SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA
(Sponsored by the Exhibition Society)
Tarnaka Secunderabad
Affiliated to Osmania University, Approved by AICTE & PCI
B.Pharmacy Course Accredited by NBA
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CIRCULAR

Topic: "Generic drug submission and approval process(FDA)"

Organized By: Department of Pharmaceutics

Speaker: Dileep Kumar Kanthala, Regulatory consultant, laboratoire RIVA Inc, Canada.

Dear Staff & Students,

We are pleased to inform you that we are going to conduct a lecture on **"Generic drug submission and approval process(FDA)"** by Dileep Kumar kanthala, Regulatory consultant, laboratoire RIVA Inc, Canada.

The lecture will be delivered by **Dileep Kumar kanthala, Regulatory consultant, laboratoire RIVA Inc, Canada** in our college auditorium on 11/07/2025 at 11 A.M. All faculty members, M. Pharmacy students, and Pharm.D IV and V year students are cordially invited to attend the lecture. Let us make the most of this opportunity and contribute to its grand success through your active participation.

9/7/25

(Dr. T. Mamatha)
Principal

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"Report On Generic drug submission and approval process(FDA)"

Date: 11.07.2025

Organized by: Department of Pharmaceutics, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV), Tarnaka, Secunderabad.

Time: 11:00 A.M.

Venue: Auditorium, SNVPMV.

Speaker: Dileep Kumar kanthala, Regulatory consultant, laboratoire RIVA Inc, Canada.

Department of Pharmaceutics successfully organized a guest lecture on the topic "Generic Drug Submission and Approval Process (FDA)", aimed at enriching students' understanding of regulatory pathways as well as encouraging personal well-being and happiness in the professional journey.

The event was coordinated by the Department of Pharmaceutics, led by Dr. B. Chandrashekar Reddy, Dr. Ch. Shanthi Priya, Mrs. Ch. Bhargavi, and Mrs. A. Jyothi. Anchoring duties were gracefully handled by Ms. L. Prashanthi Reddy and Ms. Joshna, M. Pharm II Semester students.

The distinguished guests were warmly welcomed with eco-friendly floral greetings. The dignitaries on the dais included: Dr. N. Srinivas, Director, SNVPMV, Dr. B. Haarika, Vice-Principal, SNVPMV, Dr. B. Chandrashekar Reddy, Professor & Head, Dept. of Pharmaceutics, SNVPMV, Mr. Dileep Kumar Kanthala, Regulatory Consultant, Laboratoire RIVA Inc., Canada.

The session commenced with a welcome address by Ms. R. Drakshayani, followed by an insightful lecture by Mr. Dileep Kumar Kanthala, who began with an introduction to the various departments and gradually navigated through the intricacies of the generic drug submission and FDA approval process.

Introduction

- **Various Departments in the Pharmaceutical Industry**

The pharmaceutical industry comprises multiple specialized departments that work collaboratively to bring safe and effective medicines to the market.

The primary departments include:

A. Drug Discovery and Research :

Drug Discovery: This is the initial phase where new compounds are identified and optimized for their therapeutic potential.

Screening by Pre-clinical Testing: Identified molecules undergo pre-clinical evaluation to assess safety and biological activity before clinical trials.

B. API R&D (Active Pharmaceutical Ingredient Research & Development)

API Research and Development: Focuses on the development of active pharmaceutical ingredients used in drug formulations.

Analytical Development: Involves testing and validation methods to ensure the quality and consistency of the drug.

Regulatory Affairs: Ensures that the drug development and manufacturing processes comply with regulatory standards.

Intellectual Property Rights (IPR): Protects innovations through patents and legal frameworks.

- **What is Regulatory Affairs?**

Regulatory Affairs (RA) is a critical function within the pharmaceutical industry that ensures compliance with all regulations and laws pertaining to drug development, manufacturing, and marketing.

Role of Regulatory Affairs Professionals:
RA professionals support the development, testing, production, and commercialization of medical products by ensuring they meet safety, efficacy, and quality standards. Their work covers pharmaceuticals, biologics, diagnostics, digital health, and more.

