

**Department:- Master of Pharmacy Pharmaceutical Regulatory Affairs
(C.G.B.S)****Subject:- List of Topics 2023-2024**

Sr. No.	Name Of Students	Thesis Title	Name Of Guide
1	Mr. Amey Umaley	Comparative study of regulatory pathways, oversight and requirements for selected drug-device combination products in the Europe and India	Dr. UjwalaN. Mahajan
2	Ms. Tanuja Chambhare	Abbreviated regulatory approval pathways and CMC requirement for recombinant and synthetic peptide in USA and Europe	Dr. Ujwala N. Mahajan
3	Mr. Jitendra Kalambe	Preparation of dossier for selected herbal product registration in Zambia and compare regulatory requirements with Zimbabwe	DrVidya P.Sabale
4	Ms. Anjali Titre	Preparation of ANDA and eCTD formats publishing for soft gelatin capsules for U.S. market	Dr. Ajay G. Pise
5	Ms. Himani Raut	Developing regulatory strategy and eCTD dossier preparation for complex generic product	Dr. Ajay G. Pise
6	Ms. Kajal Bhulaiwale	Formulation, evaluation and regulatory submission of Azithromycin tablet 500mg for russian regulatory authority	Dr. Ajay G. Pise
7	Mr. Devashish Belankar	Development and validation of cGMP documentation in alignment with WHO guidelines for compliance in a manufacturing facility, liquid formulations	Dr. Ajay G. Pise
8	Mr. Nikhil Sarkate	Formulation, evaluation and preparation of dossier for antipyretic and anti-inflammatory drug for Japan regulatory authority	Dr. Ajay G. Pise
9	Mr. Rupesh Chavhan	Exploring 3D printing for bone component fabrication: Investigating regulatory compliance in the design and manufacturing process	Dr. Ajay G. Pise
10	Mr. Rushikesh Kadu	Validation of aseptic processing in a sterile pharmaceutical manufacturing facility in accordance with ICH guidelines	Dr. Ajay G. Pise
11	Mr. Shubham Dhope	Preparation of design qualification for hormonal formulation manufacturing facility	Dr. Ajay G. Pise



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12	Ms. Riya Sahu	Formulation, evaluation and preparation of dossier for combination tablet of antihypertensive and diuretic drugs for US regulatory authority	Dr. Purushottam S. Gangane
13	Ms. Ashwini Wasake	Similarities and differences in approval process for new biological application in US and Europe	Dr. MangeshD. Godbole
14	Ms. Payal Patle	Comparative study of regulatory pathways, oversight and requirements for selected drug-device combination products in the US and India	Dr. MangeshD. Godbole
15	Mr. Nitesh Karhale	Comparative study of biosimilar drug application procedure in US and India	Dr. Mangesh D. Godbole



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