Pellets
Pharma Limited

Pellets Pharma Limited

Corporate Address: Plot Number: 784, Vivekananda Nagar, Kukatpally 500072, Hyderabad, Telangana, India
Factory: Plot No.: 8&9, TSIIC-EPIP, Pashamylaram, Sangareddy [Dist], TS – 502309, India

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"We are manufacturer of solid oral dosage forms with cGMP compliance. Our expertise is in formulation of modified release pre-formulation intermediates and finished dosages like capsules and tablets in bulk packing. We offer timely delivery of our products and indulge a transparent relation with our customers "

by

Management

Management Team

Pellets Pharma Limited

Pathuru Radha Krishna Founder	Bachelor in Pharmacy and MBA, from Manipal University; 25 years of experience in global business and corporate leadership
Pathuru Sreelatha Managing Director	Bachelor in Commerce and CWA; 23 years of experience in the pharmaceutical industry, finance, tax matters, valuations and project management
Dr Sreenivasrao B CTO	Doctor in Pharmacy from Andhra University, with 25 years of experience in Research Development, Technology Transfer, Quality Assurance, Quality Control, Plant Operations, Regulatory audits and Dossier submissions of products for Regulated markets like US-FDA, UK-MHRA, TGA, RVO & BSG-Germany, MCC, ANVISA, MOH-Oman and GCC-Gulf
Anil Kumar Venigalla COO	Masters of Science & Technology fro Andhra University, with 27 years of experience in managing operations at scale and integrating operation teams to achieve optimal productivity of the utilities. Supervised and led a team of data engineers on day to day operations.
Dr Suresh Valluri GM- R&D, QC	Doctor of Pharmacy from Andhra University with 18 + years of experience in Pharmaceutical field and expertise with Quality systems, Quality control activities and Research and Development with different drug delivery systems ranging from generic to new dosage forms from Development, Process optimization, Scale up, Technology transfer, Regulatory filing and process validation.

Introduction

- Pellets Pharma Limited (PPL) established in 2002, by a team of professionals with several decades of experience in pharmaceutical industry
- PPL is expert in product development, manufacturing & supplying of solid oral pre-formulation intermediates [Pellets (ready to fill into capsules)] and are now expanding into finished dosages such as capsules and tablets in bulk packing
- PPL is equipped with formulation development to exhibit scale manufacturing of pre-formulation intermediates for capsules & tablets in linear scale up
- We have the best infrastructure to manufacture products of world-class quality and strict compliance to cGMP and our code of conduct have earned the company the status of contract manufacturer for renowned multinational companies

Milestones

2002	Organization is established in a 1800 sft [170sq.mt] leased facility for Product development and contract manufacturing
2004-2005	Land acquired & Facility constructed for commercial scale manufacturing & Product development
2010	Facility Audited & Approved by Mexican Regulatory COFEPRIS and customers from LATAM, MENA, ROW markets
2015-2017	Research center [ARD & FRD] with pilot scale facility is commissioned. Manufacturing facility is audited and approved by WHO CDSCO.
2018	Established a new FDF facility and separate facility for manufacturing of potent and hormonal molecules
2020	Received EudraGMP compliance certification for our facility and systems
2022-2023	Renewal of EUGMP certification approved back in 2020 and expansion into finished dosages

