# Murali Krishna Javvaji

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**Pharmaceutical Executive with proven history of analytical support in design, execution and submission of high-quality IND and ANDA regulatory applications.**

## CAREER OBJECTIVE

- Pharmaceutical Executive seeking an opportunity to help people with medical conditions through drug development.

## CAREER ACCOMPLISHMENTS

- Played key role in the FDA approval of ANDA for 6 products in USA, 2 products in Canada and 2 products in Europe.
- Involved in the FDA deficiency response for critical issue's for degradation products, Drug abuse deterrent studies and Naso gastric studies.
- Full knowledge and hands on experience on most of the analytical instruments with Empower, Millennium 32, Agilent and Parkin Elmer data systems.
- Hands on experience with all types of liquid and solid formulations for tablets, capsules, soft gelatin capsules, and injectable liquids.
- Well versed with FDA, ICH & EU requirements regarding IND, NDA and ANDA submissions. Very familiar with various monographs and general chapters of USP/NF, EP, other compendium and industry standard.
- Completed numerous accredited short-courses, continuing educations and on the job training in Analytical method development, Empower advanced software, FDA inspection, GLP and cGMP compliance, Management and Supervision and Leadership.

- Member and Community Leader of American Association of Pharmaceutical Scientists (AAPS), Member of The Chemical Institute of Canada (CIC), Indian Pharmaceutical Association (IPA), and American Chemical Society (ACS).

## PROFESSIONAL EXPERIENCE

**Sr. Research Scientist (AR&D)** **2011 - Current**
**Teva Pharmaceuticals (Actavis Inc.), Weston, FL**

- Analytical Support on average yearly 6-8 FTF (First to FILE) products NDA/ANDA submission for US and European market.
- Wrote/reviewed technical documents supporting INDs/NDAs/ANDAs as part of the *CMC* (chemistry, manufacturing, control) development process.
- Conducted Drug abuse deterrent studies and Elemental analysis testing as per FDA recent guidance to support NDA/ANDA product approval.
- Developed and validated analytical methods for analysis of Active Pharmaceutical Ingredients and Pharmaceutical Finished Formulations
- Audit and review procedures, processes, data and laboratory preparedness for inspections. Participate in FDA and internal audits.

- Lead the responsibility for analytical method development, analytical method validation, stability testing, Quality Control, FDA deficiency response and technical filings to ensure delivery of company goals.
- Developed cost-effective and efficient approach to UPLC/HPLC method development based on chemical structure analysis and physicochemical property analysis
- Wrote and reviewed specifications for Active Pharmaceutical Ingredients, Finished Formulations, Method validation protocols and reports.

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**Lab manager-AR&D** **2010- 2011**
**Sancilio & Company, Inc., Riviera Beach, FL**

- Leading analytical activities of NDA and ANDA products. Demonstrated solid leadership when working on complex problems within analytical development and QC method transfers in which analysis of situations or data requires an in-depth evaluation of various factors.
- Wrote/reviewed technical documents supporting INDs/NDAs/ANDAs regarding new or emerging drug delivery systems.
- Developing analytical methods for OTC and Rx soft gelatin capsules and chewables for clinical studies and commercialization.
- Ensured that work carried out is in compliance with required standards conforming to company, cGxP, SOPs, regulatory regulations & guidelines, Health, safety and environmental guidelines.

**Lead Scientist (Group Leader)** **2006- 2010**
**Azopharma Product Development group, Miramar, FL**

- Lead a team of Scientists in support of the analytical method development, validation and stability studies on various pharmaceutical dosage forms & drug substances to support ANDA filing.
- Wrote, reviewed SOP's, STP's, stability protocols / validation protocols as per ICH guidelines
- Provided analytical support to product development team (Excipient compatibility, Bio-dissolution and comparative dissolution studies).
- Support formulation development for pre-formulation activities such as excipient compatibility and solubility studies
- Hands on experience with HPLC (Data Station software and Chemstation), UV, Varian dissolution tester, Franz diffusion cells, DCS, TGA, and all other common laboratory equipment.

**Senior Research Scientist** **2002 - 2006**
**Contract pharmaceuticals ltd (Innopharm Inc.), Toronto (Canada)**

- Provided leadership in all aspects of laboratory operations coaching and professional development of analysts; training of analysts on technical matters and analytical techniques.
- Developed and validated new test methods for various formulations: injectable, solid and semi-solids to Support the *CMC* (chemistry, manufacturing, control) development process.
- Reported and communicated results to clients, consulting data and strategy. Received GLP and cGMP compliance training.
- Audit and review procedures, processes, data and laboratory preparedness for inspections. Participate in Health Canada, FDA and internal audits.
- Resolved technical issues in legacy test methods without impacting the compliance status of test methods.
- Prepared SOPs on Instruments: GC, HPLC, Empower & ChemStation Data System, TOC, microscopy, glassware washer.

**AR&D Scientist** **1999 - 2002**
**Dr.Reddy's Laboratories Limited (India)**

- Developed and validated analytical methods for Active Pharmaceutical Ingredients and Pharmaceutical Finished Formulations as per the FDA and ICH guidelines to support NDA/ANDA submission for US, Japan, Germany and European market product approval.
- API Evaluation and vendor qualification -Analyzed raw material samples from alternate sources for compliance with in-house specifications, monographs and general chapters of USP/NF, EP, other compendium and industry standard.
- Performed analysis of Pharmaceutical Finished Formulation and Active Pharmaceutical Ingredients as per USP, BP and EP.
- Handled and Calibrated sophisticated instruments like HPLC, Spectrophotometer, Dissolution, pH meter, Karl Fisher Titration Unit, Autotitrator and Atomic Absorption Spectrophotometer and assisted in the IQ, OQ & PQ of various analytical instruments.
- Methods transferred from AR&D to quality control testing laboratories to support commercialization of the product to various markets.

