M.Pharm in Pharmaceutics, Working as Manager with Eighteen Years' Experience in Formulation Research & Development Department.

RAMESH ALLADA

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Professional Summary

- Good academic record throughout the career and secured more than 60% marks from secondary level of education to post graduation and competency in various competitive exams.
- Hands of industrial experience in design and development of parenteral products, Tablets, Capsules, Pellet Coating (Wurster Principle), PFOS, and Sachets and for regulatory markets of USA, and Europe.
- Expertise in general Pre-formulation profiling, Pre-clinical formulation development of New Chemical Entities and appreciable understanding on basic physico-chemical properties of molecules form delivery perspective and their manipulation for better delivery.
- Well versed with solubilization techniques like Cyclodextrin complexation, Solid dispersions, Amorphous generation / stabilization and Emulsion based formulation of poorly water soluble molecules.
- Have fair knowledge about salt selection, solid state characterization and solid phase manipulation of poorly water soluble molecules.
- Have good knowledge in various guidelines like FDA, Europe and ICH.
- Handled various equipment belonging to Tablets, Capsules and Lyophilized injection dosage forms.
- Handled various equipment related to technologies like Direct compression, Wet granulation (High shear/Low shear), Pellet coating, Dry granulation, Spray drying, Particle size reduction/measurement, and acquainted well with the applications of DOE, PAT Tools, DSC, pXRD, TGA and IR spectroscopy.
- Well acquainted with the documentation processes & proceeding required for technology transfer related activities of dosage forms and have good knowledge of working under cGMP, cGLP conditions.
- Very good understanding at the development cycle for generic dosage form development including excellency in regulatory requirements, patent understanding for designing of formulation strategies.
- Deep knowledge in core pharmacy related subjects like industrial pharmacy, development pharmacy, pharmacokinetics and physical pharmacy.

Technical Skills

- Parenteral dosage form development (Including solutions, dry powders and Lyophilized products) of the active ingredients from lab scale to exhibit stage for regulatory submission of US and EUROPE.
- Development of practical, predictable, stable and bioequivalent formulations of pharmaceutical dosage forms for regulatory submission to US, and Europe markets.
- Immediate release tablet, capsule, PFOS, and Sachet dosage form development of active ingredients from lab scale to exhibit stage for regulatory submission of US, and EUROPE by various manufacturing approaches like wet granulation, direct compression and dry granulation.
- Controlled release tablet and capsule dosage form development of active substances by utilizing matrix systems, diffusion systems and multi-particulate systems (utilizing Wurster principle) for regulatory submission of US, and EUROPE.
- Application of Design of Experiments (DOE), Quality by Design (QbD) principles & PAT (Process Analytical Technology) tools for the development of robust formulation and scalable manufacturing processes.
- Pre-clinical formulation development by solubilization approaches and solid state manipulation of NCE for pharmacokinetic, microbiological and toxicological studies.
- General pre-formulation profiling and dosage form development of NCE for clinical trials.
- *In-situ* single pass rat intestinal permeability studies of molecules and comparing their permeability with FDA standards.
- Preparation of SOP's/guidelines/flowcharts, and selection of equipment for the lab.

Current Work Profile:

- Organize, coordinate, motivate and control operational objectives, tasks and concrete actions of subordinates (Pharmaceutical formulation specialist and pharmaceutical formulation technologist).
- Manage the formulation development work of solid oral dosage forms for Europe market all the way from strategy through feasibility studies to submission batches.
- Support the quality-by-design work flow concept and to make sure of formulations fulfilling all the regulatory criteria for the chosen markets and within the allotted time frame.
- Support the product validation and launch efforts of the production sites involved with the products developed and answer deficiency questions from regulatory authorities.

- Liaising with operations and securing manufacturing slots and ensuring for the smooth production of submission and other GMP batches.
- To interpret pilot bio & pivotal study results and draws conclusions.
- Formal and informal collaboration with the professional individuals or groups outside the company according to the mandate of the company.
- To prepare & attend the project reviews and taking necessary actions accordingly.
- To facilitate for initiation, review and approval of SOPs related to machinery / general systems as per timely requirement.
- To ensure good communication and intra-departmental collaboration.
- Monitor team performance, salary bonuses proposals and propose for specific training sessions.

Education

- **College of Pharmaceutical Sciences, MAHE, Manipal, Karnataka, India 2003**
  Master of Pharmacy 73.55%

Professional Experience

- *Junior Scientist, Pre-clinical formulation,Dr.Reddy's Laboratories, India.* **Aug 2003 – Apr 2006**
- *Research Associate – IV, FR&D, Aurobindo Pharma Ltd, Hyderabad, India.* **Apr 2006 – Aug 2009**
- *FR&D, ABDIIBRAHIM Pharmaceuticals, Istanbul, Turkey.* **Aug 2009 – Mar 2012**
- *Senior Manager, FR&D, Aizant Drug Research Solutions, Hyderabad, India.* **Apr 2012 – Oct 2014**
- *Research Associate (A-M), FR&D, Torrent Research Centre, Ahmedabad, India* **Sep 2015 – Oct 2017**
- *Formulation Development Manager, LabormedAlvogen Pharma, Romania* **Oct 2017– present**

Computer Literacy& Other Activities

- Have advanced knowledge about general operating systems of the computer like MS word, excel and power point.
- Operated application softwares like Pallas 3.1, and ACD labs.
- German language course of elementary level-I from Deutsche- Indische gescellschaft, Manipal
- German Language certificate course-Max Muller Bhavan-Goethe Institute.

