Curriculum Vitae

BORSE GULAB B.

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Objective:

Experienced analytical chemist, cross-trained in data review, who currently holds a position testing the quality of pharmaceuticals product at GMP laboratory. A confident, enthusiastic and flexible professional who showcases excellent time management and organizational skills. Works well both individually and in a team setting. Seeking to utilize skills and education in scientific laboratory.

Work Profile:

Present Status	: General Manager – QC/ADL/RA.
Field of Interest	: Quality Assurance, Quality Control, Analytical R&D, Regulatory affairs.
Working tenure	: Working since April-2008 to till date.
Experience	: 15 years.
Time requires for joining	: Three month.

Work Experience:

1) QC/ADL/RA General Manager;

- **MENDAS PHARMA PVT. LTD. (Since Aug-2023)**
  - Overall Administration of Quality control laboratory and Analytical Development Laboratory.
  - Setup the new QC laboratory and micro lab to meet international standard.
  - Manage and monitoring daily quality activity in the lab in three shifts.
  - Literature survey for analytical method development of new projects.
  - Development & Validation of Analytical methods for cleaning samples (Tress Analysis) by UV-Spectroscopy, & HPLC.
  - Development of TLC method for rection monitoring in R&D.
  - Analytical method Development (ICH Q14) and validations of Related substances, chiral purity, Enantiomer content, Assay, Residual solvents, and Counterions methods for API as well as RM by GC and HPLC as per ICH Q2 (R1), ICH Q3A, ICH Q3C, and submitted to US, EU, CHINA, ANVISA regulatory agency.
  - Forced degradation study of API as per ICH Q1A (R2).
  - Photo-stability of API as per ICH Q1B.
  - Analytical method Development & Validation for Carry-over of KSM's, intermediates and solvents in final product for DMF/CEP submission.
  - Highly familiar with calculations used in analytical chemistry and the application of statistics.
  - Assure fully Engagement and Involvement of subordinates regarding awareness and clarity related to data integrity and adherence to ALCOA ensure the same.
  - Finalization and preparation of Specification, & method of analysis, for KSM's, RM's, Inprocess, intermediates, and Final API as per ICH Q6A.
  - Preparation and imparted training of SOPs.
  - Responsible for cross function Self inspection and Vendor audit management and implementation.

- Manage third party inspections and audits, including regulatory inspections, findings and follow-up.
- Able to support regulatory and compliance department during FDA inspections.
- Query evaluation with coordinate with regulatory department.
- Review and approval of documentation associated with key quality compliance OOS/OOT, and other quality system documents e.g.: SOP's, Protocols, reports as Appropriate as per GMP procedural.
- Manage Quality Control equipment validation, calibration and maintenance activities.
- To review and approve qualification protocols / reports (DQ/IQ/OQ/PQ) related to Quality Control Instruments, Manufacturing Equipment's, Computerized Systems, and Utilities etc.
- Timely release all RM, in process, intermediate, & and Final API samples.
- Timely deliver all validation and carryover activities to regulatory affairs department.
- Strong experience in cGMP, cGLP, ICH and FDA compliant environment.
- Communicate with outside service provider like public testing labs in characterization of new in-house impurities.
- Stability Study for existing and new drug substance as per Q1A (R2), for retest period, self-life estimation, and submission of DMF/CEP and FDA licensing.
- Stability study of Volumetric Solution.
- Overall control of Microbiology Laboratory.
- AHU Validation.
- Vendor Qualification and approval.
- Cleaning Validation of Product.
- Review of documents for preparation of DMF or CEP (Elemental analysis report as per ICH Q3D, Genotoxic risk assessment, nitrosamine impurity risk assessment)
- DMF preparation in paper Version.
- Analytical Instrument qualification.
- Purified Water system qualification.
- Computer System validation for in-house domain.
- Excel sheet validations.
- Disinfectant Efficacy in microbiology.
- Hire, manage, and develop Quality staff and to support organization goals and objectives. Conduct employee performance evaluations; assist in setting goals and objectives in alignment with the overall company goals and objectives.

