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PHARMA SERVICES

DRUGS & COSMETICS

Edward Food Research & Analysis Centre Limited

www.efrac.org

USFDA INSPECTED FACILITY

Established in the 2012, EFRAC is an USFDA Inspected & BSE Listed Company having ISO 17025:2005 Accreditation in Chemical & Biological disciplines. Drugs & Cosmetics Division at EFRAC is and advanced Pharmaceutical Testing Facility with Cutting-Edge Technology, 21 CFR Part 11 enabled & DQ, IQ, OQ, PQ, Qualified Instrumentation. EFRAC conducts a wide range of Tests in Strict adherence to the Scientifically Approved Protocols and Standards by Drug Regulators like CDSCO, WHO, MHRA & USFDA.

EFRAC's Systems & Processes ensure Precise, Reliable, Secured & Legally defensible Data of Testing.

Salient Features

- USFDA Inspected Lab
- 40,000 Sq. ft. of World- Class Analytical Facility
- 11 Regulatory Accreditations & 3 International Recognitions
- Quickest Turn Around Time (TAT) in the Industry
- 21 CFR Coupled Instrumentation for Data Integrity & Security
- LIMS Platform with Barcoding & Digital Encryption Features
- Machines with Auto-samplers, Robotic Controls & DQ, IQ, OQ, PQ Qualification
- Microbiological Sections with Pressurized & Classified Clean Rooms
- Sample Pick-up Arrangements from National & International Locations


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Efficient Food Research & Analysis Centre Limited

QUALITY AT CORE

DRUGS & COSMETICS

Edward Food Research & Analysis Centre Ltd (EFRAC) is an Unique State of the Art Laboratory accreditated with ISO/IEC17025 (NABL) Standards and offers Testing Services on Scientifically well equipped Platform & International Standards to cater to the needs of the Clients and the Regulatory Authorities with high level of Accuracy & Precision..

Drug Administration ensuring Public Health and Hygiene is one of the Prime Concern of the Government in all Countries around the World. One of Prerequisite for delivery of Healthcare is to ensure Integrity and Quality of Essential Drugs as per International Standards.

Regulators like WHO, USFDA, MHRA, CDSCO, etc sets the Global Standards for the Quality, Safety Limits, Efficacy and Purity of the Drugs and Pharmaceuticals both for human as well as Veterinary use.

Laws have been laid down prescribing Stringent Measures to safeguard the Quality and Purity of Drugs & Medicines and for recognition of the Testing Laboratories equipped with requisite Instrumentation Infrastructure with Good Laboratory Practices in order to Safeguard and Preserve the Limits, Doses, Purity, Strength of Drugs and use of Raw Materials & other Chemical Inputs and Reagents of High Purity and Quality in the Manufacturing of Drugs.

In India, provisions have been made in the Drugs & Cosmetics (D & C) Rules, 1945 as amended in 2003 for Approval of Laboratories to carry out tests on Drugs & Raw materials used in their Manufacturing Schedule C & C (I) of Rule 150 C & Cosmetics prescribes the Requirements criteria in terms of Area, Manpower, Equipment and Instruments of Drugs for Approval of the Drug Testing Laboratories.

EFRAC conducts Testing for entire Range of Drug, Cosmetics Products & Raw Materials strictly following the Norms, Standards and General Principles that have been scientifically approved by Indian Drug Regulator (CDSCO) & Internationally by WHO , USFDA, MHRA, etc.

Entire range of Drug Testing Processes at EFRAC, strictly fulfills the International Standards and thus EFRAC ensures Safe, Secured, Accurate, Legally Defensible and Reliable Data on Testing.

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PHARMA SERVICES

OHSAS

BIS

FSSAI

NABL

USFDA

APEDA

AGMARK

TEA BOARD

EIC

GAFTA

SGF

CDSCO

AYUSH

MOEF

WBPCB

USFDA INSPECTED FACILITY

Drugs & Cosmetics Division at EFRAC is an Advanced Pharmaceutical Testing Facility. With Cutting Edge Technology, we deliver High Quality Testing Services to the Pharmaceutical and Cosmetics Industry. Our Cost Effective Projects and Contractual Services, both for General and Specific Analysis encompassing the Routine Quality Control (QC) and Research & Development (R&D) Studies satisfies the constant Analytical Requirement of the Industry.

EFRAC is managed by a Talent Pool of Experts of par Excellence from all Fields of Professional Experience possessing Comprehensive knowhow, Technology updates and full of Innovative Ideas and untiring Zeal to provide Standard & Customized Analytical Solutions as a CRO with high Levels of Precision, Accuracy, Data Integrity & Reliability to meet the Requirements of the Client and Stake Holders.

Entire Work Process at EFRAC is driven by a Robust Quality Management System integrated online through LIMS Platform to Track and Record the entire Laboratory Work and Data Flow and provides role based controls.

Our thorough understanding of Internationally Accepted cGMP and GLP Requirements with Specialized Expertise in State-of-the-Art Analytical Techniques combined with unparalleled Service Support and Turn Around Time (TAT) differentiates us from our Competitors.

All the Equipments used in our Laboratories are regularly Calibrated and Qualified as per the Current Good Laboratory Practices (GLP) and the Requirements prescribed under the ISO/IEC 17025 (NABL Accreditation).

efrac PHARMA SERVICES

ANALYTICAL SERVICES

A) THERAPEUTIC & ESSENTIAL DRUGS

a. Raw Materials/Ingredients
- Active Pharmaceutical Ingredients (API's)
- Inactive Ingredients or Excipients

b. Veterinary Drugs

c. Finished Products (Formulations)

d. Surgical Dressings

B) AYURVEDIC DRUGS

a. Raw Materials
- Raw Plant Materials or Herbs
- Animal Products
- Minerals and Metals

b. Finished Products (Formulations)

