# CURRICULUM VITAE


**Alakhniranjan Mishra**

Location: **Navi Mumbai** (Maharashtra, India )
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Enriched experience of **11 plus** years of Development & Validation of Analytical Methods. In addition, experience of Elemental impurities, routine analysis, Dissolution (IVR) Studies, stability study, Impurity Profiling, technology transfer, reverse engineering, characterization of complex injectable projects.

Presently working in **Complex injectable in Analytical Development Lab. as Sr. Research Officer in Glenmark Pharmaceutical Ltd,** Taloja, Navi Mumbai since June 2018 to till date.

**Job description :**

- Working for Differentiated pharmaceutical product. (Injectables, lyophilized injection, Inhalation Suspension, Ophthalmic, Liposome injections and Suspension solution etc.).
- Analytical Method development/ characterization for non-compendial formulations (For regulated Market i.e., US and Europe).
- Analytical Method validation (Assay, Dissolution and Related substances) as per ICH and USP for DP and DS.
- Analytical method development for elemental impurities using ICP-MS and ICP-OES.
- Analytical method validation for elemental impurities as per USP 233 using ICP-MS and ICP-OES.
- Making risk assessment reports for Elemental impurities as per ICH Q3D guideline.
- Identification and evaluation of Unknown peaks (Anomalous peaks) by LCMS.
- Admixture studies of Injectable Product in different intravenous administration diluent (0.9% Saline,5% Dextrose and Ringer's injection) as per protocol.
- Analytical Method transfer from R&D to Plant location.
- Establishing method equivalency with that of compendial procedure so as to justify proposed approach.
- Preparation of Analytical Method Validation protocol, Report, Analytical Method transfer protocol and Report and Analytical Method development report.
- Preparation of the SOP's and STP's.
- Responsible for GLP compliance & Calibration of Analytical Instruments.
- Conducting pre formulation studies (Excipient Compatibility).
- Well and partially acquainted with sophisticated and novel techniques for quantification, qualification and characterization like LC-MS, Malvern 3000, Malvern -Zetasizer GPC-RI/ELSD.

## Experience

- 8 months worked as ADL officer with **Baxter Pharmaceutical Pvt. Ltd**. Ahmadabad (Gujarat) in **Analytical Development Laboratory** since February 2010 till September 2010.
- 1.5+ years worked as R&D officer with **Lupin Pharmaceutical Ltd**. Bhopal (M.P.) in **R &D (Process Analytical Development Laboratory**) since September 2010 till March 2012.
- 6+ years worked as Sr. Executive with **Sun Pharmaceutical Industries Ltd**. Vadodara (Gujarat) in **Analytical Development Laboratory** since March 2012 till June 2018.

- Presently working in **Complex injectable in Analytical Development Lab** as Sr. Research Officer in **Glenmark Pharmaceutical Ltd,** Taloja, Navi Mumbai since June 2018 to till date.

## Sun Pharmaceutical Work Profile

- Working for Differentiated pharmaceutical product. (Injectables, lyophilized injection, Ophthalmic, Liposome injections Suspension solution and Tablets etc.).
- Analytical Method development (Assay, Dissolution and Related Substances) for Non-compendial formulations (For regulated Market i.e., US, Canada and Europe).
- Analytical Method validation (Assay, Dissolution and Related substances) as per ICH and USP for DP and DS
- Analytical method development for elemental impurities using ICP-MS and ICP-OES.
- Analytical method validation for elemental impurities as per USP 233 using ICP-MS and ICP-OES.
- Identification and evaluation of Unknown peaks (Anomalous peaks) by LCMS.
- Preparation of Analytical Method Validation Protocol, Report, Analytical Method transfer protocol and Report and Analytical Method development report.
- Making risk assessment reports for Elemental impurities as per ICH Q3D guideline.
- Admixture studies of Injectable Product in different intravenous administration diluent (0.9% Saline,5% Dextrose and Ringer's injection) as per protocol.
- Preparation of the SOP’s and STP’s.

## Lupin Pharmaceutical Work Profile

- Analytical Method development for Assay and Related substances of Active Pharmaceutical ingredient (API).
- Analytical method validation of Assay and Related substances method as per ICH and USP.
- Sound understanding of developing method of analysis using various modules of HPLC with different detectors.
- Calibration of analytical instruments like HPLC, UPLC and UV etc.
- Qualification of working standard against pharmacopeial reference standards.
- Preparation of Method development report, Method validation protocol and report.

## Baxter Pharmaceutical Work Profile

- Analytical Method development (Assay and Related Substances) for Injectable products by using RP-HPLC.
- Analytical method validation (Assay and Related Substances) for injectable products as per ICH and USP.
- Calibration of analytical instruments like HPLC and UV etc.
- Qualification of working standard against Reference standards.
- Preparation of analytical method validation protocol and report.
- Preparation of Method development report.