Business Prospects

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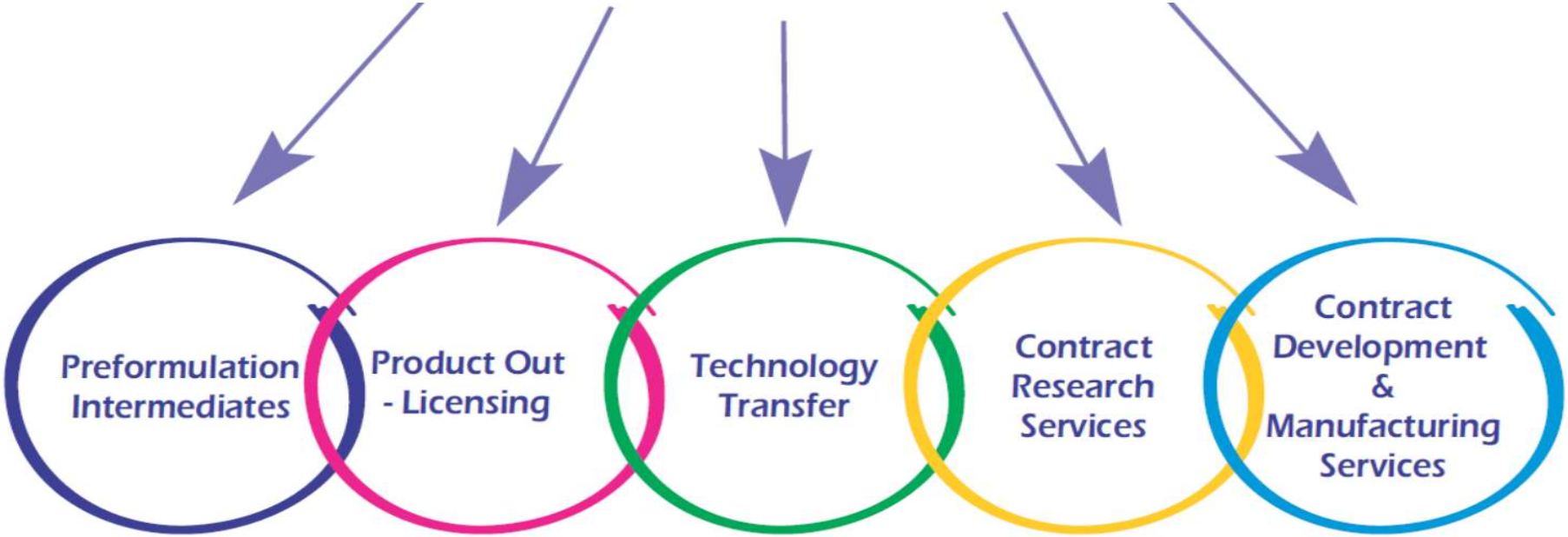

- *PELLETS FOR CAPSULE FILLING & COMPRESSION*
- *GRANULES FOR COMPRESSION*
- *FDF (TABLET & CAPSULES)*
- *DOSSIER*

Facility at a glance

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Plot size	1 Hectare
Total built up area in site	65,000 sq. Ft
Number of blocks	5
Total floor area	10,000 sq.mt [100,000 sq. Ft]
Air classification	ISO 8 process areas [0.3 micron terminal HEPA]
Purified water	500 Ltr/hr [meets BP]
Compressed air	215 cfm, oil free, with 0.01 micron filtration with 415 cfm backup
Chilled water capacity	500 TR + 300 TR
Boilers [To heat air]	800 & 400 Ltr capacity
Ware house area	80000 cubic feet
Research Centre	FR&D and AR&D; 12,000 sq. Ft area with ISO 8 classification in FRD

Manufacturing

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- ISO 8 classified areas from primary gowning rooms to process areas with temperature control and pressure differentiated.
- Manufacturing process is on campaign basis in each module.
- Each FBC machine output is considered as a batch.
- All the equipment consumables are API dedicated.
- Each module has dedicated air handling systems, with cascading from the corridor.
- Manufacturing & final packing is carried out in the same module.
- Separate entries for man and material movement.