Key Point: *Regulatory Affairs acts as a point of contact between the company, its products, and regulatory authorities.*

Importance in the Industry:
These professionals ensure that healthcare products gain and maintain market authorization while prioritizing patient safety and product quality. They also contribute to strategic planning and help companies navigate international regulatory landscapes.

- **Regulatory Affairs Workflow in Drug Development**

The flowchart presents a simplified view of the regulatory communication process in the pharmaceutical development pipeline:

Potential Drug Candidate: Identified for therapeutic use.

Corporate Team: Coordinates funding, strategy, and overall oversight.

R&D Department: Conducts research and develops the formulation.

Technology Transfer: Passes the developed formula to the manufacturing unit.

Manufacturing: Produces the drug at scale for market distribution.

Regulatory Affairs: Acts as a bridge between the company and the regulatory body.

Regulatory Agency: Reviews the documentation, compliance, and grants approval.

The Communicative/Representative role is essential throughout the process, ensuring clear communication between all departments and external agencies.

Here is a detailed report based on the content from the uploaded slides on **Generic Drugs and FDA Approval Process**:

What are Generic Drugs?

A generic drug is a medication that is scientifically formulated to be the same as a brand-name drug in the following aspects: Dosage form, Safety, Strength, Route of administration, Quality, Performance characteristics, Intended use

These drugs must demonstrate bioequivalence, meaning that they work in the same way and provide the same clinical benefit as their brand-name counterparts.

Key Point:*Generic medicines are considered equal substitutes for brand-name medicines and are interchangeable.*

- **Example of a Generic Drug**

Case Example: **Brand**: Brilinta® (Ticagrelor Tablets 60 mg) by AstraZeneca

Generic: Ticagrelor Tablets 60 mg by manufacturers like Exelan, Teva, Amneal

- **FDA Standards for Generic Medicines**

To receive FDA approval, companies must submit an Abbreviated New Drug Application (ANDA) showing that the generic drug is bioequivalent to the brand-name product. The generic drug must match the brand in the following areas: Same active ingredient,Same strength, Same dosage form (e.g., tablet, capsule), Same route of administration (oral, topical, etc.), Same use indications, Acceptable inactive ingredients, Equivalent duration of effect, Manufactured under strict, regulated conditions, similar to brand-name drugs, Packaging and container must be appropriate and safe, Labeling must match that of the brand-name drug, Patent issues and market exclusivities must be resolved or expired.

The availability of reference samples and complete approval documentation through Drugs@FDA streamlines the process of developing generics. These resources are instrumental in ensuring regulatory compliance and establishing bioequivalence, which are prerequisites for FDA approval of generic drugs.

Showed the structured approach to regulatory submissions using the eCTD format and the ESG NextGen portal. The organization of data ensures clarity and compliance, while digital tools like Test Submission help in error-checking and seamless interaction with regulatory bodies like the FDA. Mastery of this process is essential for any regulatory affairs professional working in the pharmaceutical industry.

- **FDA Review and Approval Process for ANDA**

outlines the timeline and key steps involved in the FDA review and approval process for an Abbreviated New Drug Application (ANDA). This process ensures that generic drugs meet the required safety, efficacy, and quality standards before they are made available to the public.

Month-wise Timeline for ANDA Review

Month 1: Submission and Filing Review Begins

Month 2: Filing Review Completion

Month 3: Discipline Review Begins

Months 3–8: Ongoing Review

Month 9: Final Review and Facility Inspection

Month 10: Action Letter Issued

Timelines for Approval

ANDA Type : Standard Original ANDA - 10 months

Priority Original ANDA - 8 months

- **Dossier Modules – Generic Drugs Submissions**

The listed modules are:

Module I – Country specific information

Module II – CTD Summaries

Module III – Data on Quality

Module IV – Non-clinical study reports

Module V – Clinical study reports

- **Definition of Drug Master File (DMF)**

"A Drug Master File (DMF) is a submission to the FDA of information, usually concerning the Chemistry, Manufacturing and Controls (CMC) of a drug product or a component of a drug product, to permit the FDA to review this information in support of a third party's submission. Other non-CMC information may be filed in a DMF."

