CURRICULUM VITAE

Dr. Suresh Reddy. Yelampalli

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Career Objective:

Develop my career in Novel Analytical Research and Development where I will be a valuable quality team member by contributing quality ideas and work for an organization where there is an ample scope for individuals as well as Organization growth.

Professional Summary:

I have been 12.2 years of Experience in analytical Research and development in Quality control department. I have been developed Novel-Stability indicating methods by using RP-HPLC, NP-HPLC, UPLC, UV spectrophotometer and LC-MS techniques and having a rich experience on solid orals, semi-solid dosage forms, hard gelatin capsules, Ophthalmics and Injections.

Professional Synopsis:

S.No	Position	Name of the Company	Period
1	Asst. Director QC	Less laboratories Inpha-Medis Annaba region, Algeria	15th May 2022 to till date
2	Manager QC	**Rus Bio Pharm Group (PSK Pharma),** Dubna city, Moscow Region, Russia	17th Dec 2019 to 29th Apr 2022
3	Deputy Manager QC	**Suven Life Sciences,** Pashamylaram, Hyderabad, Telangana, India	08thSep 2016 to14thDec 2019
4	Officer (AR&D)	**NATCO Pharma Ltd,** Kothur, Hyderabad, Telangana, India	17thSep 2014 to 05thSep2016.
5	Chemist-L3 (AR&D)	**Optimus generics Ltd** Jadcherla, Telangana, India	19thJul 2013 to 6thSep 2014.
6	Jr. Executive (AR&D)	**Vivimed labs Ltd** Jeedimetla, Hyderabad, Telangana, India	26thMay2010 to 18th Jul 2013

Education Qualifications:

Ph. D (2014 - 2020)	:	**Doctor of Philosophy** (Ph.D) in Analytical Chemistry from K L University, Vijayawada, Andhra Pradesh, India. Thesis entitled **"Analytical Method Development and Validation for the Determination of Impurities in Various Pharmaceutical Drugs and Finished Dosage forms by using Sophisticated Analytical Techniques"**
Post – Graduation (2008 - 2010):		**Master of Sciences** (M. Sc) in Chemistry from S.V. University, Andhra Pradesh, India.
Graduation (2005-2008)	:	**Batchelor of Science** (B. Sc) in Bio-technology, Botany and Chemistry, S. K. University Andhra Pradesh, India.

Employment Chronicle:

Less Laboratories Inpha-Medis, EUMA & ROW approved based company

Current Assignments are:

- Planning and monitoring of analytical related activities in Quality control department.
- Shift management of team members.
- Responsible for analytical method development and validations of different dosage forms like Tablets, Capsules, Oral solutions, Nasal sprays, DPI and Injectables as per regulatory standards.
- Monitoring and review of comparison studies of OSD and Injectable products against reference products (Bio and pop bio studies).
- Responsible for Process Qualification batches analysis planning and submission of COA's to Registration department in time.
- Responsible for Commercial batches analysis planning (In-Process, Finished and Stability) and submission of COA's to Registration department in time.
- Preparation and review of Analytical Method validation Protocols, Data sheets & Reports.
- Responsible for the Regulatory authority & Customer queries.
- Review and approve Laboratory Investigations (OOS and OOT) & assist in problem solving.
- Review and approval of Procurement of Pharmacopeia Reference standards, impurities standards.
- Review of Finished product procedures (STP/MOA) and specifications for correctness against the current pharmacopeias and ICH quality guidelines.
- Review and approval of SOP's (Standard Operating Procedures) and test methods along with change controls.
- Tracking CAPA & its effectiveness.

- Responsible for GLP, cGMP and Data integrity.
- Responsible for the new Instruments procurement, up gradations & necessary qualification.
- Review of all laboratory data for conformance to cGMP regulations.
- Responsible for hiring new joiners and Analyst Qualifications and training evaluation.
- Review of laboratory solution logbooks, equipment daily calibration and monitoring logs for adherence to SOPs.