C) COSMETICS

a. Raw Materials

b. Finished Products

D) WATER

a. Raw Water/Potable Water

b. Purified Water

c. Water for Injection

d. Water for Haemodialysis

e. Water System Validations

E) PACKAGING MATERIAL

a.Plastic Container (Drum)

b. Glass Bottle

c.Blood Bag

d. Corrugated Box

e.Tetra Pack Material Laminate

f. PVC Bottle/Foil for Blister

g. Aluminium Foil

SPECIALIZED SERVICES

a. Stability/Shelf Life Studies

b. Extractable & Leachable Studies

c. Analytical Method Development & Validation

d. Method Optimization and Verification

e. Microbiological Validations

f. Antibiotics Assay

g. Forced Degradation Studies

h. Cleaning Validation

UPCOMING SERVICES

a.Preclinical Studies

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PHARMA SERVICES

ANALYTICAL SERVICES

MODERN & AYUSH DRUGS

The Pharmaceutical Industry uses a very large Variety of Raw materials and a large Array of Ingredients is involved into the Manufacturing of a Single Product. It is often difficult, if not impossible for a Pharmaceutical Manufacturer to have In-house Testing Facilities and Capabilities for all the Ingredients and Products.

EFRAC's Pharma Testing Division offers a Complete Solution for Testing of Pharmaceutical Raw Materials including Pharmaceutical Drug Substances, Intermediates, Excipients etc.

Pharmaceuticals and related Industries require Commitment for GLP, cGMP & Stringent Quality System, Robust Data Integrity Compliance which EFRAC has demonstrated over the Years through its Comprehensive Setup for Testing Drugs thus ensuring Quality & Reliability.

- Ingredient Testing
- Formulation Drug Testing
- Surgical Dressing/ Medical Device Testing
- Veterinary Drugs Testing
- Cosmetics/Cosmeceuticals Testing
- Pharmaceutical Water Testing
- Microbiological Testing
- Ayurvedic Testing


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PHARMA SERVICES

INGREDIENT TESTING

Pharmaceutical Ingredients or the “Raw Material”, may be Natural, Semi-Synthetic Or Synthetic Chemical Compounds or Biologically Derived Products, which are used for Formulation of Various Dosage Forms. The Ingredients which have Therapeutic value are referred as Active Pharmaceutical Ingredient (API) and Ingredients which have no Therapeutic Action but are used to formulate a Dosage Form are known as Excipients. All Ingredients used in Formulation require Routine Analysis to ascertain the Quality of Finished Product.

EFRAC's Pharma Testing wing routinely performs QC Analysis according to CGMP Quality Standards for the APIs, Bulk Drugs, Intermediates, Excipients, Finished Products & Packaging Materials for Systematic and Stringent Physical, Chemical and Microbiological Analysis as per the Standardized Validation or Pharmacopoeial Protocols to ascertain the Quality of the Finished Product.

PARAMETERS

Assay (Chemical and Microbiological) • Bacterial Endotoxin Test (BET) • Boiling Point/Range • Melting Point/Range • Clarity and Color of Solution • Congealing Temperature/Range • Distillation range • Elemental Analysis • Enantiomeric Purity • Fatty Acid Composition • Heavy Metals (Quantitative) by AAS, ICP OES, ICP-MS • Identification by FT-IR, Chemical Analysis etc. • Impurities and Related Substances • Limit Tests (Quantitative Estimation) • Microbial Limit Test (MLT) • Nitrogen Estimation • Specific Optical Rotation • Particle Size Distribution • Polymorphism • Residual Solvents and Organic Volatile Impurities • Sensory Evaluation • Sterility • Steroid Assay • Sulphur Dioxide Estimation • Viscosity • TGA Analysis • DSC Analysis

INSTRUMENTS

LC-MS MS (QQQ) • GC- (FID) • GC- (HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • AAS – (Flame, GTA, VGA) • ICP OES • ICP-MS • TOC Analyzer • UV -Visible Spectrophotometer • Brookfield Viscometer • CHNS & O Analyzer • FT-IR • Ion Chromatograph • Karl-Fisher Autotitrator • TGA • DSC • Particle Size Analyzer

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Japanese Pharmacopeia • United States Pharmacopeia

FORMULATION DRUG TESTING

Pharmaceutical Formulation is the Process in which Different Chemical Substances including the Active Drugs are formulated to produce a Final Medicinal Product. The Dosage Form or Formulation varies according to the Route of Administration.

- Enteral or Oral: Tablet, Capsule, Oral Liquid, Oral Powder
- Parental: Intravenous, Intraarterial, Intraosseous Infusion, Intra-Muscular, Subcutaneous, Intrathecal, Intracerebroventricular, Rectal
- Topical: Epicutaneous (Cream, Lotion, Ointment, Paste), Inhalational, Ophthalmic & Otic Products, Transdermal Patches

At EFRAC our Expert Group of Scientists can determine the Quality, Purity and Stability of your Finished products in accordance with Pharmacopoeial Monographs (EP, BP, USP and JP) and/or to Client Recommended Procedures and Specifications to cater the Regulatory Requirements of both the Domestic as well as Export Markets.

PARAMETERS

Assay (Chemical and Microbiological) • Bacterial Endotoxin Test (BET) • Boiling Point/Range Melting Point/Range • Clarity and Color of Solution • Congealing Temperature/Range • Distillation Range • Elemental Analysis • Enantiomeric Purity • Fatty Acid Composition • Heavy Metals (Quantitative) by AAS, ICP OES, ICP-MS • Identification by FT-IR, Chemical Analysis • Impurities and Related Substances • Limit Tests (Quantitative Estimation) • Microbial Limit Test (MLT) Nitrogen Estimation • Specific Optical Rotation • Particle Size Distribution • Polymorphism • Content of Active Ingredient • Deposition of the Emitted Dose • Description • Disintegration Test • Dissolution Study • Osmolarity • Friability Testing • Uniformity of Content/Uniformity of Dosage Units • Residual Solvents and Organic Volatile Impurities • Sensory Evaluation • Sterility • Steroid Assay • Sulphur Dioxide Estimation • Viscosity • TGA Analysis • DSC Analysis

