Mandar Deshpande

Summary of skills and experience
Montville, NJ 07045
mandar31377@gmail.com
2013658744

A skilled scientific professional with more than 23 years of experience in the pharmaceutical industry for the wide scope of pharmaceutical dosage forms. with expertise in Analytical method development, Method validation, CMC, Regulatory support, Project management, Analytical transfer, Preparation and reviewing of SOP, Preparation of validation protocol and reports, Deviation investigation, and CAPA, data interpretation in CMC and cGMP environment, author and reviewer of Testing procedures, Analytical reports and technical documentation, knowledge of GLP, USP/ICH and industry guidance required for the generic pharmaceutical product development and submission.Strong technical, investigational and problem solving skills required for commercial product analysis and new product development.

Work Experience

Senior Scientist

Alembic labs llc - West Caldwell, NJ
October 2017 to Present

Management of Project from reviewing of API DMF, Qualification of vendor methods (for API), development of product, to analytical technology transfer.
Preparation and collection of documents needed for Intra laboratories technology transfer.
Preparation of analytical strategy for new products and Reference Product characterization.Preparation of Elemental Impurities assessment report as per ICH guideline.
Preparation of Residual assessment report as per ICH guideline.
Support in the preparation of QBd report for Analytical part.
Documentation as per GMP requirements for submission / guidelines.
Supporting regulatory requirements by preparing justification of specification, validated testing procedure and collecting test data required for CMC section completion.
Analytical Method development for abbreviated new drug products using various analytical techniques and instrumentation using analytical data acquisition software.
Performing Analytical Method validation studies/protocol/report writing as per USP and ICH guidelines and current industry requirement.
Drug-excipient compatibility studies and formulation support in product development
Forced degradation studies of the API and formulation product.
Development for the chromatographic purity/leachable/extractable studies of the complex formulation product,
Development and validation of dissolution methods.
Calibration Of the instrument like HPLC, UV spectrophotometer, Weighing Balances, dissolution testers, Friability tester, Disintegration tester, Gas chromatography instrument .
Operation of instruments like, HPLC, UHPLC (Arc systems), UPLC, GC, UV spectrophotometer, FTIR, Karl fisher titrator, Potentiometric titrator, Polarimeter, Malvern mastersizer, Dissolution tester.
Analysis of the stability samples of research and development and quality control samples.

Method development and validation using Gas Chromatography.
Analysis of drug substances and drug products as per compendial pharmacopeia and In-house method.

Scientist, Analytical R&D

Orit laboratories LLC - West Caldwell, NJ
October 2005 to October 2017

ORIT laboratories, NJ Oct. 2005 - Oct. 2017 Scientist: (Analytical Research and development)

• Management of Project from reviewing of API DMF, Qualification of vendor methods (for API), development of product, to analytical technology transfer.
• Analytical Method development for abbreviated new drug products using various analytical techniques and instrumentation using analytical data acquisition software.
• Performing Analytical Method validation studies/protocol/report writing as per USP and ICH guidelines and current industry requirement.
• Preparation of analytical strategy for new products and Reference Product characterization
• Drug-excipient compatibility studies and formulation support in product development
• Forced degradation studies of the API and formulation product.
• Development for the chromatographic purity/leachable/extractable studies of the complex formulation product,
• Development and validation of dissolution methods.
• Supporting regulatory requirements by preparing justification of specification, validated testing procedure and collecting test data required for CMC section completion.
• Calibration Of the instrument like HPLC, UV spectrophotometer, Weighing Balances, dissolution testers, Friability tester, Disintegration tester, Gas chromatography instrument .
• Operation of instruments like, HPLC, UHPLC (Arc systems), UPLC, GC, UV spectrophotometer, FTIR, Karl fisher titrator, Potentiometric titrator, Polarimeter, Malvern mastersizer, Dissolution tester.
• Analysis of the stability samples of research and development and quality control samples.
• Method development and validation using Gas Chromatography.
• Analysis of drug substances and drug products as per compendial pharmacopeia and In-house method.

