Vittarthaa Life Sciences

Plot No. 29, Fourth Cross,
Bommasandra Industrial Area,
KIADB, Anekal Tq., Bangalore – 560 099
Karnataka, India
Phone: +91 80 35893150/ 35893151/ 48527566
Mobile: 9686623006/ 9845812503
E-mail: bd@vittarthaa.com
www.vittarthaa.com

Non-confidential Document

In private circulation only

वित्तार्थ [*vittārtha*]; *an expert* *Lit. L. Sanskrit*

Estd. 2016

Vittarthaa life sciences is a specialist and deep domain expertise, with Scientific and Technical knowledge to provide solutions to Life Sciences Industry.

With the rise of globalization, increasing market volatility and demand for scientific reasons in global health care for all living beings, *Intelligence Solutions* has become a core facet of business innovation.

Vittarthaa has carved out a niche platform as premier service provider of *Intelligence Solutions* after recognizing the evident need for custom solutions in Life Sciences Industry.

The reason, Vittarthaa was founded to address issues that, most Marketing Solutions were data-centric and generic in nature regardless of scale, strategy or requirements, often out of date and sometimes inaccurate.

Today's business needs a meaningful solution with sustainable business models that are holistic in approach to provide *Intelligence Solutions* to all Industries in the business of Human, Animal, Plant Health & its Environment.

Scientific Expertise

Vittarthaa Life Sciences is a Drug/Product Discovery and Development company focused on identifying unmet clinical/market needs to develop Novel molecules.

Research programs are oriented on integrated approach towards target-based discovery strategies and phenotypic screening for end point evaluation. Vittarthaa focuses on innovative Discovery and Development approaches for progressing molecules into market.

Expertise

Preclinical Biology and Clinical phenotypic assessment of endpoint

Scientific comprehension and interpretation from gene regulation to endpoint phenotypic expression

Creation of Target Product Profile on drug or product

Scientific know-how on translational interpretation of results form animal studies to man

Design Preclinical Development strategy to support regulatory submission

Formulation and Development

Small batch Manufacturing

Capabilities

In-Silico (*Dry lab*)

Molecular Pathways, data mining and curation, network biology, cleaning validation, Regulatory affairs

Small molecules, Biologicals and phytochemicals

Physiochemical profiling/synthesis, fractionation and purification technology, characterization, analytical studies, in-silico and drug delivery formulation

Primary Research Activities (*in-vitro*)

Assay Development - cell line, Gene expression analysis, metabolomics, antibody generation and ADME/PK

Proof of concept (*in-vivo*)

Animal models for Oncology, Pain & Inflammation, Liver disease, Diabetes, Obesity & Cardiovascular, Wound, Respiratory and Infection
Immunization, Antibody generation, Immunohistochemistry

Safety Assessment (*in-vitro* & *in-vivo*)

Toxicity, Genetic toxicity, Immunogenicity, Histopathology and clinical pathology

Clinical Trials

Herbal, Cosmetics and Nutrition

Non-confidential Document

In private circulation only

Technology Platform

- Cell culture Facility
- Viral Culture lab
- Whole tissue culture lab - Vibratome
- Molecular Biology
- Real Time PCR
- ELISA
- Western blotting
- Microbiology
- Phytochemical Extraction
- Formulation lab

- Multiplex reader
- Cryo-sectioning
- Clinical Pathology
- Histopathology
- Fluorescence Microscopy
- Flow Cytometry and Mass spectrometer
- Individual Ventilated cage system
- *C. elegans* lab
- Zebra fish facility
- Animal Facility

Institutional Biosafety committee (IBSC)

Institutional Animal Ethical Committee (IAEC)

Independent Ethical committee for clinical trials (IEC)

DSIR (applied)

Pollution control board clearance

Import-Export Licence (DGFT)

Non-confidential Document

In private circulation only

Dry Lab & Regulatory

Hazard and Risk Assessments

- ✓ *Safety Expert Reviews*
- ✓ *Preparation of Cleaning Validation Document ADE, PDE, OEL and OEB.*
- ✓ *Genotoxicity Assessment*
- ✓ *Pharmaceuticals & Biopharmaceuticals impurities risk assessment*
- ✓ *Consumer-Product Ingredients Assessment*
- ✓ *Cosmetic Product Safety*

