FORMULOGIC PHARMA

Corporate Presentation

ABOUT US

FORMULOGIC PHARMA

Formulating a healthy future

Formulogic is an R&D-based pharma manufacturing company based at Bengaluru, India.. We have state-of-the-art infrastructure and an expert team with diverse experience in research & development and manufacturing. We manufacture world-class pharmaceutical products through innovation at affordable prices

- ✓ Complete R&D services for oral solid dosage forms, including tablets, capsules, injectables, pellets, oral liquids, and semi-solids dosage forms such as ointments, creams, and gels used for topical application.
- ✓ Custom manufacturing services for solid oral dosage forms, ointments, creams, gels, and pellets.

MISSION AND VISION

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At the heart of everything we do!

Mission

To serve quality medicines at an affordable price.

Vision

To be the leading pharmaceutical company producing Safe and Quality medicinal products.

OUR PARTNERSHIP APPROACH

WHY Formulogic?

- Values
- Differentiators
- Our Team
- Integrity

UNIQUE EXECUTION APPROACH

- Ideas for Success
- Experience
- Time bound project delivery
- Work towards new Innovation

MONITOR & REPORT

- Governance Structure
- Reporting Metrics
- Quality Assurance
- Risk Management

Formulogic COMMITMENT

- Quality
- Transparency
- Collaboration
- End to End responsibility

BUSINESS CAPABILITIES

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You can count on us!

- Formulation Research and Development
- Analytical Research and Development
- Technology Transfer
- Custom Manufacturing Services
- Regulatory Affairs and Compliance

FORMULATION DEVELOPMENT

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- Literature Search and Patent Review.
- Innovator characterization studies.
- Design of Preformulating studies.
- Formulation development based on Quality-By-Design (QbD) tools at all stages. Design of experiments (DOE) along with risk assessment strategies.
- Adopting Ultra short accelerated stability studies (ASAP prime software approach) during development to resolve stability issues

Cont.....

FORMULATION DEVELOPMENT

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- Dissolution and Impurity comparison and profile matching.
- Scaleup trials followed by process optimization.
- Technology Transfer to cGMP Manufacturing Unit.
- Manufacturing of Engineering batch followed by 3 Submission Batches.

BIOEQUIVALENCE STATERGY:

1. Preparation of BE study design and executions
2. Review and Evaluation of Pilot scale results and design study design for Pivotal study.

ANALYTICAL RESEARCH AND DEVELOPMENT

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- Literature Search
- Method development
- Method validation/verification
- Drug product Reverse engineering
- Identification of degradation products
- Stability sample analysis
- Develop additional methods if required on a project basis
- Life Cycle Manage of Old Methods and including Troubleshooting

TECHNOLOGY TRANSFER

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- Our technology transfer team consists of the following members with years of expertise and are experienced personnel.

  R&D process technologist, DQA representative and ARD representative.

- Direct communication between technical members will be available, as well as effective and timely communication with regulators.

- A functional Sending and Receiving Unit will be in service.

- Development, transfer, production, and documentation will all be efficient.

CUSTOM MANUFACTURING

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- Our manufacturing unit is fast, efficient, flexible, and technically capable.
- Our facilities are cGMP compliant, as well as meeting environmental and safety norms.
- During the discovery phase of a project, we collaborate closely with our customers to find and qualify the best component materials.
- Prior to release, all finished goods are tested to determine whether it satisfies specified or exceed our clients' expectations and criteria.
- On request, certified test reports (CTR’s) or certificates of analysis (CoA’s) may be supplied.

REGULATORY AFFARIES

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Regulatory Affairs:

- Advisory Consulting
- Regulatory writing for DMF, CEP, Dossier, and Gap Assessment with customization
- Expert in the preparation of ANDA/EU MAA's and Other Country Specific Formats
- End to End support for eCTD
- Deficiency Management till product approval

Regulatory Compliance:

- Post Approval of product launch and regulatory compliance support
- Life cycle management like Annual reports, Variations, and product renewals

