Kalpana Shah ***Cell: 848-467-1887***
1713 Solook drive ***ks_122503@Yahoo.com***
Parlin, NJ 08859

Summary of Qualifications:

- 15+ years of experience in the pharmaceutical field based with a strong analytical background along with broad-base knowledge of instrumental analysis.
- Acquired proficient pharmaceutical industry experience as well as extensive knowledge of USP, NF, cGMP and MSDS.
- Extensive hand-on experience with proficiency of analytical instruments such as: HPLC, UPLC, GC, UV-VIS, Karl Fisher and dissolution apparatus, transfer module connected with dissolution bath apparatus.
- Extensive experience in analytical method development / validation.
- Organized, detail-oriented individual with excellent documentation and communication skills.
- Background in GMP, compliance Investigation, stability testing, and data review.

PROFESSIONAL EXPERIENCE:

Teva/Actavis, Elizabeth, NJ ***04/2003-02/2017***
Scientist II, Analytical Development Department (2011-Present)

- Analyzed assay, related compounds, content uniformity,dissolution,water content, identification and blend uniformity testing of finished and stability solid dosage forms using HPLC,UPLC,UV/Visible spectrophotometer, and Karl Fisher titration.
- Analyzed peptide products for release and stability in support of INDs, NDAs.
- Prepare documents including protocols, methods, and reports.
- Review and approve/ disapprove change controls in QUMAS and Trackwise associated with assigned projects and provide regulatory comments and required documents as applicable.
- Perform protocol execution and sample testing with compliance with cGMP requirements.
- Performed validation tests such as, precision, accuracy, linearity, standard and solution
- Stability and filters studies.
- Develop in-house test methods.
- Calibrated laboratory instruments.(HPLC, pH meter, fraction collector and balance)
- Peer Reviewed notebooks.
- Train new and current employees.
- Participates in integration assessment.
- Actively participate in lab safety committee.
- Proficiency in Empower software.

Actavis, Elizabeth, NJ
Associate Research Scientist II, Analytical Development Department (2006-2011)
Cleaning validation, process validation studies and report preparation.

- Forced degradation studies for many drug substances and finished products.
- Defined and resolved problems on projects, successfully completed lab work and met documentation deadlines.
- Review of stability products test to ensure quality results.
- Test method transfers.
- Gas Chromatography analysis.

Actavis, Elizabeth, NJ
Chemist III, Quality Control Department ***(2003-2006)***

- Performed dissolution and drug release testing of finished & stability samples by using HP-Chemstation and UV Spectrophotometer.
- Performed routine analysis on finished product and stability samples according to USP/NF or in-house methods.
- Laboratory instruments troubleshooting maintained and calibrated instruments.
- Performed cleaning rinse titration, LOD, etc.,

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Pfizer, Morris Plains, NJ (Contractor) ***10/2002-03/2003***
Sr. Associate Scientist, Method Validation Department

- Performed method robustness studies. Tested variables such as mobile phase proportions, column and filter types in determining optimum conditions for test methods.
- Interpreted the data generated and made recommendations for preparation of test methods.
- Hands-on experience of analytical development, validations of dosage forms e.g. tablets, capsules, oral liquids, soft gels, ointments, etc.
- Maintained compliant laboratory notebooks.

Medicos Laboratory, South Plainfield, NJ ***01/2002-10/2002***
Analytical Chemist

- Wrote Standard Operating Procedures for laboratory equipment.
- Performed physical testing of solid dosage forms and chemical testing of in-process and finished products.
- Performed analysis of assay, related compound, content uniformity, and blend uniformity testing using Hitachi HPLC following in-house and USP methods.
- Performed scheduled calibration of laboratory equipment, including dissolution apparatus, UV spectrophotometer, and pH meter.
- Maintained documentation according to cGMP.
- Reviewed stability results.

Able Laboratory, Inc., South Plainfield, NJ ***02/2001-12/2001***
Lab Associate, Research & Development Department

- Performed analysis of assay, content uniformity, and blend uniformity testing using Waters HPLC following in-house methods.
- Performed dissolution testing of in-process, finished product, and stability samples.
- Generated reports and notebooks with clear and accurate results.

Education

Bachelor of Science, Chemistry and Physics 1994
D.N. Science University

Medical Laboratory Assistant 2001
National Health Career Association, East Orange, NJ

Computer Applications 1995
Baroda Productivity Council Center, Baroda

Eastern Analytical Symposium, Inc. 2008
HPLC method Development in Pharmaceutical Analysis

Pharmaceutical GMP Professional 2012

Eastern Analytical Symposium, Inc. 2016
Advanced HPLC /UPLC Part 1&2: Fundamental and Pharmaceutical Application

Computer Skills

- Proficient in Windows and Microsoft Office including Word, Excel, and Power Point.
- Proficient in Empower, Chemstation and Peak-Pro software.
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