New Product Development

- ✓ *Efficacy Expert Reviews – Pharma/Nutra/Herbal & Cosmetics*
- ✓ *Commercial Product Discovery and Development*
- ✓ *Product Cycle Management*
- ✓ *Product reviews based on Science/Manufacturing/Licensing/Marketing*
- ✓ *System Biology*

Regulatory

- ✓ *Dossier Preparation – IND, ANDA, NDA review and submission*
- ✓ *Intellectual Property (IP) assistance*
- ✓ *New Facility design & Establishment*
- ✓ *Social CRM Engagement*

Quality

- ✓ *Data Integrity Assurance & Validation*
- ✓ *GxP Compliance Services*
- ✓ *SOP preparation and review*

Others: Scientific Communications for publication in peer-reviewed high impact scientific journals

Cleaning validation & Genotoxicity assessments

- Preparation of cleaning validation documents: Acceptable Daily Exposure (ADE)/ Permissible Daily Exposure (PDE) as per USFDA/EMA/ other global regulatory agencies in manufacturing of Drug Products/APIs.
- Preparation of Occupational Exposure Limit (OEL) and Banding the Occupational Exposure Limits (OEB), Risk identification/ Hazard identification in the manufacture of different medicinal products in shared facility or dedicated facility.
- In-silico Toxicity Assessment, Genotoxicity & Carcinogenesis of unknown pharmaceutical impurities.
- Assessment and science-based strategy for establishing acceptable intakes for drug products/APIs nitroso-amine impurities.
- Assessment of all possible process related impurities in the manufacturing scheme, such as organic impurity, inorganic impurity, catalyst, elemental impurity and residual solvents and derivation of acceptable intake.
- Identification and assessment of all synthesis related nitroso-amine impurity and N-nitroso-amine drug substance related impurities (NDSRIs) in the manufacturing scheme.

Non-confidential Document

In private circulation only

Dry Lab & Regulatory

- Preparation of MSDS (Master Safety Data Sheet)
- In-silico Genotoxicity and carcinogenesis prediction
- Toxicological assessment of impurities in Pharmaceutical agent or active pharmaceutical agent (API)
- Toxicological Assessment of impurities in Cosmetics
- Prediction of drug metabolism and assessment of toxicological profiles of all metabolites
- Chemical toxicity assessment by in-silico model for industrial chemical, food additives, colouring agent
- Biological evaluation of Medical Devices as per ISO 10993, Part 17.