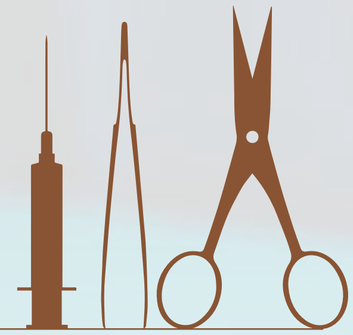
INSTRUMENTS

LC-MS MS (QQQ) • GC- (FID) • GC- (HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • AAS – (Flame, GTA, VGA) • ICP OES • ICP-MS • TOC Analyzer • UV -Visible Spectrophotometer • Brookfield Viscometer • CHNS & O Analyzer • FT-IR • Ion Chromatograph • Karl-Fisher Autotitrator • TGA • DSC • Particle Size Analysis

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Japanese Pharmacopeia United States Pharmacopeia

SURGICAL DRESSINGS/ MEDICAL DEVICES



A Surgical Dressing can have a number of Purposes depending on the Type, Severity and Position of the Wound, although all purposes are focused towards promoting Recovery and preventing further harm from the Wound. The Multifarious Properties desired in a Surgical Dressing i.e. Ceasing bleeding, Absorbing Exudates, Debriding Lacerations, Accelerating Healing, easing Physical / Psychological Trauma & preventing Infections and Mechanical Damage necessitate Stringent Adherence to Quality Standards as per Schedule F II of Drugs and Cosmetics Act.

EFRAC conducts Wide Range of Quality Tests for Material & Performance Analysis on Surgical & Allied Products like Absorbent Cotton Wool, Absorbent Gauze, Absorbent Lint, Bleached Bandage Cloth, Cloth for Plaster of Paris, Sterilized Umbilical Cotton Tape, Sterilized Umbilical Polyester Tape, Surgical Blade, Surgical Scissor, Suture & Ligature, Other Surgical Tools and render Services to Manufacturers to comply with requisite Standards of Schedule F II of Drugs and Cosmetics Act.

PARAMETERS

Absorbency • Acidity • Alkalinity • Colouring Matter • Ether Soluble Substances • Fluorescence Foreign Matter • Foreign Fibres • Freedom from Optical Whitener • Identification Penetration Test • Length & Width • Loss on Drying • Scouring Loss Percent • Sterility • Surface Active Substances • Tensile Test • Threads per dm • Water Soluble Substances • Weight in g/m2 (GSM)

INSTRUMENTS

UV -Visible Spectrophotometer • Digital Polarimeter • Digital Refractometer • Flame Photometer • Hot Air Oven • Muffle Furnace • pH & Conductivity Meter • Refrigerated Centrifuge • Rota Evaporator • Tensile Tester • Compression Tester • Bursting Strength Tester • Colorimeter • Auto Titrator • Karl Fischer Titrator • Sieve Tester • UV Chamber • Vacuum Dryer

METHODS

British Pharmacopeia • Drugs and Cosmetics Act and Rules. • European Pharmacopeia • Indian Pharmacopeia • Indian Standard (IS) • ISO • ASTM • United States Pharmacopeia

VETERINARY DRUG TESTING

Veterinary Drugs are Allopathic Medicines used within Animal Husbandry not only to cure and prevent Diseases, but also to increase Weight Gain and Tranquilize them during Transportation. These are group of Drugs which are used to cater to Preventive/Curative and Promotional Healthcare of Pet, Domestic and Wild Animals.

EFRAC performs Complete Analysis of all Contemporary Veterinary Products like Dip Concentrates, Intra-mammary Infusions, Premixes, Veterinary Aerosols, Veterinary Diagnostics, Veterinary Oral Liquids, Veterinary Oral Powders, Veterinary Tablets, Veterinary Vaccines and Veterinary Parenteral Preparations along with Analytical Method Development, Validation and Stablity Studies.

PARAMETERS

Assay (Chemical and Microbiological) • Bacterial Endotoxin Test (BET) • Boiling Point/Range • Melting Point/Range • Clarity and Color of Solution • Congealing Temperature/Range • Distillation Range • Elemental Analysis • Enantiomeric Purity • Fatty Acid Composition • Content of Active Ingredient • Deposition of the Emitted Dose • Description • Disintegration Test • Dissolution Study • Osmolarity • Friability Testing • Uniformity of Content/Uniformity of Dosage Units • Phenol in Vaccines and Antisera • Heavy Metals (Quantitative) by AAS, ICP OES, ICP MS • Identification by FT-IR • Impurities and Related Substances • Limit Tests (Quantitative Estimation) • Microbial Limit Test (MLT) • Nitrogen Estimation • Specific Optical Rotation • Particle Size Distribution • Polymorphism • Residual Solvents and Organic Volatile Impurities • Sensory Evaluation • Sterility • Steroid Assay • Sulphur Dioxide Estimation • Viscosity • TGA Analysis • DSC Analysis • Particle Size Analysis

INSTRUMENTS

LC-MS MS (QQQ) • GC- (FID) • GC- (HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • AAS – (Flame, GTA, VGA) • ICP OES • ICP-MS • TOC Analyzer • UV -Visible Spectrophotometer • Brookfield Viscometer • CHNS & O Analyzer • FT-IR • Ion Chromatograph • Karl-Fisher Autotitrator • TGA • DSC • Coulometer • Friability Tester • Hardness Tester • Disintegration Test Apparatus • Dissolution Test Apparatus • Penetrometer • BP/MP Apparatus • Potentiometer • Particle Size Analyser

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Japanese Pharmacopeia • United States Pharmacopeia

COSMETICS TESTING

A "Cosmetic Product" is any Substance or Mixture intended to be placed in Contact with the Various External Parts of the Human Body (Epidermis, Hair System, Nails, Lips & External Genital Organs) or with the Teeth and the Mucous Membranes of the Oral Cavity with a purpose exclusively or mainly Cleaning them, Perfuming them, Changing their appearance and/or Correcting Body odors and/or Protecting them or keeping them in good Condition.