Types of DMFs

Type I: Manufacturing Site, Facilities, Operating Procedures, and Personnel (no longer applicable)

Type II: Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product

Type III: Packaging Material

Type IV: Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation

Type V: FDA Accepted Reference Information

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The title "FDA Websites Demonstration"

https://www.fda.gov/

https://www.fda.gov/drugs

https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

https://dailymed.nlm.nih.gov/dailymed/index.cfm.




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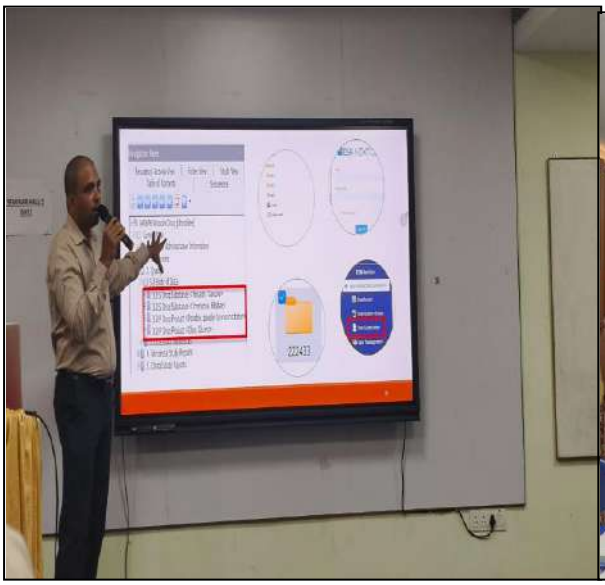

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Guest lecture by Dilip Kumar on 11th July 2025

Sl.No	Name	Designation	Signature
1	Dr.N.Srinivas	Professor & Director	
2	Dr.T.Mamatha	Professor & Principal	
3	Dr.B.Haarika	Professor & Vice-Principal	
4	Dr.S.Hemalatha	Professor & HOD	
5	Dr.S.Anuradha Bai	Professor & HOD	
6	Dr.T.Venu	Professor & HOD	
7	Dr.Vivek Sagar	Professor & HOD	
8	Dr. B. Chandra Shekar Reddy	Professor & HOD	
9	Smt.R.V.S.Latha Sree	Associate Professor	
10	Dr.K.Neelima	Associate Professor	
11	Dr.B. Siva Jyothi	Associate Professor	
12	Dr. M.Swetha	Associate Professor	
13	Dr. S.Rohini Reddy	Associate Professor	
14	Dr. CH.Shanthi Priya	Associate Professor	
15	Dr.K.Vinutha	Associate Professor	
16	Dr. K.R.V.S. Chaitanya	Associate Professor	
17	Dr. M. Sreekanth	Associate Professor & HOD	
18	Dr. P. Ravi Kumar	Associate Professor & HOD	
19	Mrs. K. Geethanjali	Associate Professor	
20	Smt.Leemol Shaju	Sr. Assistant Professor	
21	Smt.G.Srilalitha	Assistant Professor	
22	Smt.Ch.Bhargavi	Assistant Professor	
23	Smt.N.Indira Rani	Assistant Professor	
24	Smt.S.Muni Sireesha	Assistant Professor	
25	Smt. P.M.Sameera	Assistant Professor	
26	Dr. R.Prasanthi	Assistant Professor	
27	Ms.S.Divya	Assistant Professor	
28	Dr.Akaram Sujala	Assistant Professor	
29	Smt.Azmeer Jyothi	Assistant Professor	
30	Smt.K. Silpa	Assistant Professor	
31	Smt.P.Kavitha Babu Rao	Assistant Professor	
32	Mrs. A.Shailaja	Assistant Professor	
33	Mrs.Jutta Swathi	Assistant Professor	
34	Dr Jithender	Assistant Professor	
35	Dr. V. Santhoshini	Assistant Professor	
36	Dr. Hadiya Iram	Assistant Professor	
37	Ms. P. Sri Varsha	Assistant Professor	
38	Dr.M. Shiva Rama Krishna	Assistant Professor	
39	Mrs. J. Sarika	Assistant Professor	
40	Mrs. P. Uma	Assistant Professor	

