# INDUSTRIAL PHARMACY II

## (THEORY)

DR. NITIN VASANTRAO DEVHADRAO
DR. ASHWINI NITIN DEVHADRAO
MS. VIRASHRI ATMARAM DHUMAL
MS. JYOTI DIGAMBAR LOKHANDE
MS. GAYATRI KAILAS JAWALE

Kripa Drishti Publications, Pune.

# INDUSTRIAL PHARMACY II (THEORY)

**Dr. Nitin Vasantrao Devhadrao**
Associate Professor and Head Department of Pharmaceutics,
Dnyanvilas College of Pharmacy, Dudulgaon,
PCMC Pune, Maharashtra.

**Dr. Ashwini Nitin Devhadrao**
Associate Professor, Pharmaceutics Department,
Dnyanvilas College of Pharmacy, Dudulgaon,
PCMC, Pune, Maharashtra.

**Ms. Virashri Atmaram Dhumal**
Assistant Professor, Pharmaceutics,
Dnyanvilas college of pharmacy, dudulgaon,
PCMC, Pune, Maharashtra.

**Ms. Jyoti Digambar Lokhande**
Assistant Professor, Dnyanvilas College of Pharmacy Dudulgoan,
PCMC Pune, Maharashtra.

**Ms. Gayatri Kailas Jawale**
Assistant Professor, Dnyanvilas College of Pharmacy Dudulgoan,
PCMC Pune, Maharashtra.

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Authored By: **Dr. Nitin Vasantrao Devhadrao**
**Dr. Ashwini Nitin Devhadrao**
**Ms. Virashri Atmaram Dhumal**
**Ms. Jyoti Digambar Lokhande**
**Ms. Gayatri Kailas Jawale**

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# PREFACE

**Industrial Pharmacy** is a subfield of pharmaceutical science and technology that focuses on large-scale drug development, production, distribution, and quality assurance. or the transformation of unprocessed materials into specific dosage forms. The goal of Industrial Pharmacy is to provide, in one book, a comprehensive overview of the many pharmaceutical equipment and processes that are regularly used in the manufacturing of pharmaceutical dosage forms, as well as quality control tests of those dosage forms. Comprehending intricate pharmaceutical concepts and manufacturing procedures for pharmaceutical dosage forms is made simpler with the aid of pictorial/graphical illustrations. Considering that it is essential for pharmacy students to grasp the fundamental ideas involved in developing medications into appropriate and reliable dosage forms.

**Scope:** This Course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

**Objectives:** Upon Completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms.
2. Understand the process of technology transfer from lab scale to commercial batch.
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

# Abbreviations

Abbreviated Antibiotic Applications (AADAs)
Abbreviated New Drug Application (ANDA)
Absorption, Distribution, Metabolism, And Excretion (ADME)
Active Pharmaceutical Ingredients (APIs)
Adverse Drug Reactions (ADRs)
Adverse Events (AEs)
American Association of Pharmaceutical Scientists (AAPS)
American National Standards Institute (ANSI)
American Society for Quality (ASQ)
Artificial Intelligence (AI)
Asia Pacific Accreditation Cooperation (APAC)
Asian and Pacific Centre for Transfer of Technology (APCTT)
Australian Register of Therapeutic Goods (ARTG)
Biotech Consortium India Limited (BCIL)
Bovine Spongiform Encephalopathy (BSE)
Case Report Form (CRF)
Central Drug Standards and Control Organization (CDSCO)
Central Drugs Testing Laboratories (CDTL)
Certificate of Pharmaceutical Product (COPP)
Certificates of Analysis (CoA)
Certified Calibration Technician (CCT)
Certified Food Safety and Quality Auditor (CFSQA)
Certified Manager of Quality (CMQ)
Certified Master Black Belt (CMBB)
Certified Medical Device Auditor (CMDA)
Certified Pharmaceutical GMP Professional (CPGP)
Certified Quality Auditor (CQA)
Certified Quality Engineer (CQE)
Certified Quality Improvement Associate (CQIA)
Certified Quality Inspector (CQI)
Certified Quality Process Analyst (CQPA)
Certified Quality Technician (CQT)
Certified Reliability Engineer (CRE)
Certified Six Sigma Black Belt (CSSBB)
Certified Six Sigma Yellow Belt (CSSYB)
Certified Software Quality Engineer (CSSQE)
Certified Supplier Quality Professional (CSQP)
Chemistry, Manufacturing, and Control Information (CMC)
Climate Technology Center and Network (CTCN)
Clinical Research Organization (CRO)
Clinical Study Report (CSR)
Clinical Trial Agreement (CTA)
Clinical Trial Registry- India (CTRI)

