

KUMAR SUMAN
M.PHARM (PHARMA CHEMISTRY)
PGDP IPACKAGING TECHNOLOGY
IIP MUMBAI

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18 plus yrs of rich experience in Pharmaceutical Packaging Development covering Injectables & Drug device combination Products and Ophthalmics as well shop floor experience of packaging solid Oral dosage forms liquids & ointments.

CAREER HIGHLIGHTS



MACLEODS PHARMACEUTICALS PVT.LTD (MUMBAI)

As AGM, Head Packaging Development (Injectables & Medical Device Development)
(JULY-2022 – TILL DATE)



SUN PHARMACEUTICAL INDUSTRIES LIMITED (VADODARA)

As Manager-I, Packaging Development (Injectables & Medical Device Development)
(AUG-2016----JULY2022)



WOCKHARDT RESEARCH CENTRE AURANGABAD.

As Research Scientist, Packaging Development (Injectables & Ophthalmics)
(DEC-2014-----JULY 2016)



AGILA SPECIALTIES PVT. LTD. BANGALORE (MYLAN PHARMACEUTICALS INC)

As Senior Executive, Packaging Development Cell (Injectables & Ophthalmics)
(JUNE 2012-----NOV 2014)



DR. REDDY'S

DR. REDDY'S LABORATORIES LIMITED, HYDERABAD

As Junior Manger Packaging Operations (FTO-III) (SOLID ORALS & LIQUIDS)
(MARCH 2010----- MAY 2012)



TORRENT PHARMACEUTICALS LTD. BADDI (Himachal Pradesh)

As Senior Executive Packaging Operations. (SOLID ORALS & LIQUIDS)
(OCT 2005---MAY 2009)

JOB PROFILE [CURRENT]

MACLEODS PHARMACEUTICALS LIMITED. R&D MUMBAI

Heading Packaging Development Department (Injectables & Medical Device)

Leading Packaging Development team for the Development of products packaging for domestic, semi-regulated and regulated markets for R&D, Exhibit/stability & commercial.

- Lead the Team Device Functionality Tests and for preparing Regulatory Submission Packages (Device History File or DHF) for combination products. Fully implement Regulatory Guidelines such as ISO 11608, ISO 13485, ISO 14971, ISO 11040, FMEAs, Risk Management/Control, Human Factor Equivalency Studies, and Response to queries from Drug Authorities
- Define strategy for Drug Device Combination Products (DDCP) and align across functions such as Business Development, Intellectual Property (IP), Portfolio, Formulation, Quality, Regulatory, & Manufacturing.
- Develop & execute end-to-end Packaging Solutions across all formats including Auto Injectors, PEN Injectors, Prefilled Syringes, Vials, Ampoules, Cartridges etc., in partnerships with Design teams, Prototype Suppliers, and Manufacturers (of Devices, Cartridges, PFS, Vials, Ampoules, Rubber/Plunger Stoppers etc.)
- Review and approval of Innovator analysis, Pack proposals, Specification, MOA, SOPs, MPC, MPCR, Risk assessments, Trade dress, equivalencies, shipping study, artwork, BOM, Change part & packaging instrument qualification at R&D .
- Alternate vendor material analysis and specification equivalency.
- Machine trial protocols and report preparation. Various study on packing material-protocols and report preparation
- In house Device Threshold Analysis Report & Comparative Use related Risk Assessment Controlled correspondence with FDA.
- Initiation of In house Device assembly & testing machine for Pen Device and Auto injectors.
- Packaging Development of Ophthalmic Drug Products for US/EU & Domestic Markets.
- Development of Nasal Spray, Nebulizers & Metered Dose Inhalation(MDI) products for US ANDA filing.
- Experience in validating, & implementing various Primary Packaging Lines, Device Assembly Lines, Secondary & Tertiary Packaging Lines in partnerships with Engineering Team and Equipment Suppliers. Achieve Material-Machine Interfaces, with maximum efficiency & productivity.
- Develop, validate, & implement various Packaging Analytical & Laboratory Testing Equipment and Operating Methods.
- Technology Transfers for Injectable & Medical Devices like Drug Device Combination Products, Vials, Ampoules, etc.
- Overall Project support for New Sterile Facility for Injectables for US products at Jammu (End to end support in selection of Packaging Machinery as per specifications and Plant Layout for Liquid, Lyophilized and complex Injectable products.



