

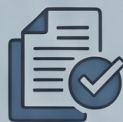
DR. BN MANI: PHARMACEUTICAL & REGULATORY EXCELLENCE

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E-mail: drbolla25@gmail.com



REGULATORY & QUALITY EXPERTISE

US & EU Market Filing Success



Proven track record in preparing and successfully filing US DMFs (Amlodipine, Cetirizine) and EU Dossiers (Omeprazole, Lansoprazole, Rabeprazole).

Global Standards Compliance



Deep functional knowledge of USFDA, ICH, WHO, and ISO 17025 GLP guidelines for laboratory setup and compliance audits.



Multi-Regional Dossier Preparation

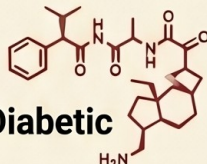
Expertise in creating technical documentation for regulated markets (USA, EU) and non-regulated markets, including submissions for Russia and the Middle East.



RESEARCH & TECHNOLOGY TRANSFER

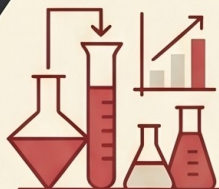
API & Ayurvedic Tech Transfer

Successfully completed analytical method development and technology transfer for various RP-HPLC methods to leading Indian manufacturing companies.



Novel Anti-Diabetic Discovery

Isolated a novel α -amylase inhibitor peptide from marine sources with 73% structural similarity to Tendamistat, currently under clinical trials.



Specialized Dissolution Studies

Developed validation methods for Curcuminoids in SGF/SIF mediums to study sustained release properties and IVIVC.

ACADEMIC & PROFESSIONAL MILESTONES

104

GATE All India Rank: 104

Demonstrated high-level competitive excellence by achieving a top-tier national rank in the Graduate Aptitude Test in Engineering.

12 Years of Academic Leadership



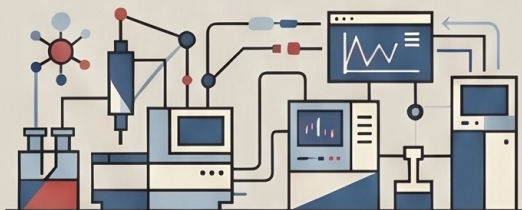
Served as Head of the Department of Pharmaceutics at Viswanadha Institute of Pharmaceutical Sciences from 2011 to 2023.

1st Rank in M.Pharmacy



Recipient of the Prof. K. Sambamurthy Shastriyabdiipoorthy Prize for achieving a grade of 80.1% at Andhra University.

LABORATORY & TECHNICAL PROFICIENCY



High-End Analytical Instrumentation

Expert in qualifying and calibrating Shimadzu HPLC Class VP series, Lab India UV Spectrophotometers, and Tablet Dissolution Apparatus.



Specialized Bio-Assays

Proficient in microbiological inoculation, protocol development, and validation of microbial assays and SDS-PAGE.