Non-confidential Document

In private circulation only

Research Facility at Bommasandra Industrial Area

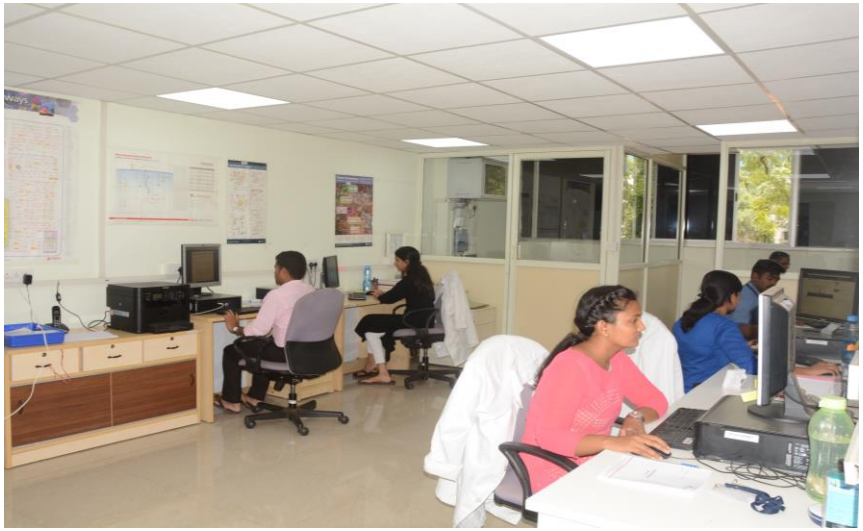
Non-confidential Document

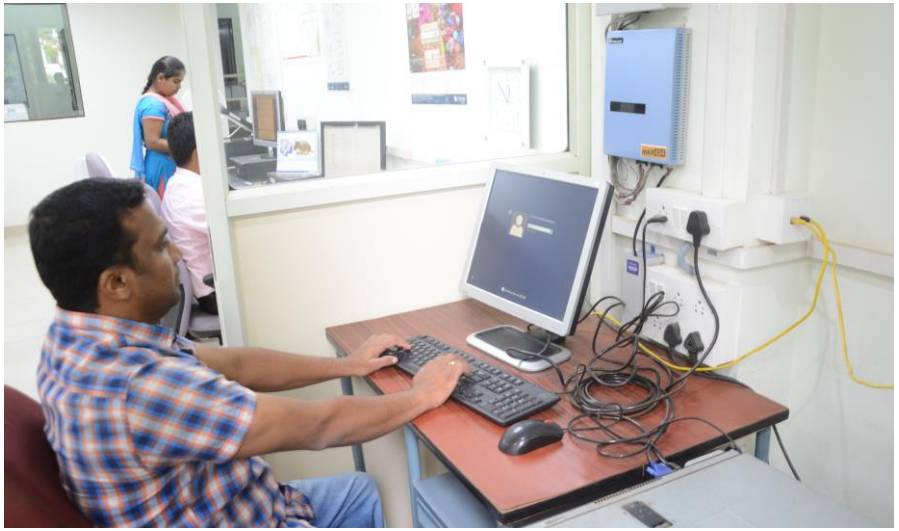
In private circulation only

Research Facility at Bommasandra Industrial Area

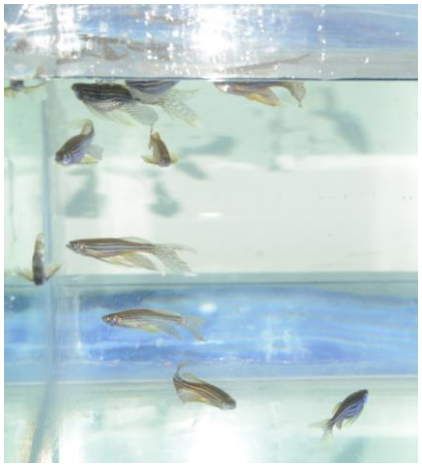
Research Facility at Bommasandra Industrial Area

Research Facility at Bommasandra Industrial Area



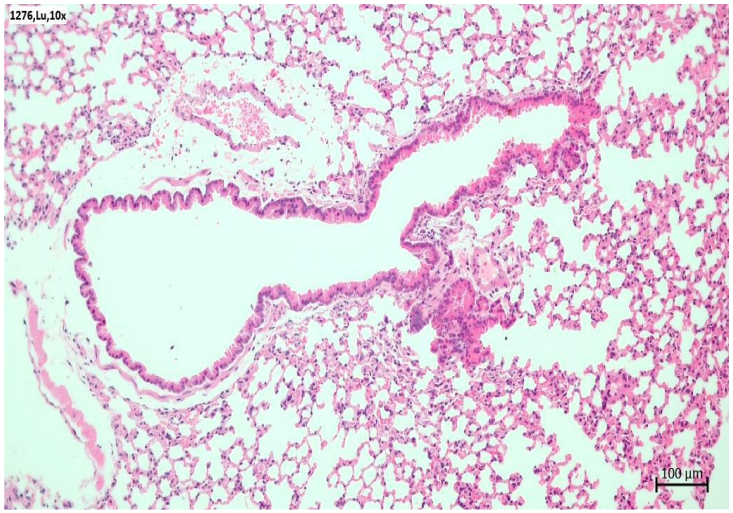


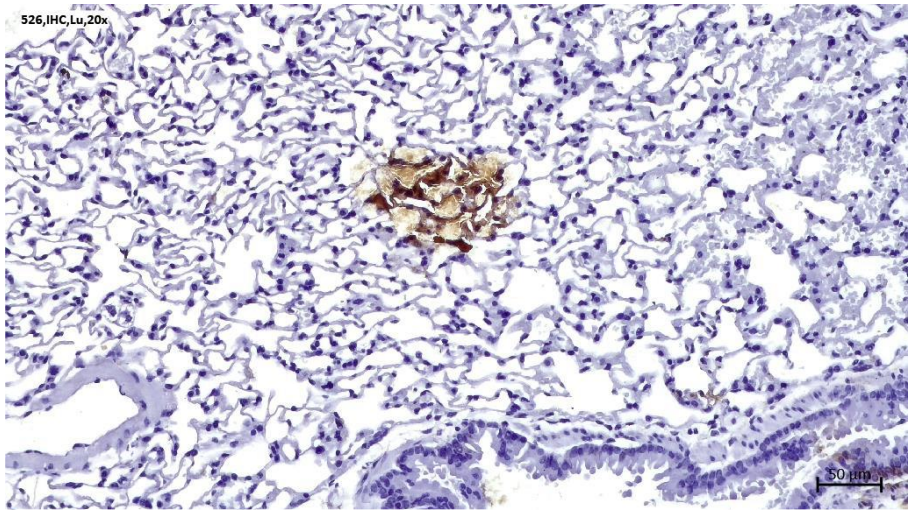
Research Facility at Bommasandra Industrial Area

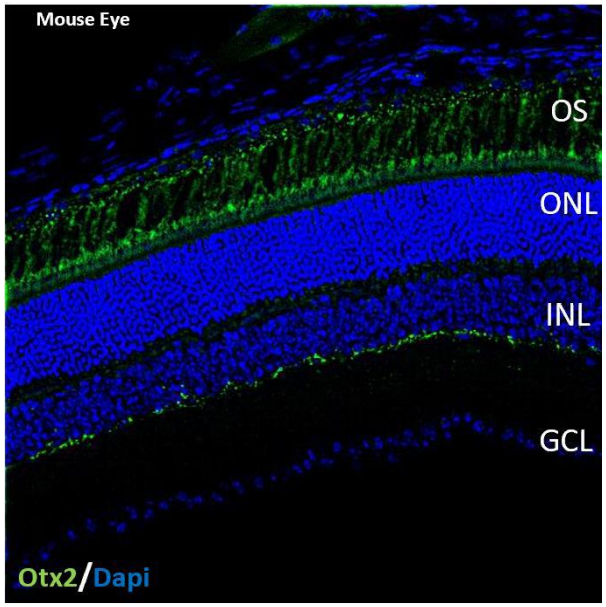


Research Facility at Bommasandra Industrial Area

Sample Experiment Results

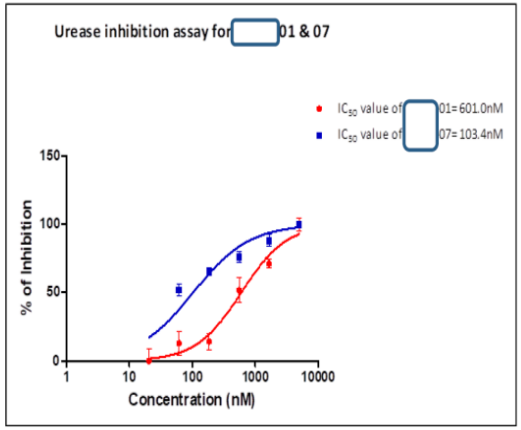






[redacted]-01 and [redacted]-07 sample- GraphPad processed data

log(inhibitor) vs. normalized response -- Variable slope	[redacted]-01	[redacted]-07
Best-fit values		
LOGIC50	2.779	2.015
HILLSLOPE	1.207	0.9714
IC_{50}	601.0	103.4
Std. Error		
LOGIC50	0.07111	0.07260
HILLSLOPE	0.2149	0.1520
95% Confidence Intervals		
LOGIC50	2.631 to 2.926	1.864 to 2.165
HILLSLOPE	0.7612 to 1.653	0.6562 to 1.287
IC50	427.9 to 844.0	73.10 to 146.3
Goodness of Fit		
Degrees of Freedom	22	22
R^2	0.8747	0.8665
Absolute Sum of Squares	4306	3493
Sy.x	13.99	12.60
Number of points		
Analyzed	24	24



Clinical Research Site

Our mission is to provide solutions to drug/product discovery & development that directly impact the cost, predictability, quality and speed.

We provide superior predictive solutions, which allows the to de-risk their discovery & development programs by enabling decisions at the early stages.

We take businesses from where they stand today, to where they need to be tomorrow.

This is achieved by delivering real change and forging relationships based on trust, understanding and accountability in our results.

Contact:
Suvarna M
Phone: +91 80 35893150 / 35893151
Mobile: +91 9686623006/ 9845812503
Email: bd@vittarthaa.com
www.vittarthaa.com

Thanks...