(JUL-2022
TILL DATE)

JOB PROFILE [PREVIOUS]

Sun Pharmaceutical Industries Limited Baroda(R&D):

Expertise in Development of Packaging components: *(End to end support in Development of Packaging material from Innovator Characterization (RLD), filling of Exhibit batches, clinical studies to commercial Launch)*

- ▲ GLASS VIALS
- ▲ GLASS AMPOULES
- ▲ RUBBER STOPPERS
- ▲ NASAL PUMP ACTUATORS
- ▲ HDPE CONTAINERS
- ▲ OPHTHALMIC CONTAINERS & CLOSURES (PRES FREE)
- ▲ NEBULISERS (Plastic LDPE)
- ▲ ALU FLIP OFF SEALS
- ▲ BLISTER FILMS & FOILS
- ▲ PREFILLED SYRINGES
- ▲ COC & COP SYRINGES & VIALS
- ▲ MDETERED DOSE INHALATION (MDI)
- ▲ INFUSION BAGS
- ▲ CARTRIDGES
- ▲ PEN DEVICES (Disposable & reusable)
- ▲ AUTOINJECTORS

Regulatory Filing Activities

- ▲ Device Performance & Functionality studies on UTM as per ISO11608, ISO13485, ISO11040
- ▲ Preparation of Threshold Analysis report & Use Related Risk Assessment for Drug Device Combination products & Devices.
- ▲ FDA Controlled correspondence for Pen device ANDA suitability and device finalization.
- ▲ Preparation & circulation of Design History Files (DHF) for Drug Device Combination Products.
- ▲ Providing all vendor related Documents, declarations & Letter of Authorization for Packaging Materials for ANDA Submissions & Europe Filing.
- ▲ Addressing ANDA Deficiency & Queries of all other markets.
- ▲ Support in Variation Filing documents & post Approval changes (PAS, CBE-30 & CBE-0)

Product Launch Support & Commercial Packaging Development

- ▲ Working closely with site Project Team for Launch support for Injectable Products
- ▲ Finalizing Packaging Machines Line Layout as per Product Requirement
- ▲ Approval of Machine Layout Drawings for Blister and Autocartinator.
- ▲ Selection of common change Parts as per product Pack size, line speed and Layout.
- ▲ Support in Automation of Launch Products.
- ▲ Release of Commercial Pack styles to Plant along with BOM Quantities.

Packaging Innovation & Quality Improvement:

- ▲ RFS to RTU Migration for Elastomeric Closures for Injection products.
- ▲ Implementation of cost effective Low Migration Labels for Semipermeable containers
- ▲ Develop & Implement innovative carton design for IP infringing Products.
- ▲ Development of Dual Labels and foam labels to reduce breakage & Market complaints.
- ▲ Development of Treated Glass vials and ampoules for buffer free injections



(AUG-2016
JULY 2022)

JOB PROFILE [PREVIOUS]

Wockhardt Research Centre Aurangabad:

Packaging Design & Development of Injectable & Sterile Ophthalmic Products

- ▲ For ANDA submissions (US/EU).
- ▲ Injectable CRI (Controlled Release Formulations) for NDA Submission (Global).
- ▲ NCE (New chemical Entities) for NDA Submission (Global) .
- ▲ Sterile Ophthalmic Products(US/EU)
- ▲ Inhalation Dosage Form(US)
- ▲ Parenteral Oncology Products (US)
- ▲ Out sourced & site Transfer Projects.