2) QC/QA Manager;

- **Amgis Lifescience Ltd. (Nov-2021 to July-2023)**
  - Overall administration of Quality control laboratory.
  - Manage and monitoring daily quality activity in the lab in three shifts.
  - Literature survey for analytical method development of new projects.
  - Development of Analytical methods for Related substances, chiral purity, Enantiomer content, Assay, Residual solvents, and Counterions by Gas Chromatography & High-Performance Liquid Chromatography.
  - Development & Validation of Analytical methods for cleaning samples (Tress Analysis) by UV-Spectroscopy, & HPLC.
  - Analytical method validations of Related substances, chiral purity, Enantiomer content, Assay, Residual solvents, and Counterions methods for API as well as RM by GC and HPLC as per ICH Q2 (R1), ICH Q3 A, ICH Q3C, and submitted to US, EU, CHINA, ANVISA regulatory agency.
  - Forced degradation study of API as per ICH Q1A (R2).
  - Photo-stability of API as per ICH Q1B.

- Analytical method Development & Validation for Carry-over of KSM's, intermediates and solvents in final product.
- Highly familiar with calculations used in analytical chemistry and the application of statistics.
- Finalization and preparation of Specification, & method of analysis, for KSM's, RM's, Inprocess, intermediates, and Final API as per Q6A.
- Preparation of Quality Control department SOPs.
- Co-ordinate with R&D department in new product development.
- Able to support regulatory and compliance department during FDA inspections.
- Query evaluation with coordinate with regulatory department.
- Timely release all RM, in process, intermediate, & and Final API samples.
- Timely deliver all validation and carryover activities to regulatory affairs department.
- Strong experience in cGMP, cGLP, ICH and FDA compliant environment.
- Preparation and characterization of in-house impurities.
- Communicate with outer parties like public testing labs for characterization of new impurities.
- Stability Study for existing and new drug substance as per Q1A (R2), for retest period, self-life estimation, and submission of drug master file and FDA licensing.
- Stability study of Volumetric Solution.
- Overall control of Microbiology Laboratory.
- AHU Validation.
- Vendor Qualification.
- Open part DMF in paper Version.
- Analytical Instrument qualification.
- Purified Water system qualification.

3) ADL Assistant Manager;

❖ **Melody Healthcare Pvt. Ltd. (Feb-2015 to Nov-2021)**

- Overall administration of analytical development laboratory.
- Literature survey for analytical method development of new projects.
- Development of Analytical methods for Related substances, chiral purity, Enantiomer content, Assay, Residual solvents, and Counterions by Gas Chromatography & High-Performance Liquid Chromatography.
- Development & Validation of Analytical methods for cleaning samples (Tress Analysis) by UV-Spectroscopy, & HPLC.
- Analytical method validations of Related substances, chiral purity, Enantiomer content, Assay, Residual solvents, and Counterions methods for API as well as RM by GC and HPLC.
- Forced degradation study of API.
- Photo-stability of API.
- Analytical method Development & Validation for Carry-over of KSM's, intermediates and solvents in final product.
- Preparation of protocol and report for method validations of Related substances, Assay and Residual solvents.
- Review of protocol and report for method validations of Related substances, Assay and Residual solvents.
- Highly familiar with calculations used in analytical chemistry and the application of statistics.
- Finalization of Specification for KSM's, intermediates, and Final API.
- Co-ordinate with R&D department in new product development.
- Coordinating & resolving analytical issues within the QC department.
- Able to support regulatory and compliance department during FDA inspections.
- Query evaluation with coordinate with regulatory department.

- Timely deliver all validation and carryover activities to regulatory affairs department.
- Strong experience in cGMP, cGLP, ICH and FDA compliant environment.
- Preparation and characterization of in-house impurities.
- Communicate with outer parties like public testing labs for characterization of new impurities.
- Stability Study for new drug submission of drug master file and FDA licensing.
- Preparation of Standard Operating Procedure, Method of analysis, Certificate of Analysis.
- Maintaining the records of ADL departments (Instrument calibration, Analytical method developments records, instrument logbooks etc.)
- Review of Routine documents like Analytical reports, instrument calibrations etc.
- Daily work planning of ADL department by coordinating with R&D department and Regulatory department.