EFRAC has wide range of Capability to analyze Varied Cosmetic Products like Skin Care Creams, Lotions, Powders, Perfumes, Lipsticks, Fingernail & Toe Nail Polish, Eye & Facial Make Up, Hair Removers, Permanent Waves, Colored Contact Lenses, Hair Colors, Hair Sprays & Gels, Deodorants, Hand Sanitizer, Baby Products, Bath Oils, Bubble Baths, Bath Salts, Butters and many other Types of Products.

Cosmetic Testing Services also include a variety of Protocols on Preservation Efficacy Tests - PET (Challenge Testing for Cosmetics), Microbiological Testing, Allergen Determination, Assays on Traces - Impurities, Patch Test, Stability Testing for Cosmetics, Efficacy Studies, Safety Assessment, Product Information File (PIF) Compilation and Notification to the European Authorities (CPNP).

PARAMETERS

Physical Parameters (Description, Appearance, Fineness) • Sensory Evaluation • Adhesion Test • Blush Test • Pay of Test • Scratch Test • Softening Point • Foaming Power • Alcohol Content • Assay • Available Fluoride Ion • Calcium Thioglycolic • Cloud Temperature/Point • Colour/Clarity • Consistency • Moisture and Volatile Matter • Dye Ingredients • Free Carbonated & Caustic Alkali • Glycerol Content • Heavy Metals (Quantitative) • Limit Tests • Matter Insoluble in Alcohol/ Boiling Water/Cold Water • Melting Range/Point • Nonvolatile Alcohol Soluble Mass • Particle Size of Undispersed Pigments • Synthetic Detergent • Test for freedom from Boric Acid • Thermal Stability • Total Fatty Substance/Matter • Viscosity • Microbiological Testing • Tests for specific Organisms • Microbial Limit Test (MLT)

INSTRUMENTS

LC-MS/MS • GC- (FID/ECD/TCD/MS) • HPLC (FLD/ PDA/ ELSD/ RID) • AAS – (Flame, GTA, VGA) • ICP OES ICP MS • IC –CD/AD/UV • Particle Size Analyzer • UV-Visible Spectrophotometer • Brookfield Viscometer • Polarimeter • Colorimeter • Pay of Test Apparatus • Penetration Test Apparatus Scratch Test Apparatus • Tintometer • Abbe's Refractometer • Vacuum Dryer

METHODS

Japanese Pharmacopeia • United States Pharmacopeia • British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Bureau of Indian Standards (IS) • ASTM • ISO

PHARMACEUTICAL WATER TESTING

Water plays a Central Role in the Production of Pharmaceuticals. It is widely used as a Raw Material, Ingredients & Solvents in Processing, Formulation & Manufacturing of Pharmaceutical Ingredients, Intermediates & Finished Products. The most Stringent Quality Requirements apply to Pharmaceutical Water, both as a Product Component and in Industrial Consumption. Physico-chemical and Microbiological Quality Control are essential for Manufacturing in accordance with GMP and are prescribed by Law.

EFRAC has facility for Complete Analysis of Raw Water (Potable water), Purified water, Water for Injection, Water for Hemodialysis as per different Pharmacopoeial and other Regulatory Requirements. EFRAC also provides Service for Water System Validation as per USEPA, WHO, BIS, ICH, cGMP. Apart from the Routine Testings in Water, EFRAC also offers Testing of Dioxin, Furans and Dioxin like PCBs in Water.

PARAMETERS

Physio Chemical Parameters • Organoleptic Parameters • Minerals • Anions and Cations • Heavy Metals • VOCs & SVOCs • Trihalomethane • Organic & Inorganic Disinfectants • Halo Acetic Acids • PAH • PCB • Total Organic Carbon (TOC) • Pesticides (As per IS, EU, FDA, WHO, EPA) • Dioxins and Furans • All Microbiological Tests (As per IS, EU, FDA, WHO, EPA) • Radioactive Compounds (Alpha and Beta Emitters)

INSTRUMENTS

HR GC HRMS • LC-MS/MS • GC- (FID/ECD/TCD/MS) • GC-MS/P&T/HS • HPLC (FLD, PDA, ELSD, RID) • FTIR • AAS – (Flame, GTA, VGA) • ICP OES • ICP MS • IC –CD/AD/UV • UV -Visible Spectrophotometer • TOC Analyzer • CHNS & O Analyzer

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Japanese Pharmacopeia • United States Pharmacopeia • WHO Guidelines • IS 10500-2012 • IS 4251-1967 • APHA • US FDA BAM • Council Directive 98/83/EC • USEPA

MICROBIOLOGICAL VALIDATIONS

Pharmaceutical Microbiology involves the Study of Microorganisms associated with the Manufacture of Pharmaceuticals e.g. minimizing the number of Microorganisms in a Process Environment, excluding Microorganisms and Microbial Biproducts like Exotoxin and Endotoxin from Water and other starting Materials, and ensuring the Finished Pharmaceutical Product is Sterile.

Microbiological Analysis is the Integral part of Pharmaceutical Analysis. Absence of Micro-organisms or Sterility is of utmost importance in case of all Parenteral Preparations. Environmental monitoring is necessary in all steps of Pharmaceutical processing.

EFRAC's Microbiology Laboratory is designed to meet Stringent Regulatory Requirements with Class 10K Clean Rooms, Unidirectional Flow, Pressure Control Devices, AHUs, Terminal HEPA Filters, Coved edges and Epoxy Flooring.