Strengths

- Good observation and analytical reasoning with strong oral and written communication skills along with Interpersonal, management and leadership abilities.
- Keen learner and a strong believer in teamwork and integrity.
- Adaptable to change comfortably and brings closure to work in a timely fashion.
- Maintaining familiarity with current scientific literature.
- Motivated self-starter with a can-do attitude and have practical Hands-on bench work experience.

Publications

- A. A. Shirwaikar., and **A. Ramesh.** Fast disintegrating tablets of Atenolol by dry granulation method. Indian J. Pharm. Sci., July-August 2004, 422-426.
- "Pharmaceutical composition of Febuxostat" patent applied for India with application number 3125/CHE/2012.

Projects undertaken

1. Intravenous formulation development of an Anti-infective category NCE molecule at 50 mg/ml concentration using complexation with Hydroxy Propyl-β-Cyclodextrin. Hyderabad, India.
2. Formulation development of lyophilized powder for injection of anti-bacterial drug combination product **by patent challenging strategy**. Hyderabad, For US and Europe markets.
3. Formulation development of lyophilized powder for injection of anti-bacterial category product. Hyderabad, For US and Europe market
4. Formulation development of dry powder injectable of β-lactam antibiotics for intravenous and intramuscular administration for US market, Hyderabad, India.
5. Formulation development of injectable solution dosage form of novel antimicrotubule agent. Hyderabad, For Europe market.
6. Formulation and evaluation of fast dissolving Atenolol tablets as a part of M. Pharmacy program. Manipal.
7. Formulation development of an extended release tablet of an anti-anxiety drug **by patent challenging strategy.** Hyderabad, For US market.

8. Formulation development of **First-To-File** capsule dosage form of delayed release pellets of an anti-depressive drug. Hyderabad, For US and Europe markets.
9. Formulation development of an immediate release film-coated tablet dosage form of an anti-epileptic drug., Istanbul, for Europe market.
10. Formulation development of film coated immediate release tablet dosage form of an antiviral drug **by patent challenging strategy.,** Istanbul, for Europe market.
11. Formulation development of capsule dosage form of extended release pellets of an anti-inflammatory drug., Istanbul, for Europe market.
12. Formulation development of multi-unit tablet capsule dosage form of extended release pellets of a beta blocker category drug., Istanbul, for Europe market.
13. Formulation development of capsule dosage forms of delayed release pellets of a proton pump inhibitor drugs. Hyderabad for US market.
14. Formulation development of PFOS dosage form of **THREE** Cephalosporin category molecules. Hyderabad, For Europe market.
15. Formulation development of immediate-release tablet dosage form of **FIVE** Cephalosporin category molecules. Hyderabad, For Europe market.
16. Formulation development of film coated immediate release tablet dosage form of drug for treatment of premature ejaculation (PE). Hyderabad, For Europe market.
17. Formulation development of film coated immediate release tablet dosage form of an anti-arrhythmic drug. Hyderabad, For US market.
18. Formulation development of film coated immediate release tablet dosage form of a phosphate binding drug **by patent challenging strategy**. Hyderabad, For Europe market.
19. Formulation development of film coated immediate release tablet dosage form of drug for urinary inconsistency. Hyderabad, For Europe market.
20. Formulation development of extended release bilayer fixed dose combination of anti-hypertensive drug. Hyderabad, For Europe market.
21. Formulation development of film coated immediate release tablet dosage form of Xanthan oxidase inhibitor drug **by patent challenging strategy**. Hyderabad, For US market.
22. Formulation development of extended release tablet dosage form of antidiabetic drug. Hyderabad, For US market.
23. Formulation development of capsules dosage form of hyper-lipidemic drug. Ahmedabad, For US & Europe markets.
24. Formulation development of **TWO First-To-File** immediate release film coated tablets. Ahmedabad, For US & Europe markets.
25. Formulation development of capsule dosage form of delayed release pellets of a calcium ion influx inhibitor drug. Ahmedabad, for US & Europe markets.
26. Development of a discriminating intrinsic dissolution method for evaluation of phase transformation of an amorphous NCE during dissolution. Hyderabad.
27. Preparation, characterization and stabilization of an amorphous NCE, a novel COX-2 inhibitor. Hyderabad.
28. Solid dispersions of NCE for dose proportional pharmacokinetics in rats. Hyderabad.
29. Development of emulsion & micro emulsion based formulations for high log P molecules (log P>5.0) for enhancing the oral bioavailability of NCE's from CETP inhibitors category. Hyderabad.
30. Formulation development of film coated immediate release tablet dosage form of antiplatelet agent drug category molecule for Europe market, Bucharest, Romania.
31. Formulation development of film coated immediate release tablet dosage form of anticoagulant drug category molecule for Europe market, Bucharest, Romania.
32. Formulation development of uncoated tablet dosage form for hepatic function improvement for Europe market, Bucharest, Romania.
33. Formulation development of film coated immediate release tablet dosage form of cognitive-enhancing drug category molecule for Europe market, Bucharest, Romania.

References

Available on request