IP, DQA and PROJECT MANAGEMENT

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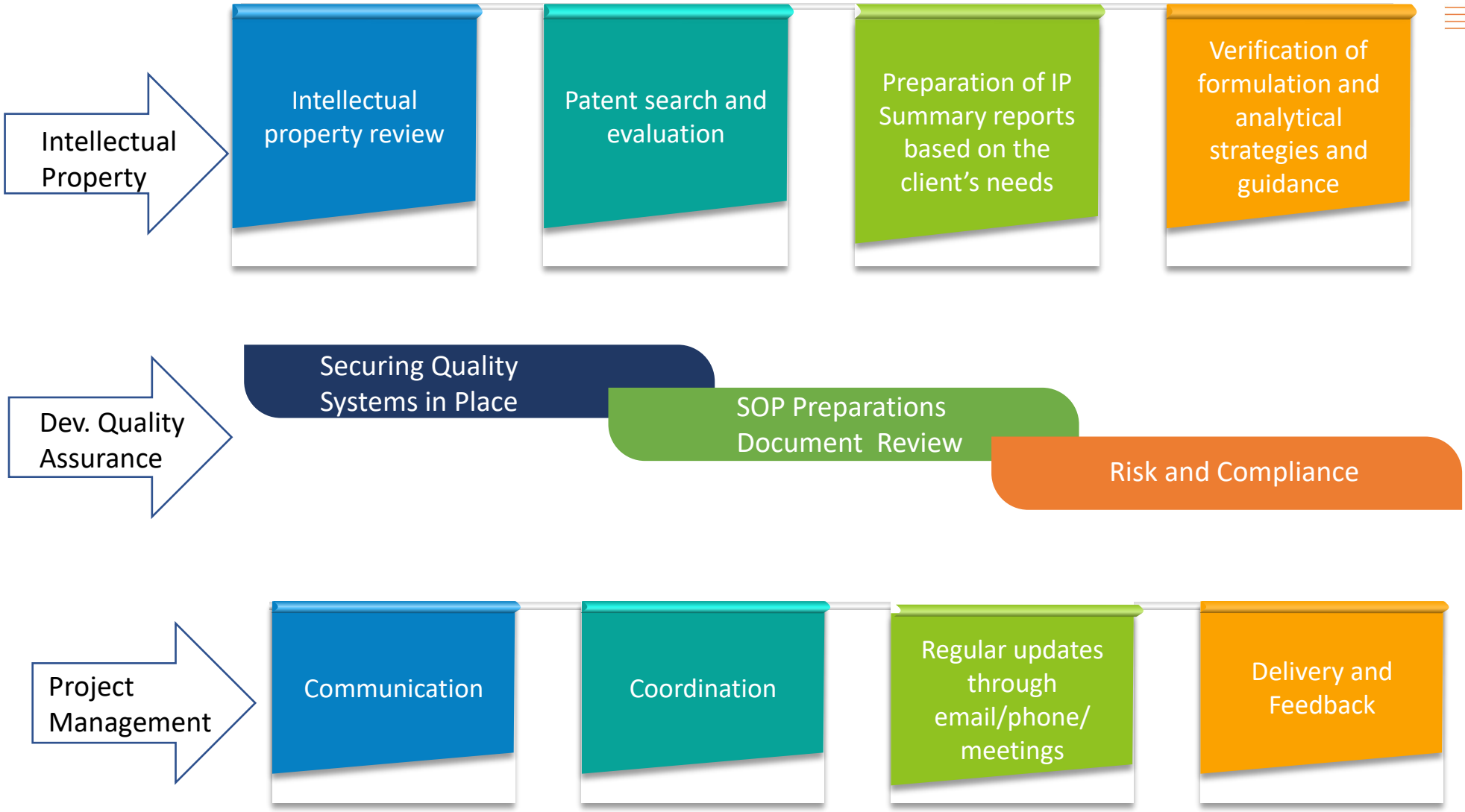

List of Equipment's

FORMULOGIC

General Equipment's	Formulation Lab (1)	Formulation Lab (2)	Analytical
Water Purifier (Avidity) TOC levels at 5ppb	Weighing balance 220 gm (Make: Aczet)	pH meter (Make: Aczet)	Semi Micro Weighing balance (Make: Radwag, Poland)
Hot air oven (Make: Aczet)	Weighing balance 3kg (Make: Aczet)	Laboratory stirrer (Make: Neuation)	pH meter (Make: Aczet)
Sieve shaker (Make: Electrolab)	Rapid mixer granulator (Make: Riddi)	Moisture balance (Make: Aczet)	HPLC (Make: Agilent / Waters)
Friability tester (Make: Veego)	Fluid bed dryer (Tabletop) (Make: VJ instruments)	Ampoule filling machine (manual)	Dissolution tester (Make: Electro lab)
Leak test apparatus (Make: Veego)	Comill (0.5 kg to 5 kg)	Autoclave	Fume Hood (lab modal 4 feet)
Hardness Tester (Make: Veego)	Bin Blender	Filtration unit/ pump	UV spectrophotometer (make: pg instruments, UK)
Tapped density tester (Make: Electrolab)	Tablet compression machine (multi tooling) 10 station (Make: Fluidpack)	Crimper/ Desealer	Magnetic stirrer
Disintegration tester (Make: Electrolab)	Tablet coating machine (0.5 kg to 2 kg)		Fume Hood
Stability chambers 250L (Make: Allyone)	Blister packaging machine (Make: Mechtek)		Refrigerator (250L)
- Accelerate (40/75) - Zone IIb (30/75)	Capsule filling machine (manual)		

List of Molecules Experienced / Handled

Product	Strengths	Product	Strengths	Product	Strengths
Paliperidone ER tablets	1.5, 3, 6 & 9mg	Isoprotenol HCl injection	0.2mg/mL	Guaiphenisin + Pseudoephedrine ER tabs	600mg+60mg
Carbamazepine ER tablets	100, 200, 300mg	Phytonadione injection	10mg/mL	Glipizide ER tablets	2.5, 5, 10mg
Phytonadione tablets	5mg	Dantrolene sodium injection	20mg/mL	Moxifloxacin Tablets	400mg
Trospium chlroide ER capsules	60mg	Dexmedetomidine HCL injection	100mcg/mL	Loratadine tablets	10mg
Alcaftadine opthalmic solution	0.25%	Nepafenac ophthalmic suspension	0.10%	Fenofibrate tablets	48, 145mg
Oxcarbazepine oral suspension	300mg/5mL	Albendazole tablets	200mg	Fenofibrate capsules	130mg
Oxybutynin ER tablets	5,10,15mg	Abiraterone tablets	250mg/500mg	Rizatriptan tablets	5 & 10mg
Glipizide ER tablets	2.5, 5, 10mg	Phytonadione tablets	5mg	Rizatriptan OD tablets	5 & 10mg
Teriflunomide tablets	7 and 14mg	Ritonavir tablets	100mg	Ibuprofen suspension	100mg/5mL
Dimethyl fumarate capsules	240mg	Tramadol HCl ER tablets	100, 200, 300mg	Tramadol + Acetaminophen tablets	37.5mg+325mg
Midodrine HCl liquid	0.05	Fexofenadine + pseudoephedrine ER	180+240mg	Loperamide capsules	2mg
Trifluoperazine tablets	1,2,5mg	Pseudoephedrine ER tablets	120mg	Methotrexate tablets	5mg
Chlorothiazide injection	500mg	Pseudoephedrine ER tablets	240mg	Tamoxifen tablets	20mg

List of Molecules Experienced / Handled

Product	Strengths	Product	Strengths	Product	Strengths
Progesterone capsules softgel	100/200mg	Palbociclib capsules	75, 100,125mg	Bendamustine injection	25mg, 100mg/vial
Afatinib tablets	20,30,40mg	Capecitabine tablets	150, 500mg	Bortezomib injection	3.5mg/vial
Enzalutamide capsules	40mg	Gemcitabine Lyo	200mg/1000mg per vial	Clofarabine injection	20mg/20ml
Letrozole tablets	2.5mg	Gemcitabine injection	200mg/1000mg/ 2000mg	Fulverstrant injection	250mg/5ml
Anastrazole tablets	1mg	Docetaxel injection	20mg/2ml, 80mg/8ml, 160mg/16ml	Plerixafor injection	20mg/mL
Abiraterone tablets	250/500mg	Irinotecan injection	40mg/2mL, 100mg/5mL	Carfilzomib injection	60mg/vial
Pazopanib tablets	200/400mg	Oxaliplatin injection	5mg/ml, 50 0r 100mg vial	Azacitidine injection	100mg/vial
Lenolidomide capsules	2.5, 5, 10, 15, 20, 25mg	Paclitaxel injection	6mg/ml, 30mg/vial	Mitomycin injection	5,20,40mg/vial
Temozolomide capsules	5,20,100,140,180, 250mg	Vinorelbine injection	10mg/ml, 50mg vial	Leuprolide injection	1mg/0.2mL
Everolimus tablets	2.5, 5, 10mg	Projesterone injection	50mg/ml	Pemetrexed injection	100/500/1000mg /vial
Imatinib tablets	100/400mg	Medroxyprogesterone injection PFS	150mg/ml	Fingolimod Capsules	0.5 and .25mg
Gefitinib tablets	250mg	Testosterone cypionate injection	200mg/ml, 10ml	Ibuprofen tablets	200mg
Pomalidomide capsules	1/2/3/4mg	Hydroxyprogesterone injection	250mg/ml, 1250mg/5ml	Mecitentan tablets	10mg

List of Molecules Experienced / Handled

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Modified Dosage Forms (solid orals)

S. No	Product	S. No	Product
1	Fexofenadine + pseudoephedrine ER	10	Guiphenisin ER tablets
2	Pseudoephedrine ER tablets	11	Propafenone ER tablets
3	Pseudoephedrine ER tablets	12	Metformin ER tablets
4	Guaiphenisin + Pseudoephedrine ER tabs	13	Loratadine + Pseudoephedrine ER tablets
5	Glipizide ER tablets	14	Niacin ER tablets
6	Acetaminophen ER tablets	15	Tolterodine ER capsules
7	Cyclobenzaprine ER tablets	16	Mesalamine ER tablets
8	Cetirizine + Pseudoephedrine ER tablets	17	Zolpidem ER tablets
9	Darifenacin HBr ER tablets	18	

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Pharmaceutical Research & Manufacturing Organization

Your Friendly, Highly Experienced, Right-Sized R&D Partner

Business Activities

- **Formulation Research**
- **Analytical Research**
- **Manufacturing**
- **Technology Transfer**
- **Regulatory Affairs**
- **Intellectual Property Rights**
- **Quality Management**

Business Model

- End to End Product Development
- Collaboration Model
- Contract Research for Specific Product
- Contract Manufacturing
- Trouble shooting Regulatory support
- Technology Transfer

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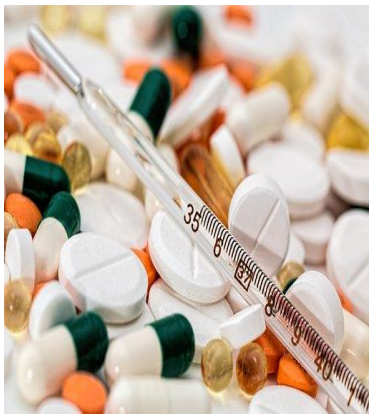
Formulation Research

- Pre-formulation
- Formulation development based on QBD
- Formulation optimization and Process development
- Innovator characterization studies

Analytical Research

- Analytical Method Development
- Method optimization
- Analytical validation
- Analytical transfer support
- Stability Studies



Manufacturing

- Manufacturing a wide range of formulations
- Streamlining manufacturing procedures to ensure compliance
- High Quality Standards

Technology Transfer

- Process transfer
- Methods transfer
- Trouble Shooting
- Process Improvements

Intellectual Property Rights

- Setting up structures to hold and manage IP
- Licensing and distributing IP
- Co-ordinating IP protection and registration
- Making introductions to research and development

Regulatory Affairs

- Dossiers and Gap Assessments with customization
- End to End support for eCTD, Post Approval Life Cycle Management
- Responding to the dossier deficiencies and support till product approval
- Post Approval of product launch and regulatory compliance support

Quality Management

- Third party audit management
- Investigation Management
- Setting-up of quality systems of GDP as per country standards

About Formulogic

- Formulogic is a science and innovation driven Research and Development & manufacturing organization providing affordable medicines with high quality standards
- Formulogic team develop various products such as Tablets, Capsules, Liquids, Semi solids, Dry powders, Complex (or) simple Injectables and Drug Device combinations.
- Formulogic manufactures solid oral dosage forms like tablets, capsules and oral solutions.

Why Formulogic?

- Innovation
- Integrity
- Quality
- Flexibility
- Excellence
- Experience

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