PARAMETERS

Detection of Pathogens • Microbiological Method Validation • Antibiotic-Microbial assays • Microbial Limit Tests (MLT) • Enumeration of Spoilage Micro-Flora • Residual Anti-Microbial Substances • Bacterial Enterotoxins • Bacterial Endotoxin Test (LAL) • Sterility Testing • Mycotoxins • Bioburden Analysis, TAMC, TYMC • Microbiological Monitoring of Indoor Air • Anti Microbial Efficacy of Medical Devices/Filters • Preservative Efficacy • Disinfection Efficacy • Potency Assays • RWC Test, SC Test • Surgical Dressings & Medical Devices • Microbiological Assays • Microbiological Assay of Vitamins • Membrane Filtration Method (All Bacterial and Fungal groups) • Environmental Monitoring Tests • Rodac or Settling Plates Count • Impact Viable Air Sampler Plates Count and Identification • Gram Staining • Identification of Bacterial Species • Identification of Fungal Species • Total Coliform E. coli • Water Heterotrophic Plate Count • Media Growth Promotion (Media Fertility) Testing • Growth Promotion Test- Qualitative • Growth Promotion Test- Quantitative • Healthcare Products & Disinfectants • Evaluation of Antimicrobial Properties of Different Healthcare Products as per Customer Supplied Protocols/ASTM Methods • MIC Testing • Neutralization Testing as per ASTM 1054-02 • Antimicrobial Effectiveness Testing of Personnel Hand Washes/Sanitizers • Germicidal value • Phenolic Disinfectants as per IS 1061 • Rideal Walker Coefficient (RWC) • Staphylococcus Aureus Coefficient (SAC) • Self-Contained BI Indicators • Spore Strip Immersion

INSTRUMENTS

Auto Diluter • Smasher • Fully Automated Autoclaves Coupled with Chart Recorders & Auto Cycle Programming Feature • Balance Integrated with Printers • Laminar Air Flow Hoods • Bio-Safety Cabinet Class A1 • LAN Integrated Bacteriological Incubators & Hot Air Ovens Coupled With 21CFR Audit Trial Software • ELISA / Microplate Reader • Real Time PCR • Binocular Microscope • Water Activity Meter • Laboratory Refrigerators with Temp Monitoring and Recording Features • Cold Room for Sample Storage

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • United States Pharmacopeia • WHO Guidelines • USEPA Guidelines • ASTM • US FDA BAM Methods • ISO Guidelines

AYURVEDIC DRUGS

According to the World Health Organization (WHO), 80% of the World Population still relies on Traditional or Herbal Medicine for their Primary Health Care needs. The major merits of Traditional Medicine seems to be their perceived Efficacy, Low Incidences of Serious Side Effects and Low Cost. Extensive & Continued usage of Traditional Medicine in the 2nd & 3rd World Nations along with increasing Popularity of the Traditional Indian System of Medicine Worldwide i.e Ayurveda necessitate Testing & Analysis Procedures and Standards to be compliant with concerned Regulations.

Ayurveda is the Traditional System of Indian Medicine which is regarded as the Oldest System of Medicine in the World (3000 years old) that is still widely being Practiced, especially in the Indian Subcontinent. Recently, there is renewed interest on Ayurvedic Medicine Globally.

Ayurvedic Drug Testing involves Testing of Ayurvedic Raw Materials (Raw Plant, Animal & Mineral Materials, Water); and Analysis of different Ayurvedic Formulations or Finished Products (Pharmacopoeia or Proprietary).

EFRAC is approved by State Drugs Control of Indian Systems of Medicine and Homoeopathy (ISM & H) and Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) & National accreditation board for Testing and calibration laboratories (NABL) for Analysis of Ayurvedic, Siddha, Unani and Homoeopathic Medicinal Products.

PARAMETERS

Identification (Macroscopic/Organoleptic/Sensory, Microscopic, Chemical) • Acetyl Value • Acid Insoluble Ash • Acid Value • Adulteration with Modern Drugs/Drug Residues • Aflatoxins (Qualitative and Quantitative) • Alcohol Content & Alcohol Soluble Extract • Analysis of Mineral Raw Materials/Metals • Assay of Marker Compounds • Boiling Point/Range • Chromatographic Fingerprinting Studies by TLC, HPLC, GC, GC-MS, LC-MS/MS • Congealing Range/Point • Ester Value • Ether Soluble Extractives • Fixed Oil Estimation • Fluorescence Analysis • Foreign Matter • Heavy Metals (Qualitative and Quantitative) • Hydroxyl Value • Iodine Value • Limit Tests • Loss on Drying/Moisture Content • Loss on Ignition • Melting Point/Range • Microbial Limit Tests and Tests for Specific Organisms • Pesticide Residues • Powdered Herb Analysis • Protein Estimation • Essential Oil Estimation • Refractive Index & Relative Density • Fatty Acid Profiling and Composition • Amino Acid Profiling • Sugar Estimation • Tap & Bulk density • Test for Mineral Oil • Total Ash, ASA and Sulphated Ash • Total Phenolic Compounds • Total Solids • Total Tannins • Unsaponifiable Matter • Viscosity • Volatile/Essential Oil Content • Water Content • Water Soluble Ash • Water Soluble Extractive

INSTRUMENTS

LC-MS MS (QQQ) • GC- (FID) • GC- (HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • AAS – (Flame, GTA, VGA) • ICP OES • ICP-MS • TOC Analyzer • UV -Visible Spectrophotometer • Brookfield Viscometer • Coulometer • CHNS & O Analyzer • FT-IR • Ion Chromatograph • Karl-Fisher Autotitrator • TGA • DSC • Digital Polarimeter • Friability Tester • Hardness Tester • Disintegration Test apparatus • Dissolution Test apparatus • Penetrometer • BP/MP Apparatus • Potentiometer

METHODS

Ayurvedic Pharmacopoeia of India • British Pharmacopeia • Food Chemical Codex (FCC) • United States Pharmacopeia • Indian Pharmacopoeia • Indian Standards (IS) • Siddha Pharmacopoeia of India • Unani Pharmacopoeia of India • United States Pharmacopeia • WHO Guidelines

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PHARMA SERVICES

SPECIALIZED SERVICES

EXTRACTABLES AND LEACHABLES

Extractables and Leachables are Group of Compounds that can be of Potent Risk and may infuse a Serious threat to Pharmaceutical Manufacturers producing API, Generics and Formulation End Products for both Domestic & Export Market. When Elements and Compounds leach into Products, from Packaging or Manufacturing Conditions they can render them unfit and even dangerous for use.

