Sudha Sivakumar

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PROFILE

[3 years experienced in drug delivery (Technology Transfer) + 4 years experienced in academics]

Pharmaceutical formulation professional proficient worked under technology transfer (Product transfer according to ICH and ANDA guidelines) in leading pharmaceutical industry. Experienced with solid oral dosage forms, of both OTC & prescription products. Experienced in development, manufacturing and documentation of generic products. Successfully technology transferred products from R&D to commercial scale. Working as Associate Professor in department of Pharmaceutics in a renowned college.

EMPLOYMENT

PAST

March 2009 – October 2011

Junior scientist in Technology transfer

US & EU Generics drug product Manufacturing

Actavis Pharma manufacturing Pvt Ltd, Chennai. India.

June 2016 – September 2016

Worked as Pharmacovigilance Associate II in Oviya Medsafe Private Ltd.

PRESENT

January 2017 – Present

Working as Associate Professor in Karpagam College of pharmacy, Coimbatore.

DRUG PRODUCT

- Responsible of New product transfers from Research & Development either bench/pilot size to the manufacturing site. In charge of developing manufacturing process and to supply clinical studies
- Proficient in scientific & accurate execution of Optimization, Exhibit and Scale up batches for product transfer
- Handling of Granulation process (Dry & Wet)
- Handling of Compression Machine (Single rotary), Fluidized bed drying, Film Coating & Rapid Mixer Granulator with accomplished knowledge on their operating principles
- Acquired knowledge on tooling's and tool drawings

- To plan the batch sizes for Process optimization and exhibit batches to meet the equipment capacities and regulatory requirements.
- Optimization of existing process for the given formulation in terms of operations, time, materials inputs and yields
- Evaluation of the data generated during optimization, exhibit, scale up and Validation batches
- Coordinating skills with FR&D, Production, QA, QC, AR&D, Stability and other related departments for smooth technology transfer of new products and troubleshooting in existing formulations
- Knowledge of theoretical basis of formulation and capability to troubleshoot the process
- Having familiarity on cGMP practices
- Budgeting, planning & procuring equipments and materials required for process optimization batches
- Knowledge of process improvisation and proficiency in process validation
- Determination of critical process parameters
- Review of literature search
- Preparation of Placebo batches for method verification, method validation and stability purpose
- Handling of change controls, Deviations and investigations. Providing resolutions in case of process failures.
- Theoretical basics on dosage form design, advances in drug delivery system, Pharmacokinetics, Bioavailability and bioequivalence studies

DOCUMENTATION

- ***Protocols*** (Process Optimization Protocol, Process Evaluation Protocols & Process Validation Protocols)
- ***Master Manufacturing Records***
- ***Batch Manufacturing Records (***Optimization, Exhibit, Scale up and commercial batches)
- ***Reports*** (Process Optimization Report , Process Evaluation Report & Process Validation Report)

PHARMACOVIGILANCE

Completed 3 months internship on Pharmacovigilance. Having basic knowledge on ICSR, PSUR and MedDRA coding

ACADEMICS

Working as Associate professor on the department of pharmaceutics.

RESEARCH WORKS

M.Pharm **:**'Stabilization, formulation and evaluation of acid labile Lansoprazole tablets by Cyclodextrin complexation'

B.Pharm **:**'Study of antidiabetic effect of Levofloxacin and its synthetic derivative'

EDUCATION

S. No.	Examination Passed	Board/University/ Organizing Institute	Year	% of Marks
1.	**Master of Pharmacy [Pharmaceutics]**	Dr.MGR Medical University, Chennai	2006 – 2008	82.17
2.	**Bachelor of Pharmacy**	Dr.MGR Medical University, Chennai	2002 - 2006	72.10
3.	**HSC**	Department of Government Examinations, Chennai	2002	90.25
4.	**Matriculation**	Department of Government Examinations, Chennai	2000	85.09

PERSONAL DETAILS

Nationality : Indian
Date of birth : 19th July 1984
Gender : Female
Marital Status : Married
Languages Known : English, Tamil & Hindi
Extra curricula's : Reading Books on science fiction, philosophy, stories & motivation.
Music, Drawing and Gardening
Seminars : Attended **CPhI** and **P-MEC** scheduled on 30 November, 2010 at Mumbai.
Attended 57th Indian Pharmaceutical Congress, Hyderabad in December, 2006
Registration : Registered Pharmacist of Pharmacy Council of India (Reg. No. 12526 A1)
Job Interests : Pharmacovigilance, Pharmacokinetics, Regulatory Affairs
Intellectual Property Management & product Selection, content writing
Strengths : Confident, Optimistic and soft spoken with good communication Skills.
Enthusiastic learner with eager for new technologies and innovations.
Possessing Strong ability to manage multiple functions while staying up to date with latest trends in industry.
Computing Skills : Proficient in MS Excel, MS office, MS Power Point.