

# RESUME

**RAJENDRA K. PHADKE**

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Seeking a position in **Management** as.... **Manager-Analytical Research and Development Department for API R&D** in the pharmaceutical and chemical industry. A competent and dedicated manager for ARD API with a **Master degree in Analytical chemistry**, who has over **25** years of experience in the pharmaceutical and Chemical industry (API & Formulation, Manufacture and Technology transfer). He is goal-oriented, has a strong foundation in knowledge and is eager to learn more.

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## ACADEMIC

### BACKGROUND:

- Appear PhD (Analytical Chemistry) from JITU University in 2014.
- M.SC (Analytical chemistry) from Madurai Kamaraj University in 2012
- B.SC (Chemistry) from Shivaji University 1996
- Certification in Chemical and Instrumental Analysis from the Food and Drug Administration, 1999

### Computer Literacy: -

- Passed one year Diploma in Computer Programming with First Class in Dec. 1998.
- Familiar with MS- Dos, Win-XP, MS-Word, Power point, MIS preparation Excel sheet.
- Chemdraw, Scifinder, QSAR (Quantitative Structure Activity Relationship), LIMS, Patent review and publication. Paper review and publication on research journals.

### Publication:

- **Eighteen papers** were published on the multiple research journals of pharmaceutical. The type of paper on the analytical method developments and validation with different instrumental technique. Also review publication on technical pharma guideline.

## STRENGTHS:

- Expertise in creating novel ideas and implementing them using the newest technologies.
- Adaptable, with a strong desire and the perseverance to actively pursue goals.
- Excellent co-ordination and communication skills and effectively oversee group competency.
- Capable of organizing and prioritizing activities to optimize resource utilization, with a logical and organized approach.
- A thorough understanding of the development and validation of analytical procedures in accordance with current regulatory requirements.
- An extensive knowledge for the quality control and quality assurance department.
- A high presence of regulatory audits such as the USFDA, MHRA, TGA, WHO, EDQM, and local FDA
- A hardworking and self-motivated person.

## TECHNICAL EXPERTISE:

- Knowledge and expertise in various instruments such as HPLC, UPLC, LC- Mass, GCHS, GCHS-Mass, ICP-Mass, DSC, TGA, Ion chromatographic, UV-VIS spectroscopy, IR spectroscopy, X-Ray diffraction, Particle Size Analyzer, Auto titrator and Karl fisher, dissolution Apparatus, Polarimeter and osmolarity.
- Analytical method development and validation for the test of Assay and Related substances, Forced degradation, Genotoxic and NDSRIs impurities and its technical review in compliance with the most recent regulatory requirements.
- A scientific evaluation for nitrosamines impurities with the help synthesis and formulation process.
- To perform the Extractables and Leachable studies.
- Responsible for addressing the regulatory queries and its responds within timeline.
- Technology transfer document preparation and arrangement for site readiness.
- Support to regulatory department in the preparation of Common Technical Document (CTD).
- Preparation of a validation master plan and assistance with periodic validation of laboratory instruments and equipment.
- Preparation of working and impurities standard along with characterisation report
- Excellent expertise and experience in analytical techniques used in synthesis, technology transfer from pilot plant to kilo lab,
- A power point presentation on technical topics and regulatory guidelines.
- Review of patent and its evaluations and DMF filing.
- A high presence in the regulatory and vendor audits.

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**EXPERIENCE PROFILE:****1. Manager-Analytical Research and Development–API, Indoco Remedies Limited- Navi Mumbai- Since October.2011 to till date.**

- Responsible to assist the team leader in the analytical method development, method validation and vendor qualification.
- Review of analytical method validation protocol and Report, Technology transfer documents, Study reports, validation master plan and stability study data
- Review of raw material, intermediate, finished products, stability specifications and Analytical technical pack.
- Preparation of technology transfer documents and active involvement within the technology transfer team.
- To assist with process familiarity, lab process demonstration, Cost assessment, vendor selection for key starting material and support to production batch troubleshooting.
- Preparation of working and impurities standard for APIs and its characterization report preparation.
- Review and feasibility of analytical methods and informed to customer relationship manager (CRM)
- Analyze and develop a standard operating process as necessary to ensure GLP compliance.
- Review and Release of third-party sample as raw material, intermediate and finished product on the form 39.
- Implementation and tracking the QMS activities as well as monitoring the DQA activities.
- A high presence in the regulatory and vendor audits.
- Strong presence in the establishing the specifications limit for raw material, intermediate and finished product.
- Power point presentation in front of the management for project development and technology transfer status.