Leachables analysis identifies Substances which migrate from Polymeric, Metallic or Glass Material into the patient and are typically a subset of those identified in the Extractables Analysis. This type of Analysis is required when there is a risk that harmful Substances may have leached into a Liquid Product, such as Eye Drops, from its Container or Packaging.

The Assessment of Extractables and Leachables in Bio-Pharmaceutical Products is an important step in Drug Product Development. Processing Equipment, as well as, primary and Secondary Container Closures are Potential Vectors for chemical Contaminants.

Extractables Analysis identifies Categorization and Quantification of Substances which could potentially migrate from Polymeric, Metallic or Glass Material into the Consumer's body through any of the Medicines consumed by them during the process of treatment. It includes Monomers and Polymer Additives such as Antioxidants, Plasticisers, Stabilizers, Dyes, Metal Catalysts & other Harmful Chemicals which may potentially migrate into the Product under Storage Conditions.

Applicable Guidelines & Regulatory Requirements - USP <1663>, USP <1664>, EMA - CPMP / QWP/ 4359/03, ICH - Q3A (R2), PQR5 (Mar 07, Sept 06), USFDA Guidance for Industry (1992, 2002)

INSTRUMENTATION

HPLC-UV, DAD • HS-GC, HS-GC-MS • GC (FID, ECD, FID-NP), GC-MS • GC-TEA (Nitrosamines) • ICP-OES, ICP-MS, AAS, FTIR • TGA, DSC • Particle Size Analyzer

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PHARMA SERVICES

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Non-Pharmacopoeial and Proprietary Combinations involve new Drugs and Excipients in Multiple Combinations and require Advanced Processing / Formulation Strategies. Thus, Product Formulation, Development and Optimization necessitate that constituents be Accurately Determined through Validated and appropriate Analytical Methodologies.

With the Advent of newer Drugs, Excipients & newer Processing/ Formulation Strategies in combination with Two or more Drugs, there is a relevant need of legitimate Analytical Methods to determine them properly. This is generally applicable for Non-Pharmacopoeial Proprietary Combination Products and therefore Essential for Formulation/ Product Development and Optimization.

EFRAC offers Economical and Strategic Solution for Method Development, Validation, Verification, Optimization Improvement, Qualification & Transfer Studies for a wide range of Modern Drugs, Ayurvedic Drugs, Nutraceuticals & Cosmetic Products by critically adhering to the Quality Standards & Integrity which are backbone for any new Drug Delivery into the Market. Our Integrated Approach to Analytical Method Standardization, all stages of Pharmaceutical Fabrication Processes namely APIs, Intermediates & all types of Dosage Forms or Finished Products has been successfully Executed in many High-Volume Projects for Clients by maintaining Strict Deadlines.

Accuracy: Closeness of Test Results to the True Value across the Range.

Precision: Degree of Agreement among Individual Rest Results applied repeatedly to Multiple Samples of a Homogeneous Sample.

Specificity/Selectivity: Ability to assess the Analyte in the presence of Components expected to be present.

Detection Limit (LOD): The Lowest amount of Analyte that can be Detected under the Stated Experimental Conditions.

Quantitation Limit (LOQ): The Lowest amount of Analyte that can be determined with Acceptable Precision and Accuracy under the stated Experimental Conditions.

Linearity: The ability to elicit Test Results that are Proportional to the Concentration of the Analyte within a given Range.

Range: The Interval between the Upper and Lower Levels of Analyte that have been demonstrated to be determined with a Suitable Level of Precision, Accuracy, and Linearity.

Robustness: The measure of its Capacity to remain Unaffected by Small but Deliberate Variations in Procedural Parameters.

Studies conducted:

Assay • Dissolution • Excipients like Preservatives and Stabilizers • Impurities and Related Substances • Microbiological Tests • Organic Volatile Impurities and Residual Solvents • Physico-Chemical Tests • Trace Elements, Metals, Metalloids and Heavy Metals

INSTRUMENTS

AAS – (Flame , GTA, VGA) • Digital Polarimeter • Digital Refractometer • Dissolution Test Apparatus • Flame Photometer • FT-IR • GC- (FID) • GC- (HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • IC • ICP-MS • LC-MS MS (QQQ) • Potentiometer • UV -Visible Spectrophotometer • DSC • TGA • Particle Size Analyzer

CLEANING VALIDATION

Cleaning Validation is the Methodology used to assure that a Cleaning Process removes Residues of the Active Pharmaceutical Ingredients (APIs) of the Product Manufactured in a piece of Equipment, the cleaning Aids utilized in the Cleaning Process and the Microbial attributes to ensure that the process and processing Equipment are suitable for Pharmaceutical Manufacturing. Potential Contaminants include Residues of the APIs, API Degradation Species, or Residues from the Cleaning Process such as Detergents or Solvents.

All Residues are removed to Predetermined levels to ensure the Quality of the Next Product Manufactured is not compromised by Waste from the previous Product and the Quality of future Products using the Equipment, to prevent Cross-Contamination and as a GMP Requirement. Acceptable Residue Limits (ARL) in Cleaning Validation is a Critical function and should be Practically Achievable, Verifiable for Logical Determination. This covers the Critical 10 ppm USP Limit Test on Materials for which no Toxicology Data is available.

Validation of Cleaning Procedures is not normally required but a Risk Assessment should be performed to make sure that there is no potential for Degradation or Microbial Contamination that may adversely impact the Quality of the Product. The Analytical Methods for Cleaning Validation should be Validated & Suitable to Quantify at the Acceptance Criterion Level. The Limit of Detection (LOD) must be lower than or equal to the Acceptance Criterion Level. Blanks must be evaluated to ensure that there is no significant interference with the Recovery of the Analyte.

EFRAC's Cleaning Validation services include Validation of Cleaning Procedures, Challenge Tests for Equipment Cleaning Process & Equipment specific Sampling through Visual inspection, Swab sampling or Rinse Sampling, Limit Test or cover a range of Analyte Concentration. The broad Cleaning Validation Sampling Techniques cover Swabbing, Rinsing & other appropriate or Specific Techniques.