Rus Bio Pharm Group (PSK Pharma-Russia), EUMA and ROW approved based company

- Planning and monitoring of analytical related activities in Quality control department.
- Shift management of team members.
- Responsible for analytical method development and validations of different dosage forms like Tablets, Capsules, Oral solutions and Injectables as per regulatory standards.
- Responsible for analytical method transfers from R&D to quality control departments and another sites.
- Expertise in conducting Forced degradation studies and Pre-Formulation studies.
- Responsible for conducting comparison studies of OSD and Injectable products against reference products (Bio and pop bio studies).
- Responsible for Process Qualification batches analysis planning and submission of COA's to Registration department in time.
- Responsible for Commercial batches analysis planning (In-Process, Finished and Stability) and submission of COA's to Registration department in time.
- Responsible for the Regulatory & Customer queries.
- Preparation and review of Analytical Method validation Protocols, Data sheets & Reports.
- Review and approve Laboratory Investigations (OOS and OOT) & assist in problem solving.
- Procurement & management of Pharmacopeia Reference standards, impurities standards and review against the online catalogs for its validity.
- Preparation and review of Analytical Method validation Protocols, Data sheets & Reports.
- Preparation of Assay, related substances, dissolution and cleaning method development reports.
- Review of Finished product procedures (STP/MOA) and specifications for correctness against the current pharmacopeias and ICH quality guidelines.
- Review and approval of SOP's (Standard Operating Procedures) and test methods along with change controls.
- Tracking CAPA & its effectiveness.
- Responsible for GLP, cGMP and Data integrity.
- Responsible for the new Instruments procurement, up gradations & necessary qualification.

- Review of all laboratory data for conformance to cGMP regulations.
- Responsible for hiring new joiners and Analyst Qualifications and training evaluation.
- Responsible for project costing estimation from analytical side.
- Review of laboratory solution logbooks, equipment daily calibration and monitoring logs for adherence to SOPs.

Suven Life Sciences-India (US-FDA and ROW approved based company)

- Planning and monitoring of analytical related activities.
- Shift management of team members.
- Responsible for analytical method development and validations of different dosage forms like Tablets, Capsules and Oral solutions as per regulatory standards.
- Responsible for analytical method transfers from R&D to quality control departments and another sites.
- Responsible for conducting comparison studies of OSD products against reference products.
- Responsible for Process Qualification batches analysis planning and submission of COA's to regulatory department in time.
- Responsible for Commercial batches analysis planning (In-Process, Finished and Stability) and submission of COA's to regulatory department in time.
- Responsible for the regulatory & customer queries.
- Preparation and review of Analytical Method validation Protocols, Data sheets & Reports.
- Review of PDR documents, In process analysis data sheets & Method development Reports.
- Review of Finished product procedures (STP/MOA) and specifications for correctness against the current pharmacopeias and ICH quality guidelines.
- Preparation & revision of SOP's (Standard Operating Procedures), by raising necessary change controls.
- Handling Change controls, Deviations, Incidents, OOS and OOT.
- Tracking CAPA & its effectiveness.
- Responsible for GLP.
- Responsible for the new Instruments procurement, up gradations & necessary qualification.
- Responsible for new joiners Analyst Qualifications and training evaluation.
- Review of all laboratory data for conformance to cGMP regulations.
- Review of laboratory solution logbook, equipment daily calibration and monitoring logs for adherence to SOPs.
- Responsible for project costing estimation from analytical side.

NATCO Pharma Ltd-India (US-FDA, EDQM, ANVISA, TGA and ROW approved based company)

- Analytical method development and validations of different dosage forms like Tablets, Capsules Oral solutions and Injectables as per regulatory standards.
- Responsible for Process Qualification batches analysis planning and submission of COA's to regulatory department in time.
- Analytical method transfers from R&D to quality control departments and another sites.
- Hold time studies for injectable bulk solutions.
- Execution of Pop-Bio studies for injections.
- Handling USFDA queries and customer queries
- Preparation of Assay, related substances, dissolution and cleaning method development reports.
- Detoxification studies.
- Preparation and execution of method validation protocols and reports as per EU, WHO, USFDA & ICH guidelines.
- Calibration of HPLC and Dissolution instruments.
- Raw material analysis.