Manufacturing Area capacity

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Maximum batch size	300 Kg
Minimum batch size	Equivalent or greater than 1,00,000 dosage units
Block 1	Re-oriented for Potent molecules
Block 2	Dedicated for Nutraceuticals and sugar/starch spheres
Block 3	Contains 3 modules and spare area for another FBC module
Block 4	Exhibit scale FDF facility
Manufacturing process times	1 – 3 days for each batch. Each machine output is considered as one batch/lot

Manufacturing capacity per month

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Production capacity	15 MT
Block 1	600 Kg
Block 2 [Nutraceuticals & Sugar/starch spheres]	4000 Kg
Block 3 capacity [FBC]	6000 Kg
Block 4 capacity [Capsulation & Tabletting exhibit scale]	1 lakh units per day
Additional capacity	2000 sq. mt process area [B5] with 4.8 mt height. Area to place another 500 to 800 Ltr FBC in Block 3

Product Development Area

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Formulation development area	Environmentally controlled with 0.3 micron Plenum HEPA. Area is equipped with 3 numbers of GPCG 1.1, 5 Ltr capacity FBC, Coating pan, RMG, Extruder & Spheronizer to prepare the pellets & granulation for formulation studies
Pilot scale area	Environmentally controlled with 0.3 micron Terminal HEPA. Area is equipped with GPCG 1.1, 25 Ltr FBC, Granulator, 5Ltr FBC, Tablet compression, Capsule filling, Dyno mill for NANO milling process, Air jet micronizer, bottle filling and blister packing, to manufacture pellets and granules for scale up & pilot bio batches. This area is also used for the manufacturing of small scale GMP commercial batches, validation batches and pilot scale Bio-Equivalence (BE) study batches.

Research Centre capabilities

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- R&D is focused towards formulation development and adaptation for scale up production, also to apply themselves for developing world-class products by participating in diverse-ranging research projects from basic research to development.
- Equipped with state-of-the-art infrastructure for development of innovative technological products
- Our R&D activities are closely focused on market needs and driven by technological progress to create unique market opportunities.
- Contract research to develop formulation for New Chemical Entities (NCEs), new applications [505 (b) (2)] and Generic formulations

Research centre offerings

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- Literature search
- Pre-formulation studies
- Formulation Development
- Analytical Development
- Scale up batches
- Exhibit batches
- Dossier preparation
- Stability studies
- Innovation and Proof of Concept

Key Research Areas

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- Wurster process
- Nano Technology
- Extrusion – Spheronization
- Wet & Dry granulation
- MUPS (Multi Unit Particulate Systems)
- Powder Layering Technology

Quality Systems

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- Online Document management system [DMS]
- Learning management system [LMS]
- Quality Management system for Change control, CAPA, Deviations & Complaints [QMS]
- FBCs control through PLCs
- Access control for critical areas of process and document.
- Networking system for HPLC
- In-house microbiology department

Ware House

- For Raw materials, Primary packing materials, Under test finished product and Finished product.
- Have HDPE drums storage & Return /Rejected FG storage.
- Separate solvent yard is available for solvent storage.
- Material exposure under ISO 8 classification.
- Controlled temperature in storage areas.
- Separate storage areas for controlled substances, Ethanol, HDPE drums, Narcotics, and cold storage.

Critical Equipments

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Equipment	Commercial	Research centre	Remarks
Fluid bed coaters	3 Nos [46 to 500 Ltr]	6 Nos [1 Ltr to 25 Ltr]	Pam-glatt
Coating pans	2 Nos [42 inch]	1No [6 & 12 inch]	NA
Driers	2 Nos [96 Treys]	2 Nos [12 Treys]	Grovers
Compression machine	12 station	8 station	Parle-Elizebeth
Capsulation machine	25000 per Hr	1000 per Hr	Dual fill
Blister packing machine	1 Nos (Mini-Bliss)	1 Nos	ACG
Tablet Coating	5 – 75kg	0.5 – 10kg	Gansons
Nano milling	Dynomill	Dynomill	WAB
Extruder/Spheronizer	12”	8”	Sunsai