## Educational Credentials

- **Master of Science (M.Sc.)- (Industrial chemistry)**
  Deptt. of Industrial chemistry
  Jiwaji University, Gwalior (Madhya Pradesh)

  **2007-2009** I$^{st}$ Division (69 %)

- **Bachelor of Science (B.Sc.)- (Industrial chemistry)**
  Govt. Model sciences college Jabalpur
  R.D.V.V University, Jabalpur (Madhya Pradesh)

  **2004-2007** I$^{st}$ Division (76 %)

- **High Secondary Certificate (HSC-12$^{th}$) (Biology)**
  St. Thomas H.S. School, Jabalpur
  Madhya Pradesh Board

  **2003-2004** I$^{st}$ Division (70 %)

- **Secondary school certificate (SSC-10$^{th}$)**
  St. Thomas H.S. School, Jabalpur
  Madhya Pradesh Board

  **2001-2002** II$^{nd}$ Division (57 %)

## Technical Skills / Instruments Handle

**Adept in handling Chromatographic Systems:**

- HPLC-Water Alliance 2695 with Empower software along with UV, PDA, RI & ELSD detectors.
- HPLC-Shimadzu-2010 with Class-VP, LC-solution software with UV, and PDA Detector.
- HPLC-Dionex ultimate 3000 with Chromeleon software along with UV Detector.
- UPLC-Water with Empower software along with UV, PDA, ELSD Detectors.
- GC-Shimadzu-17 A with LC software with FID detector.
- LCMS- SCIEX-Triple quad 4500 with Analyst software.
- IC -Thermo scientific with chromeleon software.

**In vitro Dissolution Apparatuses:**

- USP Model-I & II (Electrolab EDT-14Lx and 8-Lx)
- USP Model-IV (Flow through Cell-Sotax )

**Particle Size and other characteristics:**

- Malvern Mastersizer-2000 and 3000
- Malvern-Zeta Sizer Nano ZS 3600 (Particle size at Nano levels)
- Malvern- zeta potential measurement

**Advance characteristics Instruments:**

- Inductively Coupled plasma-Mass Spectrometer (ICP-MS)- Thermo-Fischer Scientific (iCAP RQ) and Agilent-7700.
- Inductively Coupled Plasma-Optical Emission spectrometer (ICP-OES)-Perkin Elmer.
- Atomic absorption spectrometer (AAS)- Perkin-Elmer.
- Osmometer (3250 Single-Sample Osmometer.)

- UV Spectrophotometer- Perkin-Elmer
- Liquid particle counter with Pharmspec software (HIAC).
- Potentiometric Auto-titrator & KF –Mettler Toledo and Metrohm.

## Field of Interest

- Analytical method development, validation and product characterization for complex formulations like **liposomes, Inhalation suspension, injections and lyophilized** products along with **Active Pharmaceutical Ingredients, raw materials, excipients etc.**

## Training /Industry exposure

- Industrial training in the Quality Assurance Deptt. **Flex chemical pvt Ltd. Gwalior**, (Madhya Pradesh)

  **Duration:** **45 days** (21 June-06 August, 2008)

- Industrial training in the Quality control Deptt. **Bio Synth. Pharmaceuticals**, Gwalior, (Madhya Pradesh)

  **Duration:** **1 month** (20 January-18 February, 2009)

## Post Graduate Research Project

Synthesis of "STARCH BASED ADHESIVES"
S.M.S. Govt. Model science college
Jiwaji University Gwalior, Madhya Pradesh.

## Computer Skill

- Diploma in MS OFFICE (Word, Excel and power point) and Internet Application.

## Seminar /Workshop

- Participated in seminar on Analysis of Element impurities, Pharmacopeia education programs at Ahmadabad, Gujarat, May8-2013.
- Participated in seminar of Basic of UV-Visible Spectroscopy, Role of FTIR& Application of DSC in pharmaceutical industries by Shimadzu Analytical (India) Pvt Ltd.at SPARC Baroda Gujarat,14 September-2013
- Participated in Certificate Seminar on Career Development Camp organized by Centre for Entrepreneurship Development M.P (CEDMAP) 2009.
- Participated in Nation Seminar on Recent Trends in R&D, Quality Control& Marketing in Pharmaceutical & Fine chemical Industries 2008.

## Special Remarks & Personal Skills

- Got first position in **III, IV and VI** semesters during B.Sc.
- Got Second position in **I**,**II and V** semester during B. Sc
- Good potential, desire to learn more.
- Self-motivated, ready to accept challenges in positive manner.
- Good at teamwork.
- Good behavioral and communication skills.

## Few Key Achievements

**HPLC Method development for Assay and RS method**

- Amphotericin B (Liposome)
- Doxorubicin HCl injection (Liposome)
- Epinephrine injection
- Methylprednisolone acetate suspension injection

**ICP-MS Method development for Elemental impurities**

- Water for injection and Purified water for Elemental impurities
- Zoledronic acid injection
- Doxorubicin HCl injection (Liposome)
- Amphotericin B (Liposome)
- Irinotecan injection
- Vecuronium Br for injection
- Decitabine for injection
- Atosiban solution for Injection
- Paclitaxel Conc. injection

**Currently in Glenmark Pharma:**

- Budesonide Inhalation Suspension
- Selexipag for Injection (Lyophilized Injection)
- Ferumoxytol Injection

## Personal details

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|---|---|
| Date of Birth | May 20, 1986 |
| Sex | Male |
| Nationality | Indian |
| Marital Status | Married |
| Languages known | English, Hindi and Gujrati (More than beginner, less than expert) |
| Hobbies | Playing Cricket and Listening music |
| Father's Name | Mr. Ramanand Mishra |

## References

**Mr. Balaji Sagare**
General Manager,
ANDA dept. Analytical Development Lab,
Sun pharma advanced research company Ltd. (Vadodara)
Phone Number: 09426313348

**Mr. Deepak Mishra**
Sr. Manager
ANDA dept. Analytical Development Lab
Baxter Pharmaceuticals India Pvt. Ltd (Ahmedabad)
Phone Number: 09879731457

## Declaration

I hereby declare that the information given in this resume is correct to the best of my knowledge.

**ALAKHNIRANJAN MISHRA**