Scientist, Analytical research and development (stability department)

Sandoz Ltd - Kalwa, Thane
October 2004 to September 2005

Sandoz Ltd. (India) Oct 2004 - Sept 2005
Scientist: (Analytical Research and development, Stability department)

• Development for the chromatographic purity of the complex formulation product
• Calibration of the instrument like HPLC, UV spectrophotometer, Weighing-Balances, dissolution testers.
• Analysis of the stability R&D Samples.
• Monitoring of stability chambers.
• Analysis of stability samples using Gas chromatography.
• Having experience of using various instruments like HPLC, IR spectrophotometer, UV spectrophotometer, Polarimeter, Potentiometer, Karl fisher titrator, Gas chromatograph, Dissolution tester.

Analytical Chemist (R&D)

Unique Pharmaceutical Laboratories Ltd. - Thane, Maharashtra
December 2003 to October 2004

Unique Pharmaceutical Laboratories Ltd. (A division of J.B Chemicals and pharmaceuticals Ltd.) (India)
Dec 2003 - Oct 2004
Analytical Chemist (Research and Development Lab)

• Responsible for Method development on Gas chromatography.
• Managed Validation of the methods.
• Forced degradation studies of the API and Formulation product.
• Calibration Of the instrument like HPLC,U.V spectrophotometer, gas chromatograph, dissolution testers.
• Analysis of the stability Samples.

Chemist, Quality Control

Pharmasolve specialities India Pvt. Ltd. - Vikhroli, Mumbai
October 2001 to November 2003

Pharmasolve Specialities India Pvt Ltd. Oct 2001 - Nov 2003
Chemist (Quality Control Lab)
• Responsible for managing stability department consisting of about 10-12 chemist.
• Managed Validation of the methods on HPLC.
• Responsible for Method validation on Gas chromatography.
• Forced degradation studies of Formulation product.
• Calibration Of the instrument like HPLC,U.V spectrophotometer, Polarimeter,
• IR spectrophotometer, Dissolution tester.
• Analysis of the stability Samples.
• Trained new chemists for lab method and equipments operation.
• Managed IQ, OQ & PQ of the new instruments.
• Calibration of instruments like HPLC, dissolution tester, UV Spectrophotometer.
• Handled various instruments like HPLC, Gas-Chromatograph, UV Spectrophotometer, Auto Polarimeter, Melting Apparatus, Auto titrator, Karl fisher titrator, Dissolution tester.
• Obtained certificate for actively participating in seminar conducted by Waters Corporation on Column selection and troubleshooting.

Chemist (Quality Control Lab/Stability Group)

Cipla Ltd - Mumbai, Maharashtra
May 2000 to September 2001

Cipla Ltd (India) May 2000 - Sept 2001
Chemist (Quality Control Lab/Stability Group)
• Acquired knowledge of various analytical techniques and instrumentation for pharmaceutical testing of active pharmaceutical ingredients and various pharmaceuticals dosage forms.
• Performed analysis of Raw materials, Tablets, Capsules, Ointments, Syrups, and Dry syrups using various analytical techniques.
• Trained junior chemist on new analytical techniques and instrumentation

Chemist, Research and Development (Methods)

Raptakos Brett Test Laboratories Ltd - Thane, Maharashtra
November 1998 to May 2000

Raptakos Brett Test Laboratories Ltd (India). Nov 1998 – May 2000
Chemist (Research and Development Methods)

- Responsible for the analysis of capsules, liquid, ointment and food products.
- Worked on one of the anti HIV herbal product for its natural extract

Education

Bachelor's degree in Chemistry

Mumbai university - Mumbai, Maharashtra
May 1993 to May 1997

Skills

- High-performance liquid chromatography
- Spectroscopy
- Chromatography
- CGMP
- Laboratory experience
- Research & development
- Gas chromatography
- QA/QC
- Calibration
- APIs
- GLP
- Laboratory management
- Chemistry, manufacturing & controls
- Project management
- Internal audits
- Writing skills

Assessments

Analyzing data — Proficient

December 2022

Interpreting and producing graphs, identifying trends, and drawing justifiable conclusions from data
Full results: Proficient

Indeed Assessments provides skills tests that are not indicative of a license or certification, or continued development in any professional field.

Additional Information

INSTRUMENTATION:

UPLC (Waters), UHPLC (waters Arc System), HPLC (Waters, HP, and PE) with PDA detector and Refractive index detector, GC (PE, HP), Dissolution Apparatus (Electrolab, Distek), Disintegration Apparatus, Sonic Sifter Sieve Analysis, particle size analysis (Malvern mastersizer 3000), UV-Vis Spectrophotometer, Karl Fischer Titrimetry, Polarimeter, Viscometer, FTIR.