Optimus generics Ltd-India (US-FDA, EUMA, MHRA, TGA and Health Canada approved based company)

- Analytical supporting for formulation activities.
- Effectively involved in Analytical method development and validations of different dosage forms like Tablets, Capsules and Oral solutions.
- Analytical method transfers from R&D to quality control departments and another sites.
- Preparation of Assay, related substances, dissolution and cleaning method development reports.
- Excipient compatibility studies.
- Handling MHRA regulatory queries and customer queries
- Effectively involved in method transfers from AR&D to Quality control department.
- Preparation and execution of method validation protocols and reports as per EU & ICH guidelines.
- Calibration of HPLC and Dissolution instruments.
- Maintaining laboratory notebook to meet with good document practices.
- Responsible for project costing estimation from analytical side.

Vivimed labs Ltd-India (ROW approved based company)

- Calibration of different instruments like, Analytical balances, pH meter, KF-Titrator, UV, HPLC and Dissolution instruments.

- Preparation of Volumetric solutions as per ISO standards.
- Supporting analysis for formulation activities.
- Involved in Assay and impurity analysis of Ophthalmic, OSD and injectables products method development activities.
- API and finished product method development by HPLC.

Hands on Experience In:

- Experience in GMP Quality Control Laboratory Management.
- Scientific knowledge of stability indicating method development on HPLC and UPLC.
- Knowledge in Analytical method development, Method verifications and method validations for generic products and involved in analytical method transfer activities and another sites.
- Experience in Quality control activities like releasing of raw materials, In-process, finished product and stability analysis for Qualification batches and Commercial batches.
- Handling & Investigations of QMS activities and Implementations of CAPA.
- Equipment qualifications and requalification's
- Implementation of cGMP, GLP and New lab set-up.
- Conducting internal audits.
- Hiring new joiners and their Analyst Qualifications and training evaluation.
- Worked on oral solid formulations, suspensions, Ophthalmics and Injectables.
- Worked on Oncology and OTC products.

Strengths and Achievements:

- Developed Related substances, Assay, Residual content estimation, Dissolution methods, Detoxification methods for different formulations for more than 100 products.
- Having good exposure in regulatory queries for both Solid orals and Injectables.
- Having good knowledge in Forced Degradation studies.
- Performed the compatibility and dilution studies for Injectables and submitted to Regulatory agencies.
- Successfully migrated the methods from HPLC to UPLC and H-Class.
- Handled Regulatory Queries from USFDA, MHRA, EU MA and other regulatory agencies and from Customers.
- Having ability to act independently.

Instruments Familiar:

- WATERS (ALLIANCE-2695) HPLC with PDA/ UV Detector.
- WATERS H-Class and Acquity UPLC
- Agilent (1260 infinity series) HPLC with VWD/DAD Detector.
- SHIMADZU (LC2010) with PDA/UV Detector.

- Dissolution instruments. (Lab India) & (Electro Lab)
- UV Spectrophotometer.
- Osmometer and Densitometer,
- LAF, LBPC and Particulate matter
- Clarity instrument, Hunter-lab color measurement instrument

Known HPLC Software's:

- EMPOWER-2
- EMPOWER-3
- LC-SOLUTIONS
- EZ-Chrome
- Open Lab

Research Publications:

- Development and Validation of UPLC method for determination of Lamivudine impurity profile in tablets in *'Asian journal of chemistry'* vol.30, No.5 (2018), 1065-1069.
- Analytical method validation for the determination of Tetrabutylammonium bromide content in Daclatasvir dihydrochloride by LC-MS/MS in *'Journal of global pharma technology'* 2019, Vol.11, Issue.01, 05-12.
- Development and validation of Genotoxic impurity in Esomeprazole Magnesium Trihydrate Active Pharmaceutical Ingredient by LC-MS/MS in *'Indian journal of Pharmaceutical education and Research'*, Oct-Dec 2019, Vol 53, No. 4(suppl): S642-S649.
- Analytical method development and Validation of Tinidazole tablets related substances by RP-HPLC in *'Journal of global trends in pharmaceutical Sciences'*, 2018; 9(1):4940-4950.
- Suresh Reddy. Yelampalli, J. V. Shanmukha Kumar, Useni Reddy Mallu. Development and Validation of HPLC Method for determination of Decitabine impurity profile in Decitabine for Injection 50mg/vial. '*Research J. Pharm. and Tech'*. 2019; 12(4):1885-1894.

Conferences attended:

- Faculty Development Programme on "Research Methodology" from K L University, Vijayawada campus held during 13th to 16th July 2014.
- International conference on pure and applied chemistry "IconPAC-2019: Recent advances in chemical sciences" from K L University, Vijayawada campus held during 8th to 9th March 2019.

Personal Profile:

Father's Name	: Y. Venkata Ramana Reddy
Date of Birth	: 2nd July 1987
Marital Status	: Married
Languages Known	: English, Telugu and Hindi.

Permanent Address : S/O Y. Venkata Ramana Reddy, Munagala (VIL), Nandyal (MDL), Kurnool (DIST), Pin-518511, Andhra Pradesh, India

Declaration:

The above stated information is factually correct to the best of my knowledge.

Dr. Suresh Reddy Y

Date:

Products handled:

OSD Products	
1. Molnupiravir tablets	2. Nirmatrelvir tablets
3. Favipiravir tablets	4. Tofacitinib film coated tablets
5. Deferasirox Film coated tablets	6. Fosampranavir film coated tablets
7. Etravirine tablets	8. Rivaroxaban film coated tablets
9. Apixaban tablets	10. Aprepitant capsules
11. Eltrombopag film coated tablets	12. Vildagliptin tablets
13. Lacosamide tablets	14. Sitagliptin tablets
15. Macitentan tablets	16. Sapropterin dispersible tablets
17. Miglustat capsules	18. Ritonavir capsules and tablets
19. Apremilast	20. Dabigatran capsules
21. Molnupiravir tablets	22. Dimethyl fumarate capsules
23. Favipiravir tablets	24. Lopinavir + Ritonavir tablets
25. Cinacalcet film coated tablets	26. Everolimus tablets
27. Deferasirox dispersible tablets	28. Sofosbuvir tablets
29. Imatinib mesylate capsules	30. Sirolimus tablets
31. Glycopyrrolate tablets	32. Allopurinol tablets
33. Nitazoxanide tablets	34. Cuprimine capsules
35. Phytonadione tablets	36. Chloroquine phosphate tablets
37. Fenoprofen calcium tablets	38. Meloxicam Oral suspension
39. Sulfasalazine tablets	40. Amantadine HCL capsules
41. Levodopa+ Carbidopa+ Entacapone tablets	42. Trientine HCL capsules
43. Tolcapone tablets	44. Cetirizine tablets
45. Amlodipine tablets	46. Carbidopa+ Levodopa tablets
47. Diclofenac tablets	48. Levocetirizine
49. Telmisartan + Hydrochlorothiazide tablets	50. Telmisartan +Amlodipine tablets
51. Lamivudine tablets	52. Daclatasvir dihydrochloride tablets
53. Tinidazole tablets	54. Olmesartan +Amlodipine tablets
55. Teriflonamide film coated tablets	56. Carbidopa+ Levodopa + Entacapone tablets
Injections	
1. Voriconazole	2. Omeprazole
3. Anidulafungin	4. Micafungin
5. Rabeprazole	6. Famotidine
7. Fosaprepitant	8. Azacitidine
9. Levosimendan	10. Carfilzomib
11. Esomeprazole	12. Fulvestrant
13. Decitabine injection	14. Bendamustine