Critical Equipment

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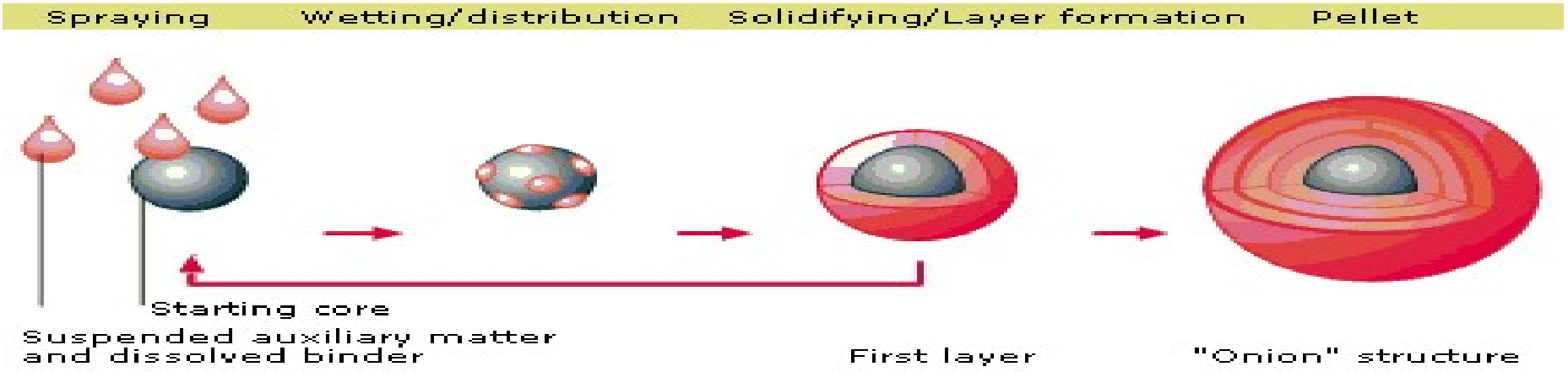
Equipment	Commercial	Research centre	Remarks
HPLC	9	12	Shimadzu
Dissolution	9	10	Electro lab
GC	1	--	Agilent
AAS	1	--	PE
Polarimeter	1	--	Anatonpar
UV Spectrophotometer	2	--	Shimadzu
Stability chambers	Walk in 6000 Ltr	Reach in 400 Ltr	Allyone

Process types

Process type 1	Drug loading & polymer loading on core material in FBC
Process type 2	Drug layering in coating pans/RMG, polymer loading in FBC
Sub part 1	Drug loading only in coating pan followed by polymer loading in FBC
Sub part 2	Drug loading in RMG [RMG, Extruder, Spheronizer] followed by polymer loading in FBC
Process type 3	Drug loading & polymer loading on Coating pan/RMG



Products

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Products	Reference	Products	Reference
Tamsulosin HCl SR Pellets	Secotex (BE), USP	Tamsulosin HCl SR + Dutasteride IR Pellets	Combodart
Venlafaxine HCl SR Pellets	Effexor XR (BE)	Galantamine HBr SR Pellets	Reminyl/USP
Esomeprazole EC Pellets	Nexium (BE), In-House	Linaclotide IR Pellets	Linzess
Aprepitant IR Pellets	Emend	Dimethyl Fumarate DR mini tablets	Tecfidera
Memantine HCl SR Pellets	Nameda XR	Memantine HCl SR + Donepezil HCl IR Pellets	Namzaric
Diclofenac Sodium SR Pellets	In-House	Fenofibrate IR Pellets/Granules	In-House, Controlip, Tricor
Indometacin SR Pellets	In-House	Omeprazole EC Pellets	USP, In-House

Products Under Development

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Name	Reference
Aspirin + Dipyridamole	Aggrenox
Carvedilol Phosphate	Coreg CR
Dexlansoprazole	Dexilant
Finasteride	Proscar
Ferrous Sulphate + Folic Acid	In-House
Fenofibrate (Sustained Release)	Lipanon
Fluvoxamine Maleate	As per US reference by Actavis
Mebeverine	In-House
Methylphenidate HCl	Ritalin LA
Methylphenidate HCl (oral suspension)	Quillivant
Vitamin C + Zinc Sulphate	In-House

