

Pradeep Sharma, Ph.D.

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SUMMARY:

- Ph.D. in analytical chemistry with 27 years of experience as analytical professional in pharmaceutical companies.
- Supported analytical portion for submission of ANDAs, IND and NDAs (505 (b)2).
- Major experience in analytical development for complex oral dosage forms, and limited experience of drug device combinations and controlled delivery injectable products.
- Contributed for two US patents of new drug delivery systems.
- Hands-on experience of Dissolutions, HPLC, GC, LCMS, Raman, IR, DSC, TGA etc.
- Designed and implemented cGMP compliant analytical lab system and participated in USFDA, MCC South Africa, MCA UK inspections.
- Has experience working with CMO/CDMOs.

EXPERIENCE:

Independent Consultant

10/2022-Present

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Provide solutions and technical strategies for successful drug substance and drug product development. Provide clients strategic directions for analytical portion of CMC development, technical problem solving, establishing CMC requirements and development of data packages acceptable to Regulatory agencies for successful drug product development.

Author and review/edit analytical portion of CMC sections for INDs, NDAs, and CTDs.

Amneal Pharmaceuticals New York,
50 Horse Block Road, Brookhaven, NY - 11719, USA
Senior Director – Analytical Research and Development

04/2006-09/2022

I have led an Analytical R&D team of 60+ Ph.D., post graduate and graduate scientists. Responsible for managing early-stage and late-stage analytical development for ANDAs and NDAs (505 (b) 2) submissions.

Collaborate internal and external stakeholders for analytical activities for new product launches, site transfers and CMOs.

I was accountable for execution of reverse engineering, pre-formulation, development of specifications, development of methods, validations, and stability studies of products under development includes vaginal drug delivery system, controlled release tablets based on oros and complex coatings, suspension filled in soft gelatin capsules and powder of suspension.

Indoco Remedies Limited,
166 CS Road, Santacruz (East), Mumbai-400098, India
Principal Research Scientist – Pharma Research Division

12/15/2004 to 01/31/2006

Facilitated the analytical support for product developments and CMC section for ANDA submissions of ophthalmic and solid oral dosage forms.

Wockhardt Limited,
Bandra Kurla Complex, Bandra (East), Mumbai-400051, India
Research Scientist – Pharma Research Division

10/15/2001 to 11/30/2004

Executed analytical development of patentable specialized composition for controlled delivery of anticancer and other molecules including peptide products, micro encapsulated products, in-situ microcarrier forming compositions, etc.

Developed and validated novel analytical methods for estimation of drug encapsulation, impurity profiling, accelerated and real-time in-vitro drug release for parenteral depot formulations.

As a part of a team, analyzed the plasma sample for the efficacy study and residual pellet analysis at injection site for a controlled release depot formulation in an animal model.

Nicholas Piramal India Limited,
67-70 Sector II, Pithampur, District- Dhar, MP- 452 775, India
Manager- Analytical Development and Quality Control

02/10/1995 – 09/29/2001

As a team member of CMO for Allergan, Siegfried, Roche, and Norton Healthcare, involved in method transfer, method validation and stability studies for ophthalmic, solid, and liquid orals. Reviewed and authored numerous laboratory standard operating procedures and test procedures. Supported the resolution of several laboratory and product failure investigations. Coordinated analytical method transfer activity with international collaborative companies.

Internal auditor of ISO 9001, ISO 14001 and GMP audits. Involved in various regulatory audits include- USFDA, ISO 9001, ISO 14001, MCC South Africa, MCA UK, WHO.

EDUCATION:

Ph.D. in Analytical Chemistry from School of Studies in Chemistry, Vikram University Ujjain, India.

M.Sc. with major in Industrial Chemistry from School of Studies in Chemistry, Vikram University, Ujjain, India.

B.Sc. in Chemistry, Zoology and Botany from Nehru College Agar Malwa, Vikram University, Ujjain, India.

PATENTS:

1. Bhagwatwar Harshal, Paithankar Mahesh, **Sharma Pradeep**, Bapat Varada, Mathakiya Ismail, Kadam Chandrashekhar, Yeola Bhushan, '**Sterile gelling agents**', PCT application filed on 10.15.2003 (No-PCT/IB/03/04509); US Patent Application#20060286130.
2. Bhagwatwar Harshal, Paithankar Mahesh, **Sharma Pradeep**, Bapat Varada, Mathakiya Ismail, Kadam Chandrashekhar, Yeola Bhushan, '**Sterile in-situ microcarrier forming gelled polymeric dispersions and processes to manufacture the same**', PCT application filed on 07.01.2004 (No-PCT/IB/2004/000003); US Patent Application#20070003626.