PARAMETERS

Organic Ingredient Residue • Inorganic Ingredient Residue • Microbial Contaminants • Toxic Organic Volatile Impurity

INSTRUMENTS

AAS (Flame, GTA, VGA) • ICP-MS • ICP-OES • FT-IR • LC-MS MS (QQQ) • GC- (FID, HEAD SPACE, ECD, MS) • GC-MS MS (QQQ) • HPLC (FLD, PDA, ELSD, RID) • IC –CD/AD/UV • Karl-Fisher Autotitrator Potentiometer • Refrigerated Centrifuge • Rota Evaporator • TOC Analyzer • UV -Visible Spectrophotometer • RT-PCR • ELISA Reader

METHODS

British Pharmacopeia • European Pharmacopeia • Indian Pharmacopeia • Japanese Pharmacopeia • United States Pharmacopeia

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PRESERVATIVE EFFICACY TESTING

Antimicrobial Preservatives are Substances added to Products to protect them from Microbiological Growth or from Micro-organisms that are introduced inadvertently during or subsequent to the Manufacturing Process. They deter occurrence of Ingress or Growth of Micro-organisms during/ after Manufacture or subsequently, during handling of Multiple-Dose Containers. Microbes can cause the Product to spoil, thus reducing its Shelf-Life, but more importantly the Potential for Contamination with Potentially Pathogenic Strains, i.e. those that cause Disease and are dangerous to end users, can greatly increase in the Absence of Preservatives. Cosmetics are well known for their ability to Support Microbial Growth. Water-based Products with a Neutral pH have shown to be the most Susceptible. In the case of Products Packaged in Multiple-Dose Containers, Antimicrobial Preservatives are added to inhibit the Growth of Micro-Organisms that may be introduced from repeatedly withdrawing Individual use Doses.

Efficacy Testing is especially an Area that highlights EFRAC's Expertise. We perform routine Preservative Efficacy Testing for wide Range of Cosmetics & Personal Care Products as per different Pharmacopoeias well as clients shared Methods.

DISINFECTANT EFFICACY TESTING

Sterile Pharmaceutical and Medical Device Manufacturing Environments require an effective Cleaning and Disinfection Program to maintain Aseptic Conditions and prevent the Microbial Contamination of the Product. The Qualification of the Chemical Disinfectants used in these Environments is extremely important, yet it is often overlooked.

There are a number of Methods for qualifying a Disinfectant published by the Association of Official Analytical Chemists (AOAC), yet these are for qualifying the Disinfectant itself. Efficacy Testing is the actual testing of the Disinfectant. As per the USP General Chapter <1072> Disinfectants, the Test system is inoculated with sufficient inoculum to demonstrate at least a 2 log Reduction for Bacterial Spores and a 3 log Reduction for Vegetative Bacteria and allowed to dry. The Inoculated System is then exposed to the desired Concentration of the Disinfectant for the desired Contact Time. The surviving Population in the Test system is determined and the log10 Reduction is Calculated.

We at EFRAC offer a Wide Range of Testing Services for Disinfectants using ASTM, EPA and Pharmacopoeial methods. The passing Criteria depends on the method used and the Label Claim desired, but is typically a percent Reduction such as 99.9%.

ANTIBIOTIC ASSAY

The Antibiotic Potency Test measures the Bioactivity or Potency of various Antibiotics. All Antibiotics must go through Potency Testing prior to Market Release.

In the Antibiotic Potency Test Procedure, Cultures are grown and adjusted using Turbidimetric Measurement Techniques. An Aliquot of the adjusted Culture is added to a Thin Layer of Agar to create a Seed Layer. Test Samples are diluted to an appropriate Test Concentration according to Labeled Potency Claims. A Reference Standard Antibiotic is diluted in a similar manner with several Dilutions used to create a Standard Curve.

The Sample Potency is estimated by averaging the Reference Standard Zone Diameters and the Sample Zone diameters on the Three Plates used. Concentrations are calculated from the corresponding Corrected Values of Zone Diameters. The log Value is converted to the antilog. The antilog Value is multiplied by the Dilution Factor to obtain the Concentration in mg/ml of Active antibiotic. These Calculations are done with a Validated Spreadsheet for Antibiotic Potency.

EFRAC has experience in Testing various Antibiotics in compliance with the Cylinder Plate Method as per different Pharmacopoeias IP, BP, USP General Chapter on Antibiotics-Microbial Assays.

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Studies Conducted:

Follow up Stability Studies, Transport Stability Studies, Photostability Studies, Freeze Thaw Stability Studies, Developmental Stability Studies, Registration Stability Studies.

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STABILITY STUDIES

Molecules deemed promising as Probable Candidates for API/ Pharmaceutical Formulation during the Drug Discovery Process are exposed to Stability Testing, which is Integral to develop New Drug Candidates i.e., APIs and Pharmaceutical Formulations/Products for establishing their Shelf Life or Expiry Date. Influence or possible interaction of Packaging Material with Drug Products during Shelf Life Period should also be studied.

It is also important during Routine Manufacturing Process to monitor Product Quality with respect to Time and Environmental Conditions.

As per ICH Guidelines our Stability Storage Facility is equipped with Stability Chambers controlled by 21 CFR Part 11 Requirements with Online Temperature and RH Data Recording, Auto Alarm and Mobile Text Warning Facilities. We cover a wide range of Environmental Conditions such as:

Refrigerated Condition — 5°C

Primary ICH Long Term Condition (For Zone I to II) — 25°C/ 60% R.H

Intermediate ICH Condition (For Zone Ivb) — 30°C / 75% RH

Intermediate ICH Condition (For Zone I to Iva) — 30°C / 60% RH

Accelerated ICH Condition (For Zone I to IV) — 40°C / 75% RH

ICH Option 1 and 2 with light Intensity Recording — Photo stability

*Custom Storage Conditions can be Programmed to meet Client Requirements.


excess
Me
Me
OH
HO
OH
200 mL
+ 5%
150
100
50

FORCED DEGRADATION STUDY

Forced Degradation Study (or Stress Testing) typically involves Exposure of Drug Substances or Formulations thereof to Environmental Stress Conditions namely Heat and Humidity and Light for Solid-State Studies. For Liquid State Studies the Drug Substance/Formulation is exposed to a range of pH values, Freezing and Thawing. It is also referred as Accelerated Stability Study.

