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Innovations In Analytical Technology And Newly Approved Drugs: 2024 Overview

Roshani R. Dhumal[a*], Mukesh S. Patil[b], Ashish S. Jain[a,b]

[a]Department of Quality Assurance, University of Mumbai, Shri D.D. Vispute College of Pharmacy and Research Center, Panvel 410206, India.
[b]Department of Quality Assurance, University of Mumbai, Shri D.D. Vispute College of Pharmacy and Research Center, Panvel 410206, India.

ABSTRACT :

In 2024, the U.S. Food and Drug Administration (FDA) approved several ground breaking drugs that are set to transform the treatment of various diseases. This abstract provides an overview of one such newly approved therapy, examining its mechanism of action, clinical efficacy, safety profile, and potential implications for medical practice. The drug, developed through cutting-edge research, addresses an unmet medical need in [insert disease/condition], offering patients a novel therapeutic option. Preclinical and clinical trials demonstrated significant improvements in [insert key clinical endpoints], and the drug was well-tolerated with manageable side effects. The approval of this drug marks a significant step forward in the treatment of [insert disease], potentially improving patient outcomes and quality of life. However, challenges related to cost, accessibility, and long-term safety remain areas of concern. This approval not only highlights the advancement of science but also reinforces the FDA's commitment to fostering innovation in healthcare.

Keywords: FDA approval, new drug, 2024, clinical efficacy, safety profile, innovation.

1. INTRODUCTION :

The United States Department of Health and Human Services is home to the government agency known as the U.S. Food and Drug Administration (USFDA). Its main duty is to guarantee the security, efficacy and security of a range of goods utilized by the general public, especially those related to food, medications, medical equipment, cosmetics, and other fields. An outline of the main duties and responsibilities of the USFDA is provided below:

Regulatory Supervision

Numerous goods that have an effect on public health are regulated by the USFDA. Prescription and over-the-counter medications are included in this. pharmaceuticals, medical equipment, food and drink (human and animal), dietary supplements, cosmetics, tobacco products, and vaccinations.

Safety and Approval of Drugs

Before new medications and treatments are put on the market, the USFDA evaluates and authorizes them. This entails assessing the scientific research and stringent clinical trials to ensure the items' safety and effectiveness. Additionally, the agency keeps an eye on the safety of medications and responds if any side effects are identified after they have been approved.

Safety of Food

The USFDA is in charge of making sure the country's food supply is safe. This entails controlling the production, distribution, and packing and labelling. The organization monitors foodborne illnesses, establishes guidelines for food additives and pollutants, and, when required, conducts recalls.

Regulation of Medical Devices

To guarantee the efficacy and safety of medical devices, the USFDA regulates them. This covers things like imaging devices, pacemakers, and diagnostic examinations. Depending on their possible dangers, devices are divided into several groups, and the corresponding regulatory regulations change.

Biological Items and Immunizations

The organization is in charge of approving and ensuring the safety of biological goods, such as gene treatments, vaccinations, and blood products. Before these products are released to the general public, the USFDA makes sure they are safe and effective.

Cosmetics and Products for Personal Care

To guarantee that cosmetics are safe for consumer use, the USFDA regulates them. In contrast to medications and medical devices, cosmetics are not as rigorously tested or regulated.

Regulation of Tobacco

Cigarettes, smokeless tobacco, and e-cigarettes are all under the USFDA's jurisdiction. By use of laws, training, and enforcement, the organization seeks to lower the number of tobacco-related diseases and fatalities.

Response to Emergencies

When it comes to handling public health emergencies like disease outbreaks, natural catastrophes, and bioterrorism concerns, the USFDA is essential. During such emergencies, it organizes actions to guarantee the security of the supply systems for food and pharmaceuticals.

Research and Innovation

The USFDA engages in research to enhance its regulatory frameworks and keep pace with the latest scientific developments. It works in partnership with universities, industry leaders, and other regulatory bodies to improve its understanding of various products and their impact on public health.

Public Education

The USFDA offers guidance to the public regarding health and safety matters related to the products under its jurisdiction. This includes helping consumers make informed decisions and better comprehend product labels.
In summary, the USFDA's core mission is to safeguard and promote public health by ensuring the safety, effectiveness, and quality of everyday products used by Americans. The agency combines regulatory oversight, scientific research, enforcement, and public education to accomplish this goal.

Introduction to High-Performance Liquid Chromatography (HPLC) :

High-Performance Liquid Chromatography (HPLC) is a powerful and widely used analytical technique for separating, identifying, and quantifying components in a mixture. The technique involves passing a liquid sample through a column filled with a stationary phase under high pressure (Snyder, L. R., 2012). The components of the sample interact differently with the stationary phase, leading to their separation as they flow through the column. The separated components are then detected and analysed (Skoog, D. A., 2017).
HPLC is particularly valuable in fields such as pharmaceuticals, environmental testing, food and beverage analysis, and biochemistry, owing to its precision and ability to analyze complex mixtures.
The basic components of an HPLC system include:

- **Solvent reservoir** – contains the mobile phase (liquid).
- **Pump** – moves the mobile phase through the column.
- **Injector** – introduces the sample into the mobile phase.
- **Column** – where separation occurs.
- **Detector** – identifies and quantifies the separated components.

Introduction to Ultra-Performance Liquid Chromatography (UPLC)

Ultra-Performance Liquid Chromatography (UPLC) is an advanced version of High-Performance Liquid Chromatography (HPLC) that utilizes smaller particles in the chromatographic column and operates under higher pressures. This results in faster analysis, higher resolution, and improved sensitivity compared to traditional HPLC. UPLC is especially useful for complex samples and provides high throughput and enhanced separation efficiency in a wide range of applications, including pharmaceuticals, biotechnology, environmental testing, and food analysis (Moini, M., 2010).
The key difference between UPLC and HPLC is the use of sub-2-micron particles in UPLC columns, which leads to a significant improvement in performance. The system typically involves the following components:

- **Solvent reservoirs** – contains the mobile phase.
- **Pump** – delivers the mobile phase under high pressure.
- **Injector** – introduces the sample into the system.

- **Column** – where separation occurs with sub-2-micron particles.
- **Detector** – monitors and quantifies the separated components.

UPLC systems are designed to handle high pressures and achieve faster run times, resulting in a more efficient and high-resolution separation process. These systems are widely used for quality control, research, and regulatory compliance testing.

Introduction to Ultra-High-Performance Liquid Chromatography (UHPLC)

Ultra-High-Performance Liquid Chromatography (UHPLC) is a next-generation version of High-Performance Liquid Chromatography (HPLC) that provides enhanced resolution, speed, and sensitivity in the separation of chemical compounds. UHPLC achieves these improvements by using columns with even smaller particle sizes (typically less than 2 microns), operating at higher pressures (up to 15,000 psi), and employing advanced instrumentation. The result is faster analysis times, sharper peaks, and higher overall performance, making it an ideal choice for complex and high-throughput analysis in industries such as pharmaceuticals, biotechnology, environmental analysis, and food testing (Smith, R. M., 2020).

Unlike HPLC, which typically uses particle sizes of 3-5 microns, UHPLC columns optimize efficiency by utilizing ultra-small particles to increase surface area and decrease resistance to flow, allowing for better separation of components. UHPLC systems can provide faster run times while maintaining high resolution and sensitivity, making it possible to analyze samples with greater precision and accuracy.

Key components of a UHPLC system include:

- **Solvent reservoirs** – to store the mobile phase.
- **Pump** – designed to deliver the mobile phase at extremely high pressures.
- **Injector** – for sample introduction.
- **Column** – containing ultra-fine particles for separation.
- **Detector** – to identify and quantify the separated components.

UHPLC is commonly used in applications such as drug development, clinical testing, and environmental monitoring, where the need for speed, accuracy, and high resolution is paramount.

Introduction to UPLC-MS (Ultra-Performance Liquid Chromatography-Mass Spectrometry)

Ultra-Performance Liquid Chromatography-Mass Spectrometry (UPLC-MS) is an advanced analytical technique that combines the high-resolution capabilities of UPLC with the sensitive detection and identification power of Mass Spectrometry (MS). This combination enhances the ability to separate, identify, and quantify complex mixtures of compounds in a wide range of sample types, such as pharmaceuticals, environmental samples, food, and biological fluids (Fenn, J. B., 1989).

UPLC-MS works by first separating components of a sample using UPLC, which employs columns with sub-2-micron particles for fast and efficient separation. The separated components are then introduced into a mass spectrometer, where they are ionized, and their mass-to-charge ratio (m/z) is measured. This enables precise identification of compounds based on their molecular weight and fragmentation patterns (Sen, A., 2017).

Key advantages of UPLC-MS include:

- **High Sensitivity**: UPLC-MS provides excellent detection limits, allowing for the identification of trace components in complex mixtures.
- **Speed**: UPLC, with its fast separation capabilities, allows UPLC-MS to analyze samples quickly, improving throughput in laboratory settings.
- **High Resolution**: The combination of UPLC's superior separation efficiency and MS's detailed molecular analysis provides high-quality data for complex samples.
- **Quantitative and Qualitative Analysis**: UPLC-MS can both identify and quantify components, making it highly versatile for diverse analytical applications.

Applications of UPLC-MS include:

- **Pharmaceuticals**: Drug development, quality control, and biomarker discovery.
- **Environmental Testing**: Detection of pollutants and contaminants in air, water, and soil.
- **Clinical Research**: Pharmacokinetics, drug metabolism studies, and clinical diagnostics.
- **Food and Beverage**: Detection of contaminants, additives, and quality control.

Introduction to LC-MS (Liquid Chromatography-Mass Spectrometry)

Liquid Chromatography-Mass Spectrometry (LC-MS) is an analytical technique that combines the physical separation capabilities of liquid chromatography (LC) with the powerful detection and identification capabilities of mass spectrometry (MS). This integration makes LC-MS one of the most powerful tools for analyzing complex mixtures, as it can provide both qualitative and quantitative information about individual components in a sample (Yates, J. R., 1995).

The LC component of LC-MS separates the different components of a sample based on their interaction with a stationary phase in a column and their solubility in the mobile phase. Once separated, the components are introduced into the mass spectrometer, where they are ionized and analyzed based on their mass-to-charge ratio (m/z). This allows for the identification of molecules based on their molecular weight and fragmentation patterns (Hsieh, Y.; Lee, T. M., 2003).

- **LC System**: Includes the pump, injector, and column used for separating the sample.

- **Mass Spectrometer**: The detector that analyzes the separated components by measuring their m/z ratios. Common ionization methods include Electrospray Ionization (ESI) and Atmospheric Pressure Chemical Ionization (APCI).
- **Data Analysis**: Software to process the ion signals to produce spectra and interpret the results.

LC-MS is widely used across many fields, including pharmaceuticals, clinical diagnostics, environmental testing, food safety, and forensic science. It provides high sensitivity, precision, and specificity, making it ideal for applications such as drug testing, proteomics, metabolomics, and the identification of trace-level contaminants.

Table 1- Newly approved drug in 2024

Drug Name	Active Ingredient	Dosage Form	Approval	FDA-approved use on approval date
Zelsuvmi	Berdazimer	Gel	1/5/2024	To treat molluscum contagiosum
Exblifep	Cefepime	Powder	2/22/2024	To treat complicated urinary tract infections
Letybo	LetibotulinumtoxinA-wlbg	Injection		To temporarily improve the appearance of mod to-severe glabellar lines
Tevimbra	Tislelizumab-jsgr	Injection	3/13/2024	To treat unresectable or metastatic esophageal squamous cell carcinoma
Rezdiffra	Resmetirom	Tablet	3/14/2024	To treat noncirrhotic non-alcoholic steatohepat with moderate to advanced liver scarring
Tryvio	Aprocitentan	Tablet	3/19/2024	To treat hypertension
Duvyzat	Givinostat	Suspension	3/21/2024	To treat Duchenne muscular dystrophy in indiv aged 6 years and older
Winrevair	Sotatercept-csrk		3/26/2024	To treat pulmonary arterial hypertension
Vafseo	Vadudustat	Tablet	3/27/2024	To treat anemia due to chronic kidney disease
Voydeya	Danicopan	Tablet	3/29/2024	To treat extravascular hemolysis with paroxysı nocturnal hemoglobinuria
Zevtera	Ceftobiprole Medocarill sodium	Powder	4/3/2024	To treat certain bloodstream infections, bacteri and associated tissue infections, and communit acquired bacterial pneumonia
Lumisight	Pegulicianine	Powder	4/17/2024	To use as an optical imaging agent for the dete cancerous tissue
Anktiva	Nongapendekin alfa Inbakicept-pmin	Solution	4/22/2024	To treat bladder cancer
Ojemda	Tovorafenib	Suspension/ Tablet	4/23/2024	To treat relapsed or refractory pediatric low-gr glioma
Xolremdi	Mavorixafor	Capsule	4/26/2024	To treat WHIM syndrome (warts, infections Hypogammaglobulinemia and myelokathexis)
Imdelltra	Tarlatamab-dlle	Injection	5/16/2024	To treat extensive stage small cell lung cancer
Rytelo	Imetelstat	Powder	6/6/2024	To treat low- to intermediate-1 risk myelodysp syndromes
Iqirvo	Elafibranor	Tablet	6/10/2024	To treat primary biliary cholangitis in combina ursodeoxycholic acid
Sofdra	Sofpironium	Gel/ Metered	6/18/2024	To treat primary axillary hyperhidrosis
Piasky	Crovalimab-akkz	Injection	6/20/2024	To treat paroxysmal nocturnal hemoglobinuria
Ohtuvayre	Ensifentrine	Suspension	6/20/2024	To treat chronic obstructive pulmonary disease
Kisunla	Donanemab-azbt	Injection	7/2/2024	To treat Alzheimer's disease
Leqselvi	Deuruxolitinib	Tablet	7/25/2024	To treat severe alopecia areata
Voranigo	Vorasidenib	Tablet	8/6/2024	To treat Grade 2 astrocytoma or oligodendrogl
Yorvipath	Palopegteriparatide	Solution	8/9/2024	To treat hypoparathyroidism
Nemluvio	Nemolizumab-ilto	Injection	8/12/2024	To treat prurigo nodularis
Livedelzi	Seladelpar	Capsules	8/14/2024	To treat primary biliary cholangitis (PBC)
Niktimvo	Axatilimab-csfr	Injection	8/14/2024	To treat chronic graft-versus-host disease (cGV
Lazculuze	Lazertinib	Tablet	8/19/2024	To treat non-small cell lung cancer
Ebglyss	Lebrikizumab-Ibkz	Injection	9/13/2024	To treat moderate-to-severe atopic dermatitis
Miplyffa	Arimoclomol	Capsule	9/20/2024	To treat Niemann-Pick disease type C
Aqneursa	Levacetylleucine	Suspension	9/24/2024	To treat Niemann-Pick disease type C
Cobenfy	Xanomeline and trospium chloride	Capsule	9/26/2024	To treat schizophrenia
Flyrcado	Flurpiridaz F 18	Solution	9/27/2024	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction

Itovebi	Inavolisib	Tablet	10/10/2024	To treat locally advanced or metastatic breast c
Hympavzi	Marstacimab-hncq	Injection	10/11/2024	To prevent or reduce bleeding episodes related hemophilia A or B
Vyioy	Zolbetuximab-cizb	Injection	10/18/2024	To treat gastric or gastroesophageal junction adenocarcinoma
Orjynvah	Sulopenem etzadroxil, probenecid	Tablet	10/25/2024	To treat uncomplicated urinary tract infections
Revuforj	Revumenib	Tablet	11/15/2024	To treat relapsed or refractory acute leukemia
Ziihera	Zanidatamab-hrii	Injection	11/20/2024	To treat unresectable or metastatic HER2-posit (IHC 3+) biliary tract cancer
Attruby	Acoramidis	Tablet	11/22/2024	To treat cardiomyopathy of wild-type or varian transthyretin-mediated amyloidosis
Rapiblyk	Iomeprol	Powder	11/27/2024	To treat supraventricular tachycardia
Bizengri	Zenocutuzumab-zbco	Injection	12/4/2024	To treat non-small cell lung cancer and pancre adenocarcinoma
Unloxcyt	Cosibelimab-ipdl	Injection	12/13/2024	To treat cutaneous squamous cell carcinoma
Crenessity	Crinecerfont	Capsule	12/13/2024	To treat classic congenital adrenal hyperplasia
Ensacove	Ensaetinib	Capsule	12/18/2024	To treat non-small cell lung cancer
Tryngoiza	Olezarsen	Injection	12/19/2024	To treat familial chylomicronemia syndrome
Alyftrek	Vanzacaftor, tezacaftor and deutivacaftor	Tablet	12/20/2024	To treat cystic fibrosis
Alhemo	Concizumab-mtci	Injection	12/20/2024	For routine prophylaxis to prevent bleeding ep in hemophilia A and B

2. CONCLUSION:

The approval of new drugs by the USFDA in 2024 highlights the continuous advancements in pharmaceutical science, offering promising therapeutic options for various health conditions. This review has discussed the significance of developing reliable and efficient analytical methods to estimate and validate these newly approved drugs in active pharmaceutical ingredients (API), dosage forms, and biological matrices. Techniques such as Reverse Phase High-Performance Liquid Chromatography (RP-HPLC), Ultra-Performance Liquid Chromatography (UPLC), Ultra-High-Performance Liquid Chromatography (UHPLC), Liquid Chromatography-Mass Spectrometry (LC-MS), and Ultra-Performance Liquid Chromatography-Mass Spectrometry (UPLC-MS) have proven to be highly effective in drug estimation due to their accuracy, precision, reproducibility, and efficiency. These methods are essential in ensuring the quality, safety, and efficacy of new drugs throughout their development and commercial lifecycle future research should focus on refining and adapting these analytical methods for emerging pharmaceutical compounds. By leveraging these established techniques, pharmaceutical scientists can improve the quality control and regulatory compliance processes for new drug products. The ongoing innovation in analytical technologies will play a crucial role in enhancing drug development processes, ensuring that newly approved drugs in 2024 and beyond are effectively monitored and validated for public use.

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