









Providing Integrated Research Solutions in Preclinical Biology



Nutraceuticals/Herbals



Cosmetics



Pharmaceuticals



Biopharmaceuticals



Medical Devices



Agrochemicals

About Us







- DRF has it's genesis is from a well known and reputed business house "Dabur Group of companies".
- DRF itself has 20 years of drug discovery & development experience, which it brings to its clients as a preclinical service provider.
- **▶ 65,000 sq.ft.** built-up area
- State of the art AAALAC & GLP certified integrated preclinical lab located in a well connected and serene location at National Capital Region, India
- Animal facility with 36 exclusive experiment rooms designed as per international standards

Preclinical Service Expertise



TARGET DISCOVERY

IN VITRO

IN VIVO

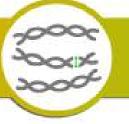
BIOMARKER DISCOVERY

CLINICAL TRIAL











Cell based screens

Target based screens

Signal transduction

- Oncology
- Metabolic Disease
- > Ophthalmic Disease
- GastrointestinalDisease
- ➤ Pain & Inflammation
- > Fertility
- > Respiratory Disease
- Dermo Pathology
- > Hair Biology

- Human Inflammation Assay
- ➤ Human MMP & TIMP Assay
- Cytokine, Chemokine, & GF Assay
- Human/Mouse/Rat Diabetes, Metabolic, and Hormone Assays
- Human/Mouse/Rat Kidney Toxicity Assays Human/Rat/Canine Disease Research Assays-Human-Cancer; Cytokine; Acute phase; Isotyping
- Cell Signaling Assays
- Apoptosis Assays

ADME-PK

Non-GLP & GLP Tox, Genotox, Analytical & Bioanalytical

Therapeutic Area Expertise





Classical animal models are used as a mandatory element for approval of the Phase-I clinical trial.

If you decide to outsource this task?

Dabur Research Foundation with over 100+ animal models encompassing wide therapeutic areas is an excellent choice

GLP Toxicology Services



ACUTE & SUB ACUTE

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Acute Dermal Irritation / Corrosion
- Acute Eye Irritation / Corrosion
- Skin Sensitization
- 7 / 14 Days Dose Range Finding Study
- 14 / 28 Days Repeated Dose Toxicity Studies

SUBCHRONIC AND CHRONIC

- 90/180 Days Repeated Dose Toxicity Studies
- Chronic Toxicity Studies
- Carcinogenicity Studies
- Combined Chronic Toxicity
 Studies

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

- One Generation Reproduction Toxicity
- Two Generation Reproduction Toxicity
- Combined Reproduction /Developmental Toxicity
- Neurotoxicity

GENOTOXICITY

- Bacterial Reverse Mutation
 Test (AMES)Salmonella
 typhimurium & Escherichia coli
- In vitro ChromosomeAberration Test
- In vivo Bone Marrow
 Chromosome Aberration Test
- In vitro Mammalian Cell Micro nucleus Test
- Mammalian Gene Mutation
 Test
- Mammalian Erythrocyte
 Micronucleus Test

Services-Cosmetic Industry



Screening Models

fficacy

Skin health

- > Skin senescence
- Skin lightening
- > Skin depigmentation
- > Anti-blemish
- > Skin Photoaging
- > Chemokine & cytokine
- > Skin Permeability Assay
- > Dermal Anti oxidants
- Hair growth promoter
- Skin permeability assessment
- Dermal Anti –inflammatories
- > Hair growth Stimulator
- Chemotherapy inducedAlopecia
- Anti Photoaging potential
- > Hair pigmentation

Alternate To Animal Test

Human Fibroblasts assay

- Dermal Fibroblasts assay
- > B16 Melanoma cell line
- Histamine estimation in Mast cell-line
- Human dermal papilla cells assay
- > Dermal fibroblast cell line
- Melanogenesis stimulatory assay in B16 melanoma cell lines
- UV induced damage using fibroblasts cell lines

Dermopathology Screen

- Psoriasis
- Eczema
- Pediculosis
- Dermatitis
- > Fungal Infection
- Warts
- > Acne
- Leucoderma/Anti Vitiligo
- > Inflammation
- Wound Healing
- > Leucoderma