Clinical Trials (CT)
Code of Federal Regulations (CFR)
Common Technical Document (CTD)
Confidential Disclosure Agreements (CDA)
Confidentiality Agreements (CAs)
Continuing Education Units (CEUs)
Control of change (C/C)
Corrective Action (C/A)
Corrective And Preventive Actions (CAPA)
Critical Control Point (CCP)
Critical Material Attributes (CMAs)
Critical Process Parameters (CPPs)
Critical Quality Attributes (CQAs)
Critical-to-Quality (CTQ)
Customer Satisfaction Score (CSAT)
Database Management System (DBMS)
Define the Quality Target Product Profile (QTPP)
Define, Measure, Analyze, Improve, Control (DMAIC)
Department of Promotion of Industry and Internal Trade (DPIIT)
Design for Six Sigma (DFSS)
Design of Experiments (DOE)
Design qualification (DQ)
Drug Consultative Committee (DCC)
Drug Controller General India's (DCGI)
Drug Inspector (DI)
Drug Master File (DMF)
Drug Regulatory Affairs (DRA)
Drug Technical Advisory Board (DTAB)
Drugs Controller General of India (DCGI)
Drugs Prices Control Order (DPCO)
Economic and Social Commission for Asia and the Pacific (ESCAP).
Electromagnetic Radiation Emitting Devices (ERED)
Electronic Common Technical Document (ECTD)
Enterprise Resource Planning (ERP)
Environmental Management System (EMS)
European Economic Commission (EEC)
European Medicines Agency (EMA)
European Pharmaceuticals Agency (EMA)
European Union (EU)
Evolution Robotics Software Platform (ERSP)
Facilities And Administrative (F&A)
Factory Acceptance Tests (FAT)
Failure Mode and Effect Analysis (FMEA)
Failure Mode, Effects and Criticality Analysis (FMECA)
Fault Tree Analysis (FTA)
Fixed Dose Combinations (FDCs)

Food and Drug Administration (FDA)
Frequently Asked Questions (FAQs)
Good Clinical Practice (GCP)
Good Distribution Practice (GDP)
Good Laboratory Practice (GLP)
Good Manufacturing Practices (GMP)
Hazard Analysis and Critical Control Points (HACCP)
Hazard Operability Analysis (HAZOP)
Heating, Ventilation, And Air Conditioning (HVAC)
Immediate Release (IR)
Indian Council of Medical Research (ICMR)
Information And Communication Technologies (ICT)
In-Process Controls (IPC)
Installation qualification (IQ)
Institutional Review Boards (IRBs)
Instrument Verification Strips (IVS)
Intellectual Property (IP)
Intellectual Property Rights (IPR).
International Association for Six Sigma Certification (IASSC)
International Clinical Trials Registry Platform (ICTRP)
International Council for Harmonization's (ICH)
International Laboratory Accreditation Cooperation (ILAC)
International Non-Proprietary Names (INNs)
Investigational New Drug (IND)
Investigator's Brochure (IB)
Manufacturing Execution Systems (MES)
Marketing Authorization (MA)
Marketing Authorization Application (MAA)
Marketing Authorization Holder (MAH)
Medicines and Healthcare products Regulatory Agency (MHRA)
Memoranda of Understandings (MoUs)
Modified Release (MR)
Mutual Recognition Arrangement (MRA)
Mutual Recognition Arrangements (MRA)
National Designated Entities (NDEs)
National Green Tribunal (NGT)
National Housing Bank (NBH)
National Institute of Medical Statistics (NIMS)
National Research Development Corporation (NRDC)
Net Promoter Score (NPS)
New Drug Application (NDA)
Non-Disclosure Agreements (NDAs)
Occupational Safety and Health Administration (OSHA)
Operational qualification (OQ)
Organization for Standardization (ISO)
Organizational Excellence (OE)

Out-of-Specification (OOS)
Over the Counter Drug (OTC)
Paris Cooperation Treaty (PCT)
Performance qualification (PQ)
Pharmaceuticals and Medical Devices Agency (PMDA)
Pharmacovigilance Program of India (PvPI)
Plan-Do-Check-Act (PDCA)
PR Investigational Site Visits (PISV)
Preliminary Hazard Analysis (PHA)
Principal Investigator (PI)
Professional Development Hours (PDHs)
Proficiency Testing Providers (PTP)
Quality Assurance (QA)
Quality by Design (QBD)
Quality Control (QC)
Quality Function Deployment (QFD)
Quality Management System (QMS)
Quality Risk Management (QRM)
Receiving Unit (RU)
Reference Material Producers (RMP)
Regulatory Affairs (RA)
Risk Priority Numbers (RPNs)
Robot Operating System (ROS)
Root Cause Analysis (RCA)
Scale-up and Post Approval Changes (SUPAC)
Semi-Solid (SS)
Sending Unit (SU)
Small Industries Development Bank of India (SIDBI)
Sponsored Programs Administration (SPA)
Standard Operating Procedures (SOPs)
State Drug Regulatory Authorities (SDRAs)
Statistical Analysis Plan (SAP)
Statistical Process Control (SPC)
Study Close-Out Visits (SCV)
Study Initiation Visits (SIV)
Subject Expert Committee (SEC)
Supervisory Control and Data Acquisition (SCADA)
Technological Action Plans (TAPs)
Technology Bureau for Small Enterprises (TBSE)
Technology Executive Committee (TEC)
Technology Information, Forecasting and Assessment Council (TIFAC)
Technology Needs Assessments (TNAs)
Technology Transfer (TT)
Telecom Regulatory Authority of India (TRAI)
Testing and Calibration Laboratories (NABL)
Therapeutic Goods Administration (TGA)