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**2. Assistance Manager–R&D API – Elder Pharmaceutical Limited, Navi Mumbai Since July.2007 to October 2011.**

- Assign daily tasks to group leaders and review the assigned tasks.
- Support to the group leaders for analytical method development as per QbD approach.
- Review of analytical method validation data, protocol, report, technology transfer documents, analytical technical pack, also raw material, intermediate, and finished products specifications.
- Active participation in the technology transfer activity.
- A high presence in the regulatory and vendor audits.
- Preparation and characterization report for working standards and impurities standard.

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**3. Group Leader -FDC Limited. Since August -2002 to July-2007**

- A stability indicating analytical method development for Assay and Related substances for Ophthalmic Solution, Tablets, Capsules, Dry syrup, Oral suspension and Ointment.
- Review and perform the analytical method validation for ophthalmic solution, Tablets, Capsules, Dry Syrup, Oral suspension and Ointment.
- Dissolution method development and validation for tablet and capsule.
- Performing the drug-Excipient compatibility study and Reserve engineer study.
- Preparation and review the analytical method validation protocol and report, Technology transfer protocol and reports and its relevant data.
- Preparation and review of Raw material, intermediate, finished products and stability specifications.
- Responsible for technology transfer to site Quality control department.
- Responsibility for regulatory query responses within stimulated time period.
- A high presence in the regulatory and Client audits at manufacturing site.

- Review of drug product stability study data and inform to formulator for further developmental study.

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**4. Officer Quality Assurance - M/s Hegel Capsule Industries Ltd.  
Since September 2000 to August-2002**

- Maintained a safe working environment by complying company protocol.
- Various records measurement for different product attributes and maintain respective IPQC activity.
- An auditor for the quality control departments and self-inspections.
- Review and approval of MFR, BMR, and BPR.
- Approvals for raw materials, intermediate, finished product and packaging material specification and its release to QC.
- Preparation and review of finished product stability study data.
- SOPs preparation in accordance with GMP guidelines.
- To be follow the QMS system.
- Release of Microbiology tests such as vitamins, calcium pantothenate and vitamin B12, water, and soil.

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**5. Sr. QC Chemist - Para Labs Pvt. Ltd. Since April 1999 to September-2000**

**6. Sr. QC Chemist – Invo Chem Laboratories. Since September 1996 to April -1999**

- Instrumental analysis of Raw material, intermediate and finished product as per Pharmacopoeias IP, BP, USP and vendor supplied method of analysis.
- Finished, product, packing material and cosmetic product analysis as per client supplied method Or ISO method.
- Calibration of instrument like FTIR, UV-Vis Spectrophotometer, Colorimeter, Karl Fischer, Fluorimeter, potentiometer HPLC and GC.
- Spectroscopies method development.

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**PERSONAL DETAILS:**

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|-----------------------|----------------------------------------------------------------------------------------------------------------------------|
| <b>Name</b>           | <b>Rajendra Krishna Phadke</b>                                                                                             |
| <b>Address</b>        | Sai Nishta Co-Operative Housing society, Flat No.205,<br>- PlotNo.80/81,88/89, Sector 6, Nerul (West). Navi Mumbai- 400706 |
| <b>Contact No</b>     | ☐ Resi.09870157945 ☐ Mobile: 9870261006                                                                                    |
| <b>Email ID</b>       | <a href="mailto:rajendraphadk75@gmail.com">rajendraphadk75@gmail.com</a>                                                   |
| <b>Date of Birth</b>  | 2 <sup>nd</sup> June, 1975                                                                                                 |
| <b>Marital Status</b> | Married                                                                                                                    |
| <b>Language Known</b> | English, Marathi, Hindi                                                                                                    |

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**REFERENCE :**

1. Nishikesh Ghorpade : Crescent Pharma limited – Head Quality Assurance  
Cell Number : 9167991978.
2. Vijay Bagul : Medley Pharmaceutical Limited – Head Analytical R&D-Formulation  
Cell Number : 9833618555.