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A Comprehensive Review on Imeglimin: Pharmacological Profile, LC–MS/MS Bioanalytical Methods, and Emerging Applications in Metabolic and Neurodegenerative Disorders

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ABSTRACT:
IMEGLIMIN (IMG) has emerged as an intriguing candidate for metabolic diseases and neurodegenerative diseases beyond its originally intended use as an antidiabetic agent. As a small-molecule therapy with multiple mechanisms of action for the treatment of metabolic diseases and nearly every class of chronic disease (including Parkinson's and Alzheimer's Disease), IMG shows great promise based on several key attributes: 1) IMG provides a novel mechanism for modulating mitochondrial function, reduced oxidative stress, and decreased inflammatory signaling pathways, all of which are involved in the development of chronic disease; and 2) the potential for broad therapeutic application is being recognized. This review summarizes the current body of literature that has examined IMG as a pharmaceutical agent, including the pharmacokinetics and safety of both pharmacologic and non-pharmacologic use of IMG. Additionally, the review will discuss the current developments in bioanlytical assays for the quantification of IMG, including but not limited to tandem liquid chromatography-mass spectrometry (LC-MS/MS). The similarities and differences in sensitivity and specificity will also be presented regarding the utilization of these analytical methods in biological samples.The key issues affecting method development and validation are highlighted throughout the review, including but not limited to matrix effects, stability, and compliance with regulations. The review then looks at new preclinical and clinical studies on the potential to repurpose IMG for neurodegenerative diseases, in addition to its primary use in managing metabolic disease. The aim of this article is to present a unified resource for researchers and clinicians incorporating pharmacological, analytical, and translational perspectives, and to identify knowledge gaps and further research needed in order to advance IMG into more widespread clinical application.

KEYWORDS: Pathological processes, Imeglimin, pharmacokinetic, Bioanalytical methodologies, Development and Validation, Parkinson's disease and Alzheimer's disease

I. INTRODUCTION:

Ongoing efforts to identify novel therapies for chronic & multifactorial illnesses (including neurodegenerative disease, metabolic syndrome and inflammatory condition) have resulted in the discovery of numerous new pharmacologic agents. One of these new agents is IMG, which may have a number of different ways that it may be able to help treat chronic & multifactorial illnesses. Initial studies indicate that this drug works primarily by improving mitochondrial function; reducing oxidative stress; and blocking proinflammatory signaling pathways. These mechanisms of action may be useful in addressing the pathological process & symptoms involved with both Parkinson's Disease, Alzheimer's Disease, and type II diabetes since standard treatments do not sufficiently address the root causes of the disease at the cellular level[1]. The increased interest in IMG as a prospective therapeutic agent has resulted in a growing need to assemble all known information regarding its pharmacodynamics, pharmacokinetics, and analytical characterization into one central location Table 1. The purpose of this review is to provide a thorough overview of IMG by including its prospective therapy, mechanisms of action, and current bioanalytical methods used to detect and quantify it. Attention will also be paid specifically to liquid chromatography–mass spectrometry (LC-MS) techniques, since these technologies have become essential tools for the development and validation of reliable assays for IMG during the drug development process, including preclinical and

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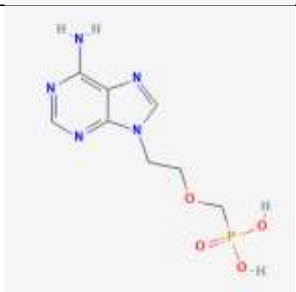
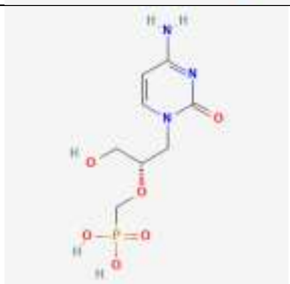
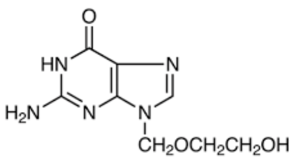
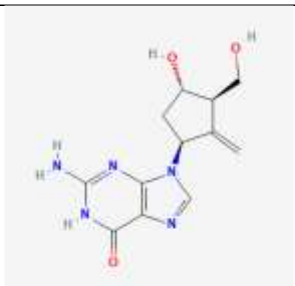
clinical studies. This review identifies the opportunities and challenges presented by IMG; therefore, this review helps establish a foundation for future research studies regarding the potential clinical use of this new compound[2-5].

Table 1 Provides information about nucleoside analogues.

Drug	Structure	IUPAC Name	Molecular weight	Solubility
Abacavir		**{(1S,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopenten-1-yl}methanol**	322.79 g/mol	Easily dissolved inMeOH, ethanol, &H_2O
Adefovirdipivoxil		2-(6-aminopurin-9-yl)ethoxymethylphosphonic acid	273.19 g/mol	Soluble in ethanol, MeOH, H_2O
Cidofovir-anhydrous		[(2S)-1-(4-amino-2-oxopyrimidin-1-yl)-3-hydroxypropan-2-yl] oxymethylphosphonic acid	279.19 g/mol	Soluble in organic solvents such as ethanol, DMSO
AVR (Zovirax)		2-amino-9-(2-hydroxyethoxymethyl)-1H- purin-6-one	225.21 g/mol	Easily dissolved in ethanol &DSMO, minimally soluble in H_2O
Entecavir (Baraclude)		2-amino-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxy-methyl)-2-methylidene-cyclopentyl]-1H-purin-6-one	277.279g/mol	Easily dissolved in organic solvents like ethanol, DMSO, DMF & slightly soluble in H_2O

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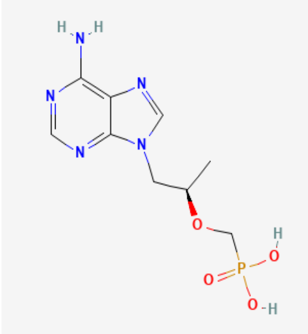
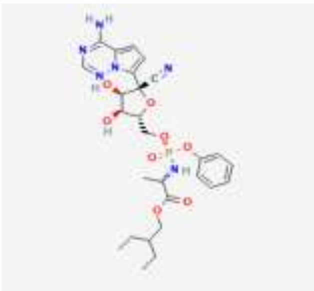
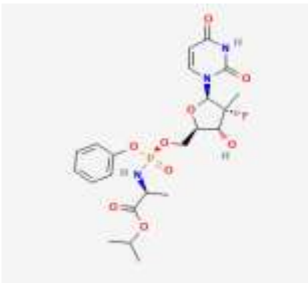
Famciclovir (Famvir)		[2-(acetyloxy-methyl)-4-(2-amino-purin-9-yl)-butyl] acetate	321.332g/mol	Barely soluble in ethanol & isopropanol & freely soluble in acetone &MeOH
Tenofovir anhydrous		[(2R)-1-(6-amino-purin-9-yl)-propan-2-yl]-oxymethyl-phosphonic acid	287.213g/ mol	Soluble in DMSO, MeOH, $H_2O$and ethanol
Remdesivir (Veklury)		2-ethyl-butyl-(2S)-2-[[[(2R,3S,4R,5R)-5-(4-amino-pyrrole-[2,1-f][1,2,4]-triazin-7-yl)-5-cyano-3,4-dihydroxy-oxolan-2-yl]-methoxy-phenoxy-phosphoryl]-amino]-propanoate	602.585g/mol	Easily dissolved in organic solvents like ethanol, DMSO, DMF & lightly soluble in distilled H_2O
Sofosbuvir (Sovaldi)		(S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)-(phenoxy) phosphorylamino) propanoate	529.453g/mol	It is insoluble in heptane, soluble in 2-propanol, easily dissolve in ethanol & acetone, & slightly dissolved in distilled H_2O

Imeglimin

In this paper, an overview is given about IMG, a new class of small molecule drug compounds called modulators. IMG (6R)-N2,N2,6-trimethyl-1,6-dihydro-1,3,5-triazine-2,4-diamine (Fig. 1), is a new drug that is being developed to address the problems of mitochondria not functioning properly, dealing with oxidative stress and suppression of the inflammatory molecules that can lead to metabolic and neurodegenerative diseases because it targets multiple pathways through which these three functional groups interact. By targeting these three different pathways, IMG can modulate cellular processes by integrating with the mitochondria's enzymes and the cellular signalling pathways to help cells generate energy more efficiently, and reduces the occurrence of oxidative damage.Because of the unique biochemistry of IMG, it has shown potential in animal studies for treating Parkinson's Disease, Alzheimer's disease, and Type II Diabetes[6].

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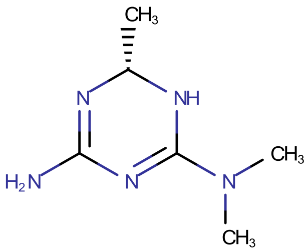

Fig 1. Chemical Structure of Imeglimin

The high specificity of IMG for targeting its receptors means that there will be little to no impact beyond the receptor, which also provides a great therapeutic index. As a result, IMG has the potential to be an excellent drug for further clinical research. The results of this research will be outlined in detail within this review through an analysis of various bioanalytical methods using liquid chromatography combined with mass spectrometry (LC/MS). The beginning of this review will provide a very brief introduction to IMG, as well as its potential applications in the field of medicine, followed by a description of LC/MS and LC/MS/MS methodologies from both the viewpoint of practical usage and regulatory matters. Due to the increasing demand for accurate assessment of therapeutic concentrations in biological samples, special consideration will be given to extraction and analysis techniques from plasma, which are essential components to verify reliability and accuracy of pharmacokinetic and pharmacodynamic studies[7].

II. IMPORTANCE OF ANALYTICAL ESTIMATION

Analytical Method Development and Validation (AMDV) is a key to success in the pharmaceutical industry and likewise for other scientific disciplines. It is used to ensure that any analytical technique used is robust, reliable, and appropriate for its application. This discussion will offer insight on AMDV, detail each of the major components involved in the process, and what this means for drug development and quality assurance[8-10].

Importance of Analytical Method Development

❖ **Establishing Methodology**

Developing an analytical method means developing and improving new and existing methods used to test and analyze products. Essentially this means that you develop or improve a method that accurately assesses the characteristics of a material or substance, (i.e.,its identity, purity, strength, and stability)[11, 12].

❖ **Regulatory Compliance**

It is required that any analytical method used during a clinical trial or to obtain regulatory marketing approval has been validated in order to show that it has sufficient accuracy, specificity, precision, and robustness. This is a requirement from regulatory agencies all around the world and is needed to be able to utilize a new drug in order to demonstrate that it will be safe and effective for patients[13].

❖ **Quality Assurance**

The analytical methods used to produce information regarding the quality of pharmaceutical products are heavily dependent upon being reliable. Validating analytical methods establishes that the analytical method is capable of consistently producing results that are in accordance with pre-established criteria. This information is especially important for pharmaceutical quality control and assurance processes throughout the drug development lifecycle. This includes evaluating all components (active pharmaceutical ingredient [API], excipient and/or deterioration products) of the drug product to ensure they have met the requisite safety and effectiveness standards[14, 15].

Key Components of Analytical Method Validation

Method validation for analytical testing looks at five main parameters:

- ✓ **Accuracy:**degree to which an analytical method's result matches the actual value.
- ✓ **Precision:** degree to which repeated measurements of the same item performed in accordance with the same conditions can produce resulting values that are all very similar.
- ✓ **Limit of detection; LOD & limit of quantification; LOQ:**lowest concentration of an analyte that can be accurately measured and/or detected.
- ✓ **System suitability testing:** testing is performed on the system (analytical equipment) before an analytical determination is performed.
- ✓ **Specificity:** can measure the analyte while having other analytes present.
- ✓ **Robustness:** analytical test will produce similar results when subjected to minor changes in method parameters.

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Method Development and Validating Process

- ✓ **Existing Methods Assessment:** Identify if there are enough existing methods or if there's a need for developing new methods.
- ✓ **Experimental Testing:** Conduct tests using current and new/modified methods according to industry standard reference materials to enable comparisons.
- ✓ **Theoretical Framework Use**: Use a theoretical basis to predict results and evaluate data.
- ✓ **Testing Methods on Actual Samples:** Use test methods to evaluate real-world samples of materials and validate their effectiveness.

Pharmaceutical Industry's Roles

Analytical procedures that are modern and innovative develop and support the life cycle of drugs by validating that they are safe, efficacious, and of high quality throughout the entire research and drug development process (i.e., development and manufacture). The following paragraphs give information about the significance of these procedures, the procedures involved, and regulatory requirements [16].

Regulatory Guidelines

Analytical method validation/development is related to guidelines from regulatory authorities. These include:

- ❖ **ICH Q2(R1):** Provides guidelines for the validation of analytical procedures.
- ❖ **FDA Guideline for Industry:** Outlines expectations for Validation of analytical techniques and processes for pharmaceuticals and biologics.

These guidelines help standardize the validation process across the industry, ensuring that all pharmaceutical products meet safety and efficacy standards.

III. ANALYTICAL TECHNIQUES FOR ESTIMATION

Pharmaceutical Analysis Techniques in figure 2:

