CURABIGSH LABORATORIES

INTRODUCTION

Curabigsh Laboratories was founded in 2022. It is engaged in pharmaceutical finished product development, analytical development, method validation, quality compliance and custom impurity synthesis activities.

Founder: Gunanidhi Panda

Holds a M.Tech degree in Analytical Chemistry from IIT, Delhi and M.Sc degree in Chemistry from Utkal University, Bhubaneswar. He has worked in the area of Pharma research for 28 years with most reputed pharmaceutical companies in India. His in-depth knowledge and rich industry experience provides a strong leadership in driving the quality work and timely project delivery.

SERVICES OFFERED

Curabigsh Laboratories offers the following services to customers

- Formulation development for USA, Europe and other regulated markets
- Analytical method development, validation and stability study for API and finished products as per ICH guidelines
- In-vitro Bio study. Phosphate binding study. Comparative multi-media dissolution profile and IVIVC
- Specialized analytical testing and characterization by high end analytical instruments (XRD, Raman, EPR, TEM, AFM and NMR etc..)
- Custom impurity synthesis for small and large molecules and peptides
- Primary reference standards and working standard preparation
- cGMP compliance of API and Finished product manufacturing facilities

FORMULATION DEVELOPMENT

1. Product development for all type of dosage forms. i.e. Tablets, Capsules, Liquids, Suspension, Powders and Injectable etc..
2. Tablets include Immediate release, Extended release, Effervescent, Chewable, Mouth dissolving and multi unit particulate systems etc..
3. Hard gelatine capsules filled with powder, small tablets, granules or pellets.
4. Products of all categories, i.e. Prescription, OTC, Monograph, Nutraceutical and Dietary supplements etc..
5. Products for different regulated and semi regulated markets and with different regulatory filing strategy i.e. Para-3, Para-IV, 505 b(2) application etc..

FORMULATION DEVELOPMENT

Process

1. Prototype formula development and compatibility study
2. Analytical method development and validation
3. Formulation quality and in-vitro dissolution evaluation
4. Stability study in accelerated, Intermediate and Real time climatic condition
5. Scale-up batch evaluation and process optimization
6. Bio-equivalence study (Outsourced to Bio-CRO)
7. Product development report
8. Technology transfer

FORMULATION DEVELOPMENT

Supporting Equipments

1. High sheer mixer granulator
2. Fluid bed dryer, top spray granulation and wurster coater
3. Multi mill
4. Blender
5. Tablet compression machine
6. Tablet coating machine
7. Capsule filling machine (Manual)
8. Blister packing machine (Manual)
9. Homogenizer

ANALYTICAL DEVELOPMENT

1. Analytical method development and validation for Assay/Impurities/ Dissolution by instrumental techniques and wet chemical methods
2. Sample analysis by different instruments i.e. HPLC, GC, Dissolution, UV-Vis spectrophotometer, IR, ICP OES, LC/MS, XRD, NMR, Polarography, DSc and TGA etc..
3. In-vitro bio study, Phosphate binding study, Multi-media dissolution profile and IVIVC
4. Residual solvents testing by GC/HS
5. Genotoxic impurity and Nitrosamine testing by LC/MS
6. Elemental heavy metal testing by ICP
7. Wet chemical analysis for API and Excipients
8. Exploratory Pharmaceutics and Reverse Engineering

SPECIALIZED ANALYTICAL TESTING

Analytical method development, validation and testing of samples by using following specialized high-end instruments

1. XRD. Polymorphic form determination
2. LC/MS. Genotoxic impurities and Nitrosamine sample analysis
3. NMR. Testing and structural characterization
4. BET analyser. Surface area testing
5. Malvern Particle size analyser
6. Characterization study by TEM, AFM, EPR, Raman and SAWXS etc..
7. Thermal analysis by TGA and DSC
8. Electrochemical testing by Polarography

ANALYTICAL DEVELOPMENT

Supporting Equipments

1. HPLC and UPLC with PDA and UV detector
2. LC-MS
3. ICP-OES
4. GC-Head space and Liquid facility
5. Particle size analyzer
6. Dissolution apparatus
7. UV-Vis Spectrophotometer
8. Karl Fischer titrator and Potentiometric titrator
9. Stability Chambers for all climatic conditions

QUALITY & REGULATORY COMPLIANCE

The highly qualified quality and regulatory professionals ensure the compliance of the product and process by detailed review of the data and on site inspection.

1. Maintaining the cGMP standard in the manufacturing area and laboratories.
2. Conduct inspections for API and Finished product manufacturing facilities
3. Review of all specifications, testing methods, analytical raw data and validation documents.
4. Review of development reports, IIG evaluation, bio study protocol and reports
5. Data compilation and review for product filing.

IMPURITY SYNTHESIS AND WORKING STANDARDS

1. We work on synthesis of impurities of various molecules including peptides and large molecules
2. We work on Nitrosamine impurities
3. Impurities of peptides and other large molecules are synthesized and/or isolated and fully characterized based on customer's requirement.
4. We make primary standards/ Working standards for non-pharmacopoeial materials with full characterization and potency definition
5. We make secondary/working standards of pharmacopoeial materials and standardize it against pharmacopoeial reference standards.

CONTACTS

Please contact us on the following address

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