Component Handling:

PFS(Prefilled syringes)- Leur Lock, stacked Needle
VIALS (COC, COP, GLASS), AUTO NJECTORS, INHALATION DEVICE

Package Analysis & Testing

- ▲ Glass Delamination Studies
- ▲ Extractables & Leachable(Benzophenone screening of cartons)
- ▲ Migration Studies of Ophthalmic containers
- ▲ Device Performance Testing on Universal Testing Machine(Zwick Roell)
- ▲ FTIR Analysis of various Packing components

Regulatory support Activities

- ▲ Providing all vendor related Documents, declarations & Letter of Authorization for Packaging Materials for ANDA Submissions.
- ▲ Addressing ANDA Deficiency

Site Transfer Activity

- ▲ Working on Site Transfer Projects like Ophthalmics & oncology projects forProjects for Jubilant Holster Canada, Orbicular Hyderabad, Gland Pharma Hyderabad.
- ▲ Providing Scope documents and conduct Gap Analysis.
- ▲ Providing Packing Material specifications and Procurement of PMs'.



(DEC-2014
to AUG-2016)



(JUNE 2012 to
NOV 2014)

Agila Specialties Pvt. Ltd. (Mylan Pharmaceuticals Inc) Bangalore India

- ▲ For ANDA Submissions of Injectable Projects
- ▲ Sterile Ophthalmic Products(US/EU)
- ▲ Parenteral Oncology Products (US)
- ▲ Cephalosporin's & Beta Lactams
- ▲ Site Transfer Projects
- ▲ Packaging Validation studies for US Market for Injectable Products

Component Handling

- ▲ PFS (Prefilled syringes- Leur Lock, stacked Needle)
- ▲ IV Bags
- ▲ Auto Injectors
- ▲ Ampoules & vials (Glass, COC, COP)




Package Analysis & Testing

- ▲ Glass Delamination studies
- ▲ Extractables & Leachable
- ▲ Device Performance Testing on Universal Testing Machine (Tinus Olsen)

Regulatory Support for ANDA Submissions & Intended commercials

- ▲ Providing all vendor related Documents, declarations & Letter of Authorizationfor Packaging Materials for ANDA Submissions.

JOB PROFILE [PREVIOUS]

 DR. REDDY'S (MARCH 2010 to MAY 2012)	<u>Dr. Reddys' Laboratories Limited,</u> <u>Hyderabad</u>
	<ul style="list-style-type: none"> ▲ Critically analyzing monthly production plan & targets as per priority, Optimizing manpower & machine utilization, shift utilization. ▲ Preparation of new SOP, & review existing ones. ▲ Documentation & Evaluation of BMR, BPR, m/c log cards as per FDA requirements. ▲ Optimization of machine out puts as per machine layout ,format change parts & speed. ▲ Sequencing packaging activities on shop floor from stereo indenting, packaging, manpower distribution to BSR Transfer. ▲ Developing Cost-cutting strategies, down, Time analysis, Revision of pack style. ▲ Over all implementation of cGMP guidelines & quality norms. ▲ Conducting Packaging Validation Studies.
 (JUNE 2009 to FEB 2010)	<u>Nestor pharmaceutical pvt. Ltd. Faridabad</u>
	<ul style="list-style-type: none"> ▲ To approve & implementation of the STPs & GTP's for Packaging Material Quality ▲ Art work & Print proof Approval of Labels Cartons & Foils ▲ Audit the Packaging Material Vendors as per GMP, Quality & Regulatory point of view with Purchase. Prepare the vendor audit & compliance report & Approve the Vendor. ▲ Coordination with Purchase Department, plant & Vendor's for Quality of packaging material & Supply of it. To approve the Qualifications of the Packaging Development Department Instruments
 (OCT 2005 to MAY 2009)	<u>TORRENT PHARMACEUTICALS LTD. BADDI (Himachal Pradesh)</u>
	<ul style="list-style-type: none"> ▲ Designing of common pack size " layout development " ▲ Improvement of productivity manpower allocation. ▲ Change over time reduction, batch planning, execution of same. ▲ Ensure the accuracy of product and packaging samples and seek approvals required. well versed with packaging machinery, packaging materials, regulatory requirements. ▲ Working knowledge of equipment like leakage tester for blister pack & container, tensile strength and bond strength tester, scuff proof tester, bursting strength tester, bursting strength tester, WVTR tester for plastic films etc.