Degradation Type	Experimental Conditions	Condition
Acid	0.1 N Hydrochloric Acid	Ambient
Base	0.1 N NaOH	Ambient
Oxidation	3 % Hydrogen Peroxide	Ambient
Photolysis	UV Lamp	Ambient
Thermal	Heat Chamber	60°C
Metal Ions	0.05 M Fe_2 or Cu_2	Ambient
Humidity	Stability Chamber	75 % RH or Greater

In ICH Q1A, Section 2.1.2 (Stress Testing), there are recommended Conditions for performing Forced Degradation Studies on Drug Substances (API) and Drug Products (Formulations). The Recommendations are to examine the Effects of Temperature (above that for Accelerated Testing, i.e., >50°C), Humidity (≥75% Relative Humidity), Oxidation & Photolysis.

ICH Q1B gives recommended approaches to assess the Photo stability of Drug Substances and Drug Products. Forced Degradation Conditions are specified in Section II (Drug Substance) and Section III (Drug Product). Photo stability Testing can be performed on the Solid or in Solution/Suspension.

EFRAC has proven Competency and Adequate Capacity to undertake all such Degradation Studies across Various Drug Matrices.

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UPCOMING SERVICES

PRECLINICAL STUDIES

Before a new Active Substance can be used as a Medicinal Product, it has to be tested for its Safety and Efficacy in Animals prior to its use in Humans. This testing in Animals is termed as Pre-Clinical Studies. Preclinical Studies are conducted to define the Pharmacological and Toxicological Effects not only prior to initiation of Human Studies but throughout the Clinical Drug Development Process. In general, Pre-clinical studies are performed to predict the Safety and Efficacy Data from the Animal Models which support the conduct of research in Human Beings. The Pre-Clinical Studies also must get approval by Regulatory Authorities.

A. PHAMACOLOGICAL STUDIES

Pharmacology deals with the Pharmacokinetic and Pharmacodynamic Properties of Drug. It is important to investigate undesirable Pharmacological Activity in appropriate Animal Models and Monitoring them in Toxicological Studies. Pharmacokinetic Studies are very important to reveal the Safety and Efficacy Parameters in terms of Absorption, Distribution, Metabolism & Excretion (ADME). These Studies give data on Absorption Rate for different Routes of Administration, which helps in dosage form Selection, Distribution Mechanism, Rate of Metabolism and Excretion; which determines the Half-Life of the Drug.

B. TOXICOLOGICAL STUDIES

Toxicological Activity of the Products can be determined using in-vitro and in-vivo Assay Methods which estimate the Clinical relatedness of the Toxicological Effects of the Drug. In-vitro studies can be performed to examine the direct effects on Cellular Phenotype and Proliferation. In-vivo studies can be performed for Qualitative and Quantitative determination of Toxicological effects. In-vivo studies to assess Pharmacological and Toxicological activities, including defining Mechanism(s) of Action, are often used to support the rationale of the proposed use of the product in Clinical Studies.

EFRAC shall set up Infrastructure for conducting Toxicology studies in accordance with National and International Regulatory Guidelines and GLP Standards (i.e., FDA, OECD, EPA-OCSPP, ICH, CPSEA, EU, JMAFF) & shall engage a Pool of Staff of experienced experts for designing Customized Studies to meet the specific needs of our Clients. These include Non-GLP Screening Studies which can be utilized to Cost-Effectively evaluate Prototypes.

PARAMETERS

Adrenocorticotrophic Hormone Assay • Gonadotrophic Hormone for LH Activity • FSH Activity • Glucagon Activity • Depressor or Histamine like substance • Pyrogen Test • Safety Test • Biological Reactivity Test • Determination of Lethal Doses, LD10 or LD 50 in Albino Mice • Skin Sensitivity/Eye Irritation • Implantation Test • Potency Testing of Rabies Vaccine • Potency Testing of Pertussis fraction on DPT vaccine • Potency Testing of Tetanus Fraction of DPT/DT/IT Vaccine • Potency Testing of Diphtheria fraction of DPT/DT Vaccine • Testing of Oral Polio Vaccine (OPV) • Potency Testing of Japanese Encephalitis Vaccine • Potency Testing of Snake Venom Serum (AVS)

GUIDELINE

21 CFR Part 58.1 Good Laboratory Practice for Non-Clinical Laboratory Studies

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INSTRUMENTATION

GC MS/MS
(AGILENT 7000 GC /MS TRIPLE QUAD)

LC MS/MS
(WATERS - ACQUITY UPLC-TQD)

GC MS
(AGILENT - 5975C TRIPLE AXIS DETECTOR)

HPLC
(AGILENT - 1260 INFINITY)

AAS
(AGILENT - 280 FS AA)

ICP OES
(AGILENT - 5100 SERIES)

ICP MS
(AGILENT - 7700 SERIES)

FTIR
(AGILENT - CARY 630)

PARTICLE SIZE ANALYZER (MALVERN - MASTERSIZER 3000)

THERMOGRAVIMETRIC ANALYZER (TGA PERKIN ELMER 8000)

DIFFERENTIAL CALORIMETRY (DSC - PERKIN ELMER 8500)

CHNS ANALYZER (ELEMENTAR - VARIO EL)

ION CHROMATOGRAPHY (METROHM - 883 BASIC IC PLUS)

UV VIS SPECTROPHOTOMETER (AGILENT - CARY 60)

AUTO TITRATOR & KARL FISHER TITRATOR (METROHM - 851 TITRANDO)

TOC ANALYZER (ELEMENTAR - VARIO TOC CUBE)

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