Specialized Service

We support Global FMCG & Cosmetics company in their claim substantiation

Services-Herbal & Nutraceutical



- > Invitro & Invivo Efficacy Models
- > ADME-PK
- Proof Of Concept
- Exploratory Toxicology
- ➤ GLP Toxicology
- Physicochemical Studies
- Claim Substantiation



Services-Pharma & Biotech



Oncology

- > Cytotoxicity Screens
- Combination Index
- Drug Uptake
- Angiogenesis Screens
- Cell Migration assay
- > In vitro Angiogenesis model
- In vitro angiogenesis VEGF
- > Apoptosis Screens
- Mechanistic Profiling
- > Target Based Screens

Immunomodulation

- Chemokine /cytokine profiling for immunomodulators ex vivo
- > Phagocytosis
- ➤ NK cell activity

Metabolic Disease

- Diabetes
- Osteoporosis
- Hypertension & Cardiovascular model
- Hepatic Steatosis & insulin resistance
- > Hepatic fibrosis

Gastrointestinal

- Digestive Stimulants
- Liver Cirrhosis
- Antiulcer

Others

- > Photodegradation
- > Rhinitis

Inflammation

- > Dendritic cell based ex vivo models
- Arthritis
- ➢ Gout
- > Irritable Bowel Disorder
- Immune cells based model
- > Respiratory inflammation
- Ocular inflammation
- > Dermal Inflammation
- > Neuronal inflammation
- > Pain & Inflammation
- > Systemic inflammation

Fertility

- Screens for Erectile Dysfunction
 - ➤ PDE5
 - > RHO Kinase
- Assessment of Galactogogue Potential

"India's largest tumor bank repository with human cancer cell lines representing 15 - 20 different cancer types"

Services-Pharma & Biotech



Metabolic Disease

- > NAFLD/NASH
- Obesity
- Dyslipidaemia
- Diabetes (type I)
- ➤ Diabetes (type II)
- > Diabetes Induced Nephropathy
- Diabetes Induced Atherosclerosis
- > Wound Healing

Gastrointestinal

- > Inflammatory bowel disease
- > Ulcerogenic Potential
- Gastric Emptying Model
- Gastric Motility Model
- > Liver Cirrhosis
- Model for screening laxative effectiveness
- > Hepatoprotective

Oncology

- > Xenograft models
- > Syngenic tumor models
- > Orthotopic models
- > Angiogenesis models
- Metastasis models
- > Leukemia models

Fertility

- Estrogenic activity
- > Dysmenorrhea
- ➤ PCOD
- > Assement of mating potential

Respiratory Disease

- Asthma
- > COPD
- Lung Fibrosis

Inflammation

- > Acute Inflammation Models
 - > Carageeneen Induced
 - > Xylene Induced
 - > LPS Induced
- Chronic Inflammation Models
 - > MIA Induced OA
 - Collagen Induced RA
 - > DSS / TNBS Induced Colitis
 - Oxazolone / DNFB Induced DTH Inflammation

Services- ADME-PK



ADME

- Metabolic stability
- Aqueous solubility
- Protein binding
- PAMPA, MDCK & Caco-2)
- CYP450 enzyme inhibition
- CYP 450 Phenotyping
- Drug-Drug interaction
- Log P, Log D
- RBC-plasma partitioning
- Plasma stability studies

PK

- Dermal permeability
- PK in rat and mouse (normal & tumor bearing animals) for IND and NDA submissions
- Rapid Pilot PK study for early preclinical support.
- Dose proportionality and gender effect studies
- Route of administration studies.
- Tissue distribution studies
- Excretion studies
- Bioavailability studies
- Statistical analysis of PK data using WinNonLin

Services-Agrochemical



Services

- Physicochemical Studies
- Analytical Chemistry
- Five Batch Analysis
- GLP Toxicology
- Genetic Toxicology