Exposure to Packaging Equipment/Machinery at Shop Floor

Equipment/Machinery	Make
VIAL/AMPOULE PACKING LINE	
Vial sticker Labeling Machine	MAHARISHI ENGG/BROTHERS INDIA
Zebra Printer for Carton label printing	ZEBRA PRINTING TECH (ZT-600)
Vial Blistering machine	IMAPG C102V
Autocartoning machine	IMAPG (A300 & IC150C)
Booklet Feeder	IMAPG
Track & Trace machine	CONDOT SYSTEMS (CSPL 800 CSPL1070)
Check weighing machine	TECHNOFOUR CW1200
Overwrapping & Bundling Machine	AUTOPACK
Automatic shipper Taping machine	SIGNODE INDIA
Online shipper overprinting machine	DOMINO PRINTING
Weighing Balance	METTLER TOLEDO/ESSAE
Palletization Machine	ALLIGATOR AUTOMATIONS/ABC PACKAGING

Exposure to Packaging Equipment/Machinery at Shop Floor	
Equipment/Machinery	Make
PFS/CARTRIDGE PACKING LINE	
PFS sticker Labeling Machine	MAHARISHI ENGG/BROTHERS INDIA
Zebra Printer for Carton label printing	ZEBRA PRINTING TECH (ZT-600)
PFS Blistering machine	IMAPG C102V
Autocartoning machine	IMAPG (A300 & IC150C)
Booklet Feeder	IMAPG
Track & Trace machine	CONDOT SYSTEMS (CSPL 800 CSPL1070)
Check weighing machine	TECHNOFOUR CW1200
Overwrapping & Bundling Machine	AUTOPACK
Automatic shipper Taping machine	SIGNODE INDIA
Online shipper overprinting machine	DOMINO PRINTING
Weighing Balance	METTLER TOLEDO/ESSAE
Palletization Machine	ALLIGATOR AUTOMATIONS/ABC PACKAGING
DEVICE PACKING LINE	
Semi Automatic Device Assembling & Testing Machine	Pentagon Assembly Automation Pune/SHL
Device sticker Labeling Machine	Pentagon Assembly Automation Pune
SOLID ORAL PACKING LINE	
Blister Packing Machine	PG 230XT, BQS, ELMACH 2500, ELMACH 2000 FB, STRIP PACKING , PG EXPRESS, , ELMACH 2000FB,
Bottle Packing Machine	CVC TECHNOLOGIES & COUNTEC
Auto Cartonator	IMA PG
Ink jet Printer	IMAGE/VIDEOJET
Check weigher	TECHNOFOUR CW1200
Liquid/Dry syrup Filing & Packing	PHARMALAB

Achievements and value addition:

- ❖ Implementation of Packaging Validation studies for Injectable & Solid Oral Dosage Forms for all regulated Markets.
- ❖ Development of Multilayer & foam Labels.
- ❖ Alternate vendor development & cost saving
- ❖ Special Carton Development by Kappa Board with Magnetic Flip cover for US Market.
- ❖ Conversion of all commercial Manual Packing to Autocartonator.
- ❖ Development of Low Migration Labels for Ophthalmic and respule products.
- ❖ Development of special grade UV protective shrink film for Antifungal Injection vials sensitive to UV.
- ❖ In house Threshold Analysis & URRR for Drug Device Combination Products.
- ❖ In house Design History File for Devices.
- ❖ Development of Benzophenone free Cartons for ophthalmic products.
- ❖ Developed Heat stable(160°C for 2 hrs Dry heat sterilization) Flip off seals for hormone Injection product
- ❖ Controlling Extractables & moisture content of rubber stoppers.
- ❖ Glass Delamination studies.
- ❖ Development of Anticounterfitting Cartons & Labels .
- ❖ Cost saving from Laminates & 3 side seal pouches.