4) Quality Control Executive;

❖ **Mehta API Pvt. Ltd. (Mar-2014 to Feb-2015)**

- Analytical method validations of Related substances, Assay, Residual solvents methods for API as well as RM by GC and HPLC.
- Forced degradation study of Related substances method.
- Preparation of protocol and report for method validations of Related substances, Assay and Residual solvents.
- Preparations of analytical method transfer protocol and report.
- Co-ordinate with outside labs for method validation.
- Preparation of Document and Maintain Record of QC.

5) Quality Control Executive;

❖ **Swati Spentose Pvt. Ltd. (July-2013 to Mar-2014)**

- Analytical method validations of Related substances, Assay, Residual solvents methods for API as well as RM by GC and HPLC.
- Forced degradation study of Related substances method.
- Preparation of protocol and report for method validations of Related substances, Assay and Residual solvents.
- Instrumentation Analysis like HPLC and GC of Finish product, intermediate and raw materials.
- Review of analytical documents and instruments log book.
- Preparation of SOPs and specification.
- Calibration and Review of all instruments.
- Preparation of Document and Maintain Record of QC.

6) Quality Control Officer;

❖ **Aristo Laboratories Pvt. Ltd. (Dec-2010 to June-2013)**

- Instrumentation Analysis like HPLC of Finish product, and raw materials.
- Preparation of working standard and maintain its consumption.
- To ensure the good ware house keeping and updation.
- Calibration and Review of all instruments.
- Review and maintain records of volumetric solutions.
- Review of analytical documents and instruments log book.

Personal Skills:

Self-confidence, Willing to learn, hard working, Sincerity and Utter devotion towards responsibility.

Academic Qualification:

- Post-Graduation Diploma in Quality Assurance.
- Advanced Post Graduation Diploma in Regulatory Affairs.
- M.Sc. (Chemistry) from Dr. C.V. Raman University with First Class.
- B.Sc. (Chemistry) from North Maharashtra University with Second Class.
- H.S.C. (Science) Passed from Nasik Board with Second Class.
- S.S.C. Passed from Nasik Board with First Class.

Industrial Experience:

- Working in M/s Ciron Drugs Pvt. Ltd. Tarapur (Boisar) as A Quality Control Chemist from Apr-2008 to June -2009.
- Working in M/s Althea Pharma Pvt. Ltd. (Daman) as a Quality Control Officer from Apr-2010 to Nov-2010.
- Working in M/s Aristo Lab. Pvt. Ltd. (Daman) as a Quality Control Officer from Dec-2010 to June-2013.
- Working in M/s Swati spentose Pvt. Ltd. (Vapi) as an Executive in Quality Control department from July-2013 to March – 2014.
- Working in M/s Mehta API Pvt. Ltd. Tarapur (Boisar) as an Executive in Quality Control department from March-2014 to Feb - 2015.
- Working in M/s Melody Healthcare Pvt. Ltd. (Boisar) as an Assistant Manager in Analytical Development Department from Feb-2015 to Nov- 2021.
- Working in M/s Amgis Lifescience Ltd. (Panoli) as a QC/QA Manager from Nov-2021 to July-2023.
- Working in M/s Mendas Pharma Pvt. Ltd. (Dahej) as a QC/ADL/RA General Manager since Aug-2023.

Personal Profile:

Name	: Mr. Borse Gulab B.
Date of Birth	: 27th March 1986
Nationality	: Indian
Gender	: Male
Marital Status	: Married
Language Known	: English, Hindi, Marathi, Gujrathi

I hereby declare that the information furnished by me is true and complete up to best of my knowledge.

Date:

Place: **(Gulab Borse)**