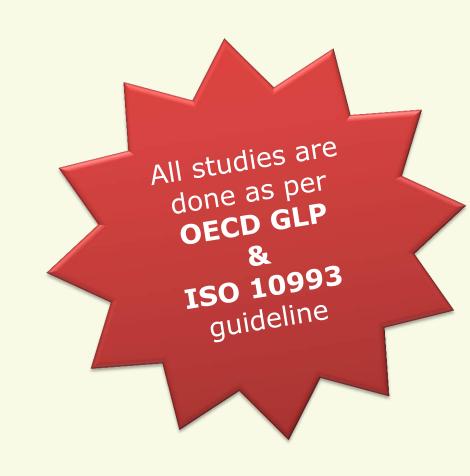
Guidelines

- OECD Guidelines Section 1 (Physico-Chem)
- OECD Guidelines Section 4
 (Toxicity)
- CIPAC Handbook for Pesticide analysis methods
- CIB & EPA
- ISO & DCGI

Services-Medical Devices

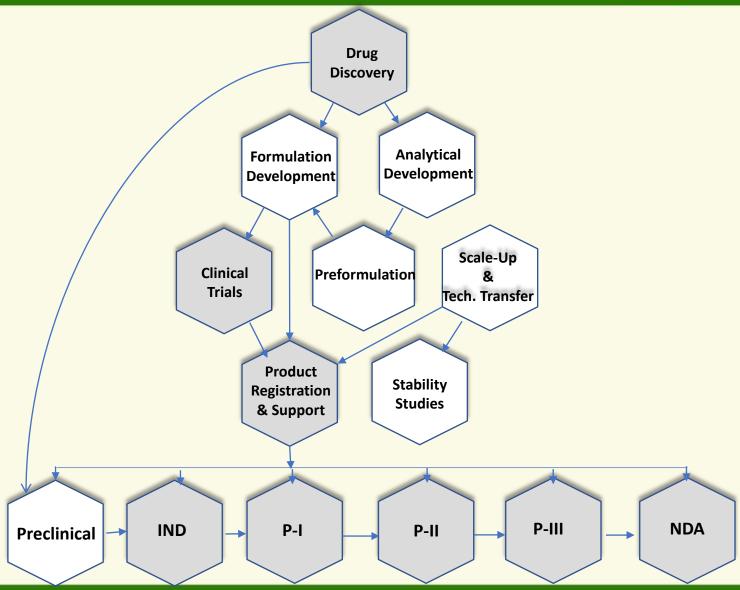


- ➤ Physicochemical Studies
- ➤ Implantation Studies
- ➤ Irritation and Hypersensitivity
- ➤ Systemic Toxicity
- ➤ Cytotoxicity and Genotoxicity
- >Immunotoxicity
- **≻**Toxicokinetics



Formulation Development





Formulation Capabilities



Preformulation Capabilities

Excipient Compatibility, Thermal Analysis (DSC, TGA), Dynamic Vapor Sorption, Particle size analysis (laser diffraction), Viscosity measurement, Solubility determination, Intrinsic dissolution, XRPD*, SEM*

Dosage Forms

- Orals (Tablet, Capsules & Powders
- Topical and Transdermal (Gels, Creams, Ointments, Lotions)
- Sterile Liquids (Solutions,
 Suspensions, Colloids, Liposomes)
- Powders (Sterile and non-sterile powder filling)
- Sterile liquid dosage formulations (ophthalmic, oral, nasal)
- Injectable drugs (intravenous, and intramuscular, subcutaneous injectables)
- Lyophilized formulations

Based on Application

- Skin care formulations
- Hair care formulations
- Oral formulations
- Topical formulations
- Indication based cosmetic products like: Anti-Ageing, Anti-Acne etc

Enabling Technologies

- Controlled release
- Delayed Release
- Sustained Release
- Modified Release
- Hot melt extrusion
- Nano technology (particle modification)
- Targeted Drug Delivery System
- Liposomal drug delivery
- Encapsulated drug delivery systems
- SEDDS
- Oral Films
- Depot injectables

Analytical Capability



Analytical capabilities

HPLC (VWD/PDA), automated dissolution testers, UV/Vis spectrophotometers, GC (headspace), LC-MS

