Hardeep Dave

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Objective

- Seeking challenging and responsible Research & Development position in Analytical Development Laboratory to develop and use, new and existing analytical test methods to determine quality, quantity & purity of Finished Pharmaceutical Dosage forms.

Professional Summary

1. An astute professional with over 10yrs extensive experience in areas of Analytical Research Laboratory.
2. Currently working with **M/s. Alembic Research Center** as **Research Scientist**.
3. Analytical chemist with extensive knowledge and experience with drug development & working in accordance with GLP, Safety & Regulatory requirement.
4. Specific experience in Related Substances Method Development, Dissolution Method Development, Assay Method Development & Partial Method Validation through chromatographic separations on Finished Pharmaceutical Dosage forms.
5. Experienced in operation, maintenance & troubleshooting of High Performance Liquid Chromatography (HPLC), Ultra Performance Liquid Chromatography (UPLC), Ultraviolet Visible Spectrometer (UV), IR(Infrared Spectroscopy) and Dissolution Apparatus.
6. Strong organisational skills with the ability to manage multiple projects simultaneously.
7. Proven excellence in collaborative & independent performance.
8. Remarkable ability to work in multidisciplinary & high intensity environment.

Career Highlights

Research Scientist **Alembic Research Centre** **Since April'2013-till Date**

- ✓ Responsible for Drug Product Development Cycle beginning from Analytical Method Development, In Process Analysis, Stability Studies & eventually Analytical Method Transfer to Plant Quality Control.
- ✓ Execution of analytical test parameters such as Dissolution, Assay, Related Substances, Swab Analysis, Content Uniformity, Water Content, Blend Uniformity, Average weight, Loss on drying etc. for drug products as requested by Formulation and Development Department.
- ✓ Perform Multimedia Dissolution activity on exhibit batches for different market such as US ,Europe, Brazil, Canada, Australia, Mexico, South Africa, Singapore etc. as per mentioned in protocol by Formulation & Development Department.
- ✓ Perform Dossier Extension related activities for finished drug products in different markets with effective timelines as mentioned by Regulatory Department.
- ✓ Perform In process, Stability analysis & routine analysis of Finished Pharmaceutical drug products manufactured by Alternate outsourced Active Pharmaceutical Ingredient.

- ✓ Preparation of reports as per regulatory requirement such as Multimedia Dissolution Report, Dissolution Development Report & Certificate of Analysis for Drug products manufactured through Alternate outsourced Active Pharmaceutical Ingredient.
- ✓ Perform Calibration of Dissolution Apparatus, HPLC as per Master Calibration Planner & daily calibration of Analytical Balance, pH meter & other laboratory equipments in compliance to GLP guidelines.
- ✓ Data compilation & primary review of generated analytical data.
- ✓ Timely report to superior for on going activities related to assigned task.
- ✓ Complete Log book entries & proper documentation related to assigned task as per in house established systems & procedures.
- ✓ Carrying out all analytical activities in compliance with internal systems and safety guidelines.

Research Officer **Accutest Research Laboratories** **Since Oct'2012-Mar'2013**

- ✓ Worked on Bio-analytical Method Validation & Study Sample Analysis on generic dosage forms of drugs for bioequivalence studies using LC-MS/MS System in conformation to GLP guidelines.
- ✓ Trained on basic hardware of LC-MS/MS (API 4000) & software (Analyst 1.4.1) for study sample analysis.
- ✓ Performed bio-analytical method validation parameters such as limit of detection, limit of quantification, stock check, selectivity, sensitivity, matrix factor, matrix effect, precision accuracy batch, extended precision accuracy batch, recovery, interference check, batch top stability, long term stability, weight extract stability, freeze thaw stability, blood stability, dilution integrity in accordance with internal SOPs.
- ✓ Conducted bio-analysis of Study samples using extraction methods such as Solid Phase Extraction method (SPE), Liquid liquid Extraction method (LLE) & Protein Precipitation method (PPT).
- ✓ Prepared list of bio-analyisis samples to undergo Incurred sample reanalysis & repeat analysis in pivotal study & timely reported to superior for assigned analytical activities.
- ✓ Prepared Report of Pharmacokinetic parameters of drug such as T_{max}, C_{max}, $T_{1/2}$, Area under curve (AUC) for each subjects based on performed bio-analysis on Pilot & Pivotal study samples.
- ✓ Calibrated laboratory equipments such as micro pipette, analytical balance, pH meter etc. in accordance with in house SOPs.
- ✓ Wrote Laboratory Note Books for bio-analytical method validation & maintained log book entries in compliance with internal guidelines.

Jr. Research Associate **Cliantha Research Ltd** **Since Jun'2011-Oct'2012**

- ✓ Worked on Bio-analytical Study Sample Analysis on generic dosage forms of drugs for bioequivalence studies using LC-MS/MS System in conformation to GLP guidelines.
- ✓ Acquired knowledge of operation & maintenance on basic hardware of LC-MS/MS (API 3000) & software (Analyst 1.4.1) & trained to perform assigned tasks.
- ✓ Initiated Pivotal study sample analysis by carrying out experiments such as stock check, blank check, dilution check, bulk spiking of calibration standards as well as Quality Control levels, pre-study, tech validation as per protocol requirements.
- ✓ Gained extensive knowledge of bio-analysis of Study samples using extraction methods such as Solid Phase Extraction method (SPE), Liquid liquid Extraction method (LLE) & Protein Precipitation method (PPT).
- ✓ Completed bio-analysis on Pilot & pivotal study samples as per protocol by using LC-MS/MS (API 3000).
- ✓ Followed master sheet for arrangement of study samples in sequential pattern as per protocol.

- ✓ Carried out Study sample analysis, Incurred sample reanalysis & repeat analysis of bio-analytical samples for assigned projects.
- ✓ Assigned to Calibrate equipments such as micro pipette, analytical balance, pH meter etc. as per established procedures & systems.
- ✓ Completed Analytical Procedure sheets, chemist note book and log book entries as required by protocols and/or SOPs.

Educational Qualifications

- **Master of Pharmacy** in Quality Assurance (2012-2014)
  Gujarat Technological University, Gujarat.
- Qualified GPAT (Graduate Pharmacy Aptitude Test) with AIR #5048 in May'10.
- **Bachelor of Pharmacy** (2006-2010)
  Gujarat University, Gujarat.

Thesis

- Title: Stability indicating Assay Method Development &Assay Method Validation of Perindopril & Indapamide in its Combined Dosage forms by using RP-HPLC method.
- Guide: Dr.Jagdish Kakadiya
- Location: Indubhai Patel College of Pharmacy & Research Center, Dharmaj.

Computing Skills

- Operating Systems: Windows 10,Windows 8,Windows 7,Windows XP, Windows Vista,Wndows 2000.
- Software/Applications : Empower 3 & Empower 1(Waters), LC solution & Lab Solutions (Shimadzu), Microsoft Office 2007, Microsoft Office 2010, MS Word, MS Excel, Powerpoint, MS Access, MS Outlook Express, Internet Explorer, Adobe Reader.

Personal Details

- ❖ Languages Known: English, Hindi & Gujarati
- ❖ Date of Birth: 29th August,1989
- ❖ Sex: Male
- ❖ Nationality: Indian
- ❖ Marital Status: Single
- ❖ Passport # J4539911
- ❖ Preferred Location: Anywhere in India