Total Quality Management (TQM)
Trade Related Aspects of Intellectual Property Rights (TRIPS)
Transfer of Technology (TOT)
Transmissible Spongiform Encephalopathy (TSE)
United States Food and Drug Administration (USFDA)
United States of America (USA)
United States Pharmacopoeia (USP)
United States Pharmacopoeia Committee (USPC)
University of California Office of the President (UCOP)
US Pharmacopeia (USP)
Utilize in-process controls (IPCs)
Validation Master Plan (VMP)
Validation Protocol (VP)
Validation report (VR)
Voice of the Customer (VOC)
World Health Organization (WHO)

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## ABOUT THE AUTHORS

**Dr. Nitin Vasantrao Devhadrao** had completed his Ph.D in Pharmaceutics from Bhagwant university, Ajmer, Rajasthan. He had completed his M.Pharm in Pharmaceutics from KLE university, Belgavi, Karnataka . He has total 13 years of UG and PG Teaching and Research Experience. Presently, working as Associate professor and Head Department of Pharmaceutics at Dnyanvilas College of Pharmacy, Dudulgaon, PCMC Pune, Maharashtra. He has published 3 Indian patents and 18 research paper and review articles in National and International reputed journal.He has guided 06 PG students. He is associated with Association of Pharmaceutical Teachers of India (APTI).

**Dr. Ashwini Nitin Devhadrao** had completed her Ph.D in pharmaceutics from Bhagwant University, Ajmer, Rajasthan. she had completed her M.pharm in Quality Assurance Techniques from Sanjivani College of Pharmacy, Kopargaon (Savitribai Phule Pune University,Pune) . she has total 13 year of UG and PG Teaching and research experience. Presently, working as Associate Professor in Pharmaceutics department at Dnyanvilas College of Pharmacy, Dudulgaon, PCMC, Pune, Maharashtra. she has published 3 Indian patents and 16 research papers and review articles in National and international reputed Journals. she is Associated with Association of Pharmaceutical teachers of India (APTI)

**Ms. Virashri Atmaram Dhumal** is presently working as Assistant Professor in Pharmaceutics at Dnyanvilas college of pharmacy, dudulgaon ,Pcmc , Pune, Maharashtra. She is currently pursuing her PhD. From Jayoti Vidyapeeth Women's University , Jaipur., She has received her master of pharmacy from Dr.Vithalrao Vikhe Patill Foundation's college of pharmacy, Ahmednagar, Maharashtra. She has received her bachelor of pharmacy from Dr.Vithalrao Vikhe Patill Foundation's college of pharmacy, Ahmednagar, Maharashtra. She has more than 3 years of industrial experience .She has published and presented several research paper in the area of formulations and development, analytical method development.

**Ms. Jyoti Digambar Lokhande** is pursuing a Ph.D in Pharmaceutics in Marathwada Mitra Mandal college of pharmacy, Kalewadi PCMC, Pune, Maharashtra. Savitribai phule Pune University. She had completed her M Pharm in Pharmaceutics from Modern college of pharmacy (for ladies). Borhadewadi, PCMC, Pune, Maharashtra. Savitribai phule Pune University. She has three years of experience in UG Teaching and Research experience. Presently working as assistant professor in Dnyanvilas college of pharmacy Dudulgoan, PCMC Pune, Maharashtra. She has published 1 Indian patent and 1 research and 2 review articles in National and international reputed journals. She is associated with the association of pharmaceutical Teachers of India (APTI).

**Ms. Gayatri Kailas Jawale** had completed her M. Pharm in Pharmaceutics from in Marathwada Mitra Mandal college of pharmacy, Kalewadi PCMC, Pune, Maharashtra. Savitribai Phule Pune University. She has 2 years of experience in UG Teaching and Research experience. Presently working as assistant professor in Dnyanvilas college of pharmacy Dudulgoan, PCMC Pune, Maharashtra. She has 2 years experience in Research Project Assistant – Rajiv Gandhi Science & Technology Commission Govt. of Maharashtra. Marathwada Mitra Mandal's college of Pharmacy Thergoan, Kalewadi Pune. She has published 1 Indian patent and 2 research in National and international reputed journals. She is associated with the association of pharmaceutical Teachers of India (APTI).

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A-503 Poorva Heights, Pashan-Sus Road, Near Sai Chowk,
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