Few snaps of facility

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Research Centre

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Our Presence

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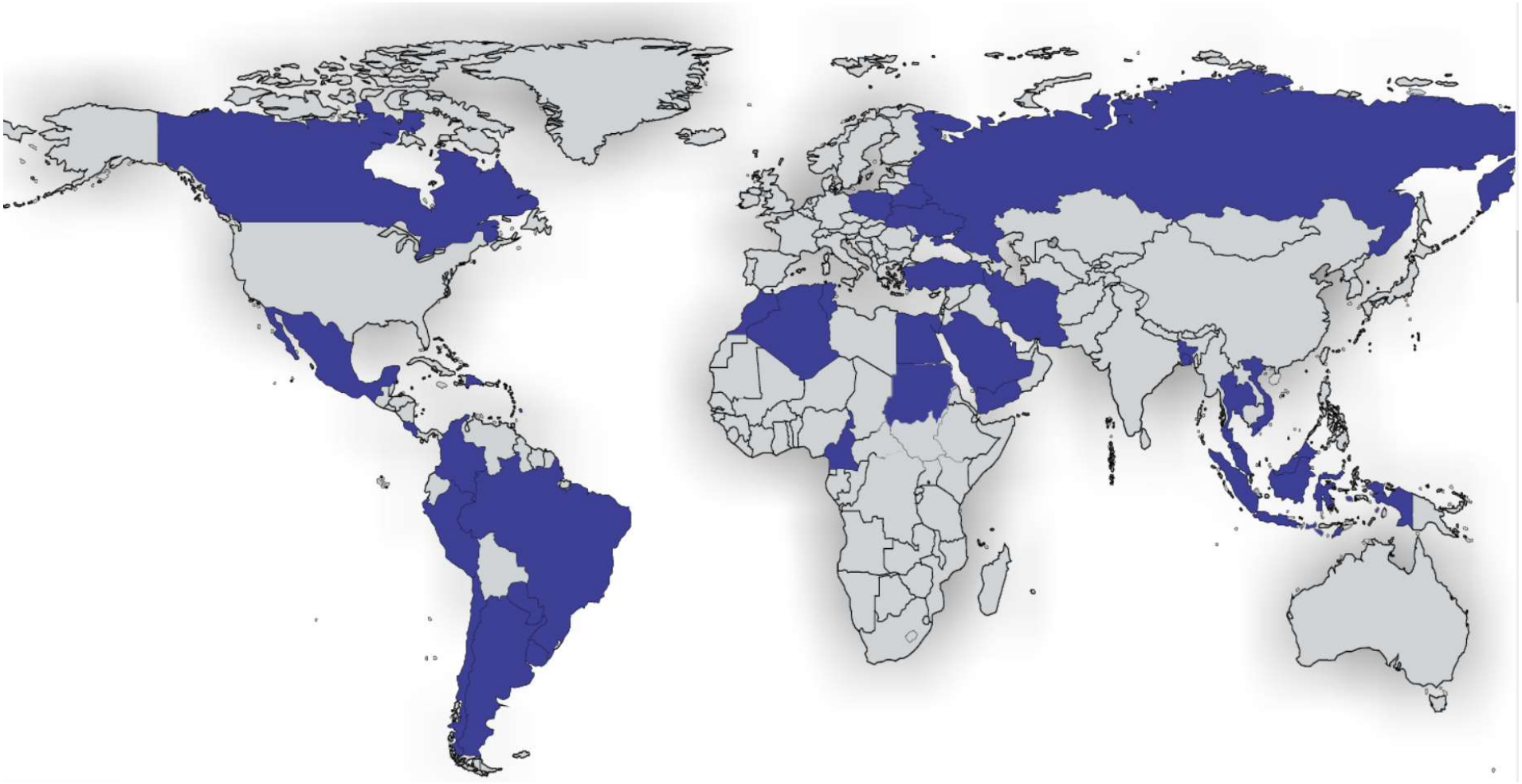

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Thank you