Sl.No	Name	Designation	Signature
41	Mr. D. Suresh	Assistant Professor	
42	Mrs. P. Rajyalakshmi Devi	Assistant Professor	
43	Mr. K. Sandeep	Assistant Professor	
44	Mrs. Ritu Jain	Assistant Professor	
45	Mrs. J. Sunayana	Assistant Professor	
46	Ms. N. Rojaramani	Assistant Professor	

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ATTENDANCE SHEET

Event: "Generic drug submission and approval process(FDA)"
Organized by
Department of Pharmaceutics

Speaker: Dileep kumar kanthala,Regulatory consultant,Laboratoire RIVA Inc,Canada **Date:11/07/2025**

Sl.No	Roll No	Name of the Student	Class	Signature
1	170420882001	A. Haritha Reddy	Pharm.D V yr	
2	170420882021	R. Madhuri	Pharm.D V yr	
3	170420882010	G. Deekshitha	" V yr	
4	170420882012	K. Vyshnavi	"	
5	170420882018	P. Snehalatha	"	
6	170420882026	Siyam Fathima	"	
7	170420882010	Gadiga P		
8	170420882029	Y. Sonia	Pharm D V yr	
9.	170420882009	D. Divya	pharm D V yr	
10.	170420882006	Ch. Deepika	pharm D V yr	
11.	170420882001	G. Akanksha	pharm D V yr	
12.	170424886009	R. prakshayani	Mpharm 1st yr	
13.	170424886007	L. prasanthi	Mpharm 1st yr	
14.	170424886010	Salma	"	
15.	170424886003	Vishnu priya	"	
16.	170424867011	Moiza	"	
17.	170424867010	Sai sree	"	
18.	170424867002	Jyothsna	"	
19.	170424867003	Mahalika	"	
20.	170424867005	Shivani	"	
21.	170424867012	Sahithi	"	
22.	170424867015	Manjula	"	
23	1704-24-867-001	Jalyasree	Pharmacology	
24	1704-24-867-002	Vaishnavi	Mpharm	
25	1704-24-867-003	Indhu	1st year	
26	1704-24-867-004	Hajeera	"	
27	1704-24-867-005	Bhanu deepika	"	
28	1704-24-867-006	Sneha	"	
29	1704-24-867-007	Swathi	"	
30	1704-24-867009	Anitha	"	
31	1704-24-867-010	Nabeela	"	
32	1704-24-867-017	Pavani	"	

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Sl.No	Roll No	Name of the Student	Class	Signature
33	1704-24-887-012	Swetha	Mphar 1st year (Pharmacology)	Swetha
34	1704-24-887-013	Sumaya	"	Sumaya
35	1704-24-887-014	U.Bharathi	"	Bharathi
36	1704-20-882-019	P. Srujana	Pharm D 3rd year	Srujana
37	1704-24-885-001	B. Nikhitha	M.Pharm Analysis 1 yr	Nikhitha
38	1704-24-885-004	G. Keerthi	"	Keerthi
39	1704-24-885-005	G. Pooja	"	Pooja
40	1704-24-885-006	K. Aishwarya	"	Aishwarya
41	1704-24-885-013	P. Ramya	"	Ramya
42	1704-24-868-001	D. Likitha	M.Pharm (PQA) 1st year	D. Likitha
43	1704-24-868-004	Gambo Nekitha	"	
44	1704-24-868-005	G. Niharika	"	G. Niharika
45	1704-24-868-007	G. Deekshitha	"	Deekshitha
46	1704-23-883-005	Jyothi	pharm D (PB) II Yr	Jyothi
47	1704-23-883-007	Nayyara Khatoon	pharm D (PB) II Yr	Nayyara
48	1704-23-883-008	Rugiar Begum	pharm D (PB) II Yr	Rugiar
49	1704-20-882-016	Nameera Khatoon	Pharm D V th YR	
50	1704-20-882-004	Ayesha Fatima	" "	Ayesha
51	1704-20-882-024	Siddia Tabassum	" "	
52	1704-20-882-025	Sidra Najam	" "	
53	1704-20-882-015	Monika Kandhan	" "	