## EDUCATION

**Institution:** **Andhra University College of Pharmaceutical sciences, India**
**Qualification:** **Master of Pharmaceutical Science (by research)**
**Thesis title:** **"New analytical methods for the determination of Losartan potassium by HPLC, UV Spectrophotometric and Flame photometric methods"**
**Year of graduation:** **1999**

**Institution:** **Gulbarga University, India**
**Qualification:** **Bachelor of Pharmaceutical Science**
**Year of graduation:** **1996**

## PUBLICATION

1. DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF CILOSTAZOL IN PHARMACEUTICAL DOSAGE FORM [IC value : 4.72]
*1Naveen Babu Kilaru*, **1Murali Krishna Javvaji**, 2Rajani Kumar Valluru, 3Krishna Mohan International Journal of Pharmacy and Biological 5 (1), 153-160,2015*

2. DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF LOSARTAN POTASSIUM IN PHARMACEUTICAL DOSAGE FORM [IC value : 4.72]
*1Naveen Babu Kilaru*, **1Murali Krishna Javvaji**, 2Rajani Kumar Valluru, 3Krishna Mohan Chinnala International Journal of Pharmacy and Biological Sciences 5 (3), 158-165,2015*

3. DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF MESALAMINE IN PHARMACEUTICAL DOSAGE FORM [IC value : 4.27]
*1Naveen Babu Kilaru*, **1Murali Krishna Javvaji**, 2Rajani Kumar Valluru, 3Krishna Mohan Chinnala International Journal of Pharmacy and Biological Sciences 7 (1), 121-12,2017*

4. DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF ROPINIROLE IN PHARMACEUTICAL DOSAGE FORM

*1Naveen Babu Kilaru*, **1Murali Krishna Javvaji**, 2Rajani Kumar Valluru, 3Krishna Mohan Chinnala* [IC value : 4.72] International Journal of Pharmacy and Biological Sciences 7 (3), 229-235,2017

5. DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF TRAMADOL IN EXTENDED RELEASE TABLET PHARMACEUTICAL DOSAGE FORM
   *1Naveen Babu Kilaru*, **1Murali Krishna Javvaji**, 2Rajani Kumar Valluru, 3Krishna Mohan Chinnala* [IC value: 4.72] International Journal of Pharmacy and Biological Sciences 8 (1), 462-468, 2018

## POSTERS AND PRESENTATION HIGHLIGHTS

Rajanii Kumar**, Murali jawaji** "Pharmacy Practice and the law" 1999 Indian Pharmaceutical Congress (IPC) (Poster)

Kiran Kilaru**, Murali jawaji** "Hospital pharmacy and dispensing" 2001 Indian Pharmaceutical Congress (IPC) (Poster)

Francis Leung, John huang, **Murali Jawaji**, Hua Chen, Joe ying "Application of Acetyl acetone as an addictive in HPLC mobile phase to improve sensitivity and reproducibility of the method in the determination of Ciclopirox in PPM level" AAPS Annual Meeting, Chicago, IL, USA. (Abstract), 2005

**Murali Jawaji**, Francis Leung, Hua Chen, Joe ying "HIGH THROUGHPUT LC-MS/MS METHOD FOR DETERMINATION OF EFAVIRENZ IN HUMAN PLASMA" 2018 AAPS Workshop on Drug Transporters in ADME, Dulles, VA, USA (Abstract), 2017

Shashi Kumar**, Murali jawaji** "Abuse-Deterrent Formulations of Opioids: Effectiveness and Value" 2018 PharmSci 360 Scientific Programming, ID#492065, Washington, DC, USA. (Symposium)

Anitha chava**, Murali jawaji** "Combating Cancer with Novel Technologies" 2018 PharmSci 360 Scientific Programming, ID# 510024, Washington, DC, USA (Abstract)

Anitha chava**, Murali jawaji** "DIABETES CARE (EYE CARE)" 2018 PharmSci 360 Scientific Programming, ID# 499222, Washington, DC, USA (Abstract)

Shashi Kumar**, Murali jawaji,** Anitha chava**,** "Dosing Errors with Transdermal Patches" 2018 PharmSci 360 Scientific Programming, ID# 510481, Washington, DC, USA (Abstract)

Shashi Kumar**, Murali jawaji,** Anitha chava**,** "Drug Discovery and Development" 2018 PharmSci 360 Scientific Programming, ID# 510340, Washington, DC, USA (Abstract)

**Murali jawaji,** Anitha chava**,** "GENERIC VERSUS BRAND MEDICATIONS" 2018 PharmSci 360 Scientific Programming, ID# 510005, Washington, DC, USA (Abstract)

**Murali jawaji,** Anitha chava**,** "Novel Bio therapeutics for the Treatment of Cancer" 2018 PharmSci 360 Scientific Programming, ID# 510493, Washington, DC, USA (Abstract)

**Murali jawaji,** Anitha chava**,** "Xenotransplantation" 2018 PharmSci 360 Scientific Programming, ID# 510493, Washington, DC, USA (Abstract)

Shashi Kumar**, Murali jawaji,** Anitha chava**,** "The Generic Drug Approval Process" 2018 PharmSci 360 Scientific Programming, ID# 510336, Washington, DC, USA (Abstract)

Shashi Kumar**, Murali jawaji,** Anitha chava**,** "Bioanalysis of Human immunodeficiency virus (HIV) Drugs" 2018 PharmSci 360 Scientific Programming, ID# 499223, Washington, DC, USA (Abstract)