, GC, GPC, GC-MS, Dissolution Apparatus (USP I, II, III, IV, VII), XRD, TPW, Rheometer and Malvern Mastersizeres.
- Proficiency in Analytical Method Development and Validation of pharmaceutical and bio-pharmaceutical products (ANDA and NCE), parenteral (Injection, powder for Injection, suspension for injection), solid oral-Rx and OTC (tablet, capsule, soft gel capsule, birth control pill), ophthalmic (solution, suspension), topical (gels) and liquid orals (syrup, powder for suspension) formulation projects.
- Experienced in Bio-relevant dissolution testing method development and “in vitro-in vivo correlation” (IVIVC) for immediate and controlled release products
- Strong analytical, problem solving and interpersonal skills with solid work ethics.

PROFESSIONAL EXPERIENCE

Amneal Pharmaceuticals, Brookhaven, New York, USA

Research Scientist- Analytical Research and Development **June 2013-Current**

- Supervising a team of analytical method development and validation scientists.
- Experience in analytical method development and validation for generic pharmaceutical product (solid oral and oral suspension doases form) on HPLC, UPLC, GPC, Dissolution Apparatus (USP I, II, III, IV, VII), XRD, TPW, Rheometer and Malvern Mastersizeres as per 21 CFR (GMP compliance) and ICH guidelines.
- Develop Analytical method for assay, content uniformity, blend uniformity, related compounds (impurity profiling), dissolution, viscosity, particle size and etc.
- Identification and quantification of excipients/polymers in solid oral formulations (immediate and controlled release tablets, capsules and beads) using HPLC, GPC and FTIR spectroscopy. Quantification of excipients and develop strategies to quantify mutually interfering excipients in drug products. Characterization of formulations with respect to the API/excipient location and particle size.
- Bio-relevant dissolution testing method development and “in vitro-in vivo correlation” (IVIVC) for immediate and controlled release products.
- Experience writing validation documents, method monograph and protocols for analytical method validation. Experience reviewing and/or approving validation documents, validation protocol, method monograph, method specification documents, reviewing laboratory notebooks.

- Critical evaluation of degradation studies in drug substance and drug products, Enrichment and separation of unknown impurity in degradation studies.
- Drug excipients compatibility study for pre formulation and final formulation
- Support to DRA to solve the FDA deficiencies.

Medcore Pharma LLC, Somerset, New Jersey, USA
Senior Research Scientist - Analytical Research and Development **December 2012-June 2013**

- Lead method development and method validation of analytical methods for active pharmaceutical ingredients and doases forms (Solid oral doases form-Rx and OTC medicine, Syrup formulations). Critical evaluation of degradation studies in active pharmaceutical ingredients and doases forms. Bio-relevant dissolution testing method development and IVIVR for immediate release and controlled release products. Perform drug excipients compatibility study for pre-formulation. Preparation of method development report, method validation protocol and report for active pharmaceutical ingredients and doases forms. Preparation of standard operating procedures and general test procedures for instrument operation and analysis. Independently review DMF and communicate to vendor in case of any query. Review laboratory notebooks, record of analysis and raw data for its accuracy and adequacy. Perform instrument preventive maintenance and calibration (mostly LC and GC). Involved in implementation of cGMP in laboratory. Perform internal audits to ensure safety and compliance in the analytical laboratory.
- Worked on different scientific instrument LC, GC, Malvern Mastersizere, Dissolution apparatus.

Aurobindo Pharma Limited (Research Center V), Hyderabad, India
Scientist 1- Analytical Research and Development **March 2010-November 2012**

- Lead method development and method validation for active pharmaceutical ingredients and doases forms (Solid oral doases form- oral contraceptive pill, ophthalmic solution, suspension and Injectable projects). Identification and quantification of excipients/polymers in solid oral doases forms (immediate and controlled release tablets, capsules and beads) using LC, GPC and FTIR spectroscopy. Characterization of formulations with respect to the active pharmaceutical ingredients/excipients location and particle size. Quantification of excipients and develop strategies to quantify mutually interfering excipients in drug products. Enrichment and separation of unknown impurities in forced degradation study. Injectable reconstitution and diluent compatibility study with different diluents that aid in ANDA filing. Determination of size and charge on globule by zeta sizer in ophthalmic suspension. Recommend and implement new analytical technologies and instruments for testing. Actively involve in implementation of cGMP in laboratory. Handled a team of 5 to 7 members for active pharmaceutical ingredients and Excipients analysis.
- Worked on different scientific instrument HPLC, UPLC, GC, Malvern mastersizer, Zeta sizer, TGA, DSC, Dissolution apparatus.

Panacea Biotec Limited "Sampann" R & D, Punjab, India
Senior Executive - Analytical Research and Development **August 2009-Febury 2010**

- Lead method development and method validation of NCE (new chemical entities) projects for pharmaceutical and biopharmaceutical products (Solid oral, Syrup, vaccine, gel formulation). Perform testing for in-process and finished pharmaceutical doases forms and stability samples. Actively participate in lead investigations of out of specification results, handling incidents, planned deviations and out of trends results. Troubleshoot analytical related issue and instrumental issue and perform root cause analysis. Perform method transfer activity from ARD to QC. Actively participate in training of scientists on new activities and continuous improvement of their analytical

skills and update new trends in cGMP and regulatory requirements. Coordinate with quality assurance and regulatory affairs departments for the queries related to analytical method validation.
- Experience on HPLC, UPLC, TGA, DSC, Malvern mastersizer, IR spectroscopy, UV-VIS spectroscopy, Atomic absorption spectroscopy (AAS), and dissolution apparatus.

Wockhardt Research Center, Aurangabad, India
Research Scientist - Analytical Research and Development **December 2007-July 2009**

- Develop new analytical method and perform mini-validation studies (Assay, Related compound, Dissolution, Chiral purity and cleaning verification) for pharmaceutical drug products (Solid oral, Syrup, Powder for Injection, Oral Solution formulations). Perform chemical analysis of raw material by IR, TLC, Malvern mastersizer and physical analysis by XRD, DSC, and viscometer. Support for identification and characterization of degradation products during stability of drug products using LC-MS, NMR, IR, and UV. Generate in house standard as per requirements of USP for routine analysis. Actively involve in equipment installation qualification, operational qualification, performance qualification, and calibration/performance verification. Preparation of method development reports, method validation protocol and report. Review of drug manufacturing file for any deficiencies and update to vendor for same.
- Experience on HPLC, UPLC, GC, XRD, DSC, Malvern mastersizer.

PROJECT HANDLE

- Experience in pharmaceutical and bio-pharmaceutical products (ANDA and NCE), parenteral (Injection, powder for Injection, suspension for injection), solid oral-Rx and OTC (tablet, capsule, soft gel capsule, birth control pill), ophthalmic (solution, suspension), topical (gels) and liquid orals (syrup, powder for suspension) formulation projects.

EDUCATION

PhD Major- **Analytical Chemistry** **2004-2008**
Maharshi Dayanand Saraswati University, Ajmer, India.
Thesis Project:
“Studies on Corrosion Inhibition Efficacy of Some Leguminosae Plants”

- Conducts research emphasizing interdisciplinary studies of corrosion electrochemistry, passivity and passivity breakdown, stress corrosion, hydrogen entry and hydrogen interactions in ferrous and aluminum-base alloys and model materials
- Extract natural compounds by using different extraction technique and separate different compound by using column chromatography and thin layer chromatography (TLC). Identified compounds by using different structure elucidation technique like UV, IR, NMR, Mass spectroscopy, GC and HPLC. Study effect of compounds on metal corrosion inhibition with different acid, alkaline and acid mixture media.
- Research studies were supported by surface morphological studies by using scanning electron microscopy (SEM) and atomic force microscopy (AFM) technique.
Thesis advisor: Dr. Raju Ratnani

Master of Science (M.Sc.) Major- **Analytical Chemistry** **2002-2004**
Maharshi Dayanand Saraswati University, Ajmer, India.

Bachelor of Science (B.Sc.) Major- **Chemistry** **1999-2002**
Rajasthan University, Jaipur, India.

INSTRUMENTAL EXPERIENCE

- HPLC (Waters, Agilent, Shimadzu), UPLC (Waters)
- Dissolution Apparatus (USP I, II, III, IV, VII)
- GC-MS (MS-QP 5000, Shimadzu)
- GC (Shimadzu), HEAD SPACE GC (Agilent), AAS (Perkin Elmer), UV (Perkin Elmer)
- XRD, Particle Sizer (Malvern Mastersizeres), IR (Tensor 27, Bruker)
- Rheometer and TPW (Sotax)

PUBLICATIONS

Editorial

- Bio-relevant Dissolution Media Development, Journal of Bioequivalence & Bioavailability (2017).
- Metal Corrosion Inhibitors, Research & Reviews: Journal of Chemistry (2017).

Research Article

- Corrosion inhibition of Aluminium by extracts of Prosopis cineraria in acidic media, Bulletin of Electrochemistry, Vol No. 22(2), pp.no.69-74, (2006).
- Inhibitive effect of Prosopis cineraria on mild steel in acidic media, Corrosion engineering, Science and Technology, Vol No. 43(3) 213-218 (2008).
- Corrosion inhibition efficacy of Capparis desidua on aluminium in acidic media, E- Journal of Chemistry, Vol. No. 4(4), pp. 450-456, October 2007.
- Synergistic effect of Calotropis plant in controlling corrosion of Mild steel in basic solution, J. Chil. Chem. Soc., 53, Nº 5 (2009) 1718
- Stability indicating analytical method development and validation of Efavirenz quantification by high performance liquid chromatographic technique, E Journal of chemistry, 2011, 8(4), 1498-1503.
- Solanum surrattence as Potential Corrosion Inhibitor, ISRN Corrosion, Volume 2012, Article ID 907676, 5 pages
- Corrosion inhibition of mild steel in nitric acid media by some Schiff bases derived from anisalidine, Polish Journal of Chemical Technology, Vol. No. 15 (1), pp. 61-67, 2013
- 7 Abstract published in proceeding of various national and international seminars and conferences.

Paper Submitted for Publication

- Forced degradation study an essential approach to develop stability indicating method, Journal of Chromatographic and Separation Technique, 2017.

Paper In Preparation

- Dissolution method development for low soluble drugs (To be submitted to Dissolution Technologies).
- Parkinsonia Extract as surface-active substance in corrosion of Aluminium (To be submitted to Material and Corrosion).
- Corrosion Behavior Aluminium in Sodium hydroxide Solutions with Prosopis cineraria extract (To be submitted to Journal of The Electrochemical Society).
- Parkinsonia aculeata as Potential Corrosion Inhibitor (To be submitted to Corrosion Science).

Invited Podium Presentation

- Manish Kumar Sharma- “Corrosion Inhibition of Aluminium in Hydrochloric Acid Solution by Naturally occurring Prosopis cineraria (Khajari)”, National conference on Resent Trends in Surface Chemistry (RTSC 05), Department of Chemistry, Guru Jambheshwar University, Hisar, India; 13-14th March 2005.

- Manish Kumar Sharma- "Effect of Alcoholic Extracts of Prosopis cineraria on Corrosion of Mild Steel in Hydrochloric Acid Solution", National Symposium on "Recent Advances in chemical Research"(RACR 05) Department of Chemistry, Rajasthan University, Jaipur (Rajasthan), India: 28-29th March 2005.
- Manish Kumar Sharma- "Solanum surratance as potential Corrosion Inhibitor", National Seminar and Expo on Botanical products, Natural Products Laboratory, Department of Chemistry, University of Rajasthan, Jaipur (Rajasthan) India; 5-7th Feb. 2005.

SEMINARS, CONFERENCES, WORKSHOP PARTICIPATED

- Participated in international conference on "Council of Surface Science and Catalysis" held on 8-9th December 2003 at Department of Pure and Applied Chemistry M.D.S. University, Ajmer (Rajasthan) India.
- Participated in international conference and expo on "Botanical products" held on 25-27th March 2006 at Natural Products Laboratory, Department of Chemistry, Rajasthan University, Jaipur, (Rajasthan) India.
- Participated in "SPSS Faculty Development Program" organized by SPSS and Depart of Population Studies, held on 18th January 2007 at M.D.S. University, Ajmer (Rajasthan) India.
- Participated in workshop on "Microbial Diversity & Desert Microbiology" held on 8-10th February 2007 at M.D.S. University, Ajmer (Rajasthan) India. Under the auspices of Ministry of Environment & Forests, Government of India.
- Volunteer in "National Service Scheme" from 2002-2003 to 2003-2004 at M.D.S. University, Ajmer (Rajasthan) India.
- Volunteer in "National Service Scheme" from 2000-2002 at Lal Bahadur Sashtri College, Jaipur (Rajasthan) India and served community for 240 hours.
- Participated in waters seminar titled " Waters Column Selection & HPLC Tips/Tricks" held om 14th December, 2016.

AWARDS, ACHIEVEMENTS AND PROFESSIONAL ACTIVITIES

- 12 years of educational and research experience in pharmaceutical analytical research and development and co-authored 7 published, research publications and 3 submitted peer reviewed high impact research publications.
- Vast experience on major Analytical techniques and instruments i.e. HPLC, UPLC, GC, GPC, GC-MS, Dissolution Apparatus (USP I, II, III, IV, VII), XRD, TPW, Rheometer and Malvern Mastersizeres.
- Selected for "STAR Award" for excellent contribution in the field of Analytical Research and Development from Amneal Pharmaceutical LLC (Current Employer).
- Supervising an analytical method development and validation team of 3 scientists.
- Elected Editorial Board member of 3 journals and appointed as journal referee of more than 15 research journals
- Selected about 30 times to judge other research works from very high impact peer reviewed journals.

CURRENT PROFESSIONAL AFFILIATIONS

- Sigma Xi, The Scientific Research Society
- American Chemical Society (ACS)
- The Electrochemical Society (ECS)
- Citizen Science Association

EDITORIAL BOARD MEMBER/ASSOCIATE EDITOR

- Editorial board member in Journal of Chromatography & Separation Techniques.
- Editorial board member in Austin journal of Analytical and Pharmaceutical Chemistry.

- Associate Editor in Journal of Analytical and Pharmaceutical Research.
- Editorial board member in Journal of Bioequivalence & Bioavailability.
- Editorial board member in Innovare Journal of Engineering & Technology.
- Editorial board member in Research & Reviews: Journal of Chemistry.

JOURNAL REFEREE

- Corrosion Science
- Corrosion engineering, Science and Technology
- Green Chemistry Letters and Reviews
- Natural Product Research
- Medicinal Chemistry Research
- Chromatographia (CHRO)
- Journal of Applied Pharmaceutical Analysis (CPA)
- EC Chemistry
- American Journal of Analytical Chemistry
- Current Pharmaceutical Analysis
- International Journal of Advances in Pharmaceutical Analysis
- International Journal of Chemical and Physical Sciences
- Pharmaceutical Science and Technology
- International Research Journal of Material Science and Engineering
- Journal of Chromatographic Science
- Current Green Chemistry
- Pharmaceutical Analytical Chemistry
- Material Science Research India
- Natural Product Chemistry & Research
- Drug Delivery and Translational Research
- International Journal of Drug Development & Research