Dosage Forms

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Stability Studies

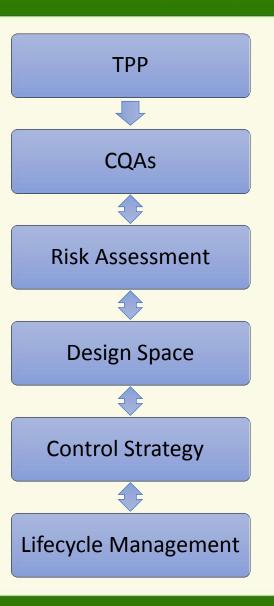
- 40C/75%RH
- 30C/65%RH
- 25C/60%RH
- 50C/75%RH
- 30C/75%RH
- 2-8C
- 50C
- 60C
- Photostability

Enabling Technologies

- Method development
- Method validation
- Method qualification
- Method transfers
- Stability studies
- Chiral analysis
- Preservative analysis's

Quality By Design Approach





- ➤ Target the product profile (TPP)
- Determine the critical quality attributes (CQAs)
- Link input material attributes and process parameters to CQAs
- > Perform risk assessment
- Develop a design space
- Design and implement a control strategy
- Manage product lifecycle, including
- Continual improvement

Global Footprints





5000+

Preclinical Studies

98%

On-time Delivery

300+

Client Served

Scientific Resource





Dr. Manu Jaggi

Chief Scientific Officer

Doctorate in Cancer Biology from National Institute of Immunology and a post graduate in Pharmaceutical Science (Gold Medalist); Dr. Jaggi is a seasoned scientific leader bringing over 20 years of successfully leading discovery research and advanced preclinical drug development teams with special focus in global collaborative drug discovery research. He holds over 100 patents and led a successful discovery team which resulted in a first-in-world clinical candidate Nanoxel™ (a polymeric Nanoparticle based drug delivery system for Paclitaxel). Dr. Jaggi has published and presented over 40 research papers in peerreviewed journals. He holds memberships in several scientific committees and has attended and presented at several international and Indian conferences and meetings.



Dr. Anu T. Singh

Vice President

Doctorate in Tumor Biology from All India Institute of Medical Science, and postdoctoral research in signal transduction alterations in adenocarcinomas at National Institute of Immunology; Dr. Anu is a seasoned scientific leader with over 20 years of comprehensive experience in new drug discovery and early preclinical drug development and scientific operations with special interest in translatory research of phytochemical based products. Dr. Anu was instrumental in discovery and development of first-inworld clinical candidate Nanoxel™ (a polymeric Nanoparticle based drug delivery system for Paclitaxel). Anu holds over 14 US Patents and more than 46 in rest of the world and several more in India. She has published and presented more than 30 research papers in peer-reviewed journals & scientific meetings.





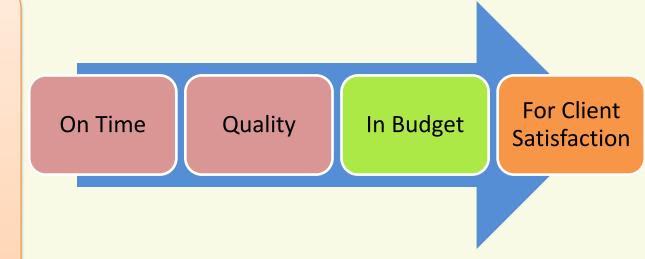
Demographics

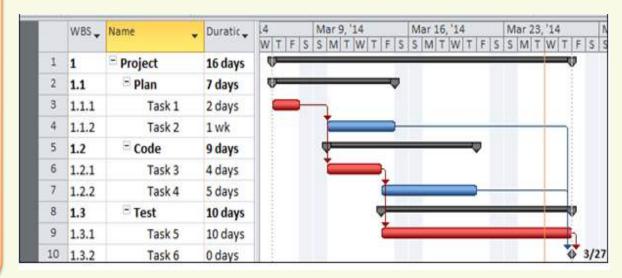


Seamless Project Execution



- Dedicated Project Manager
- Fully protocol & Regulatory compliant
- Projects are monitored on MS projects by an experienced project manager
- Metrics based project planning and execution
- Close interaction with sponsors at every stage of experiment
- Good track record of completing projects on time





Quality System



- Planning of QA activities
- Review of study plans, study reports and SOPs
- Conducts study based, process based and facility based inspections
- Reporting of inspection findings to Management and respective personnel
- Issue of QA statement in the final report
- Archiving of QA and facility documents
- > Regular GLP Training of staff
- Vendor/Supplier Audits

Test Item Control Unit

For custody and issue of all sponsor supplied sample and test items



Archival

For archival of study plans and reports as per GLP requirement



Specimen Archival

For archival of study specimen as per GLP requirement



Dabur Research Foundation





Spacious Vivarium





Air Shower





Clean Corridors





36 Experiment Rooms





Double door Autoclave





Necropsy Room





Laboratory Area





Tissue Culture Lab





Cell Biology Lab





Pharmacology Lab





ADME-PK Lab





Histopathology Lab





Biochemistry Lab





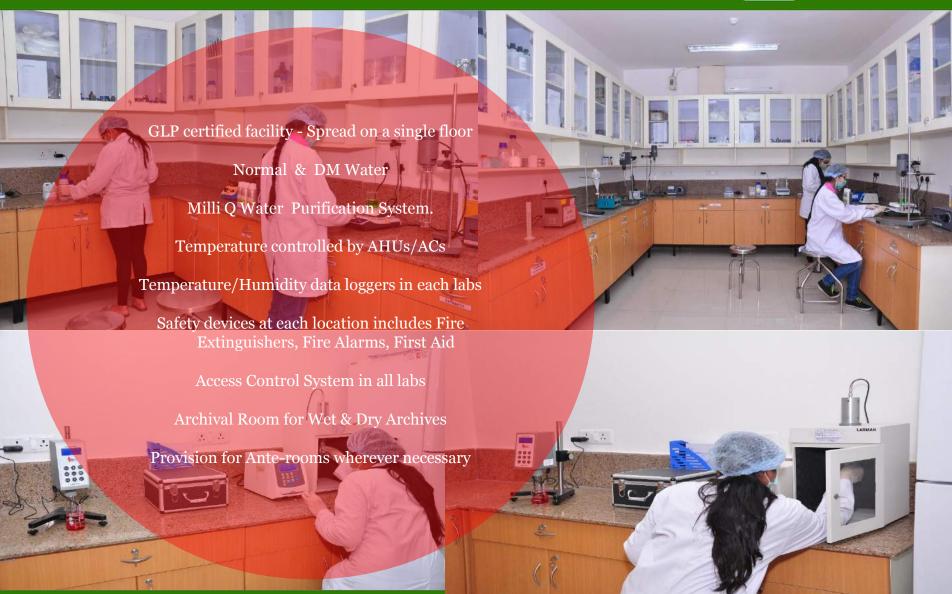
A GLIPMSE OF DEVELOPED FORMULATIONS





Laboratory Area





SPRAY DRYING AND GRANULATION





Solid Dosage Processing





Semisolids Processing





Tube Filling and Sealing





High capacity tube filling and sealing for releasing finished product for different testing and trial applications..

Spheronization and coating



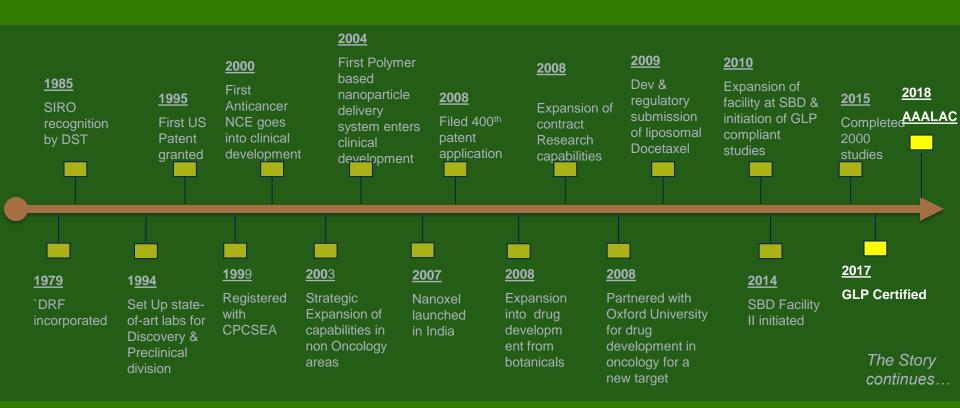


A unique method of developing all sorts of pellets for oral as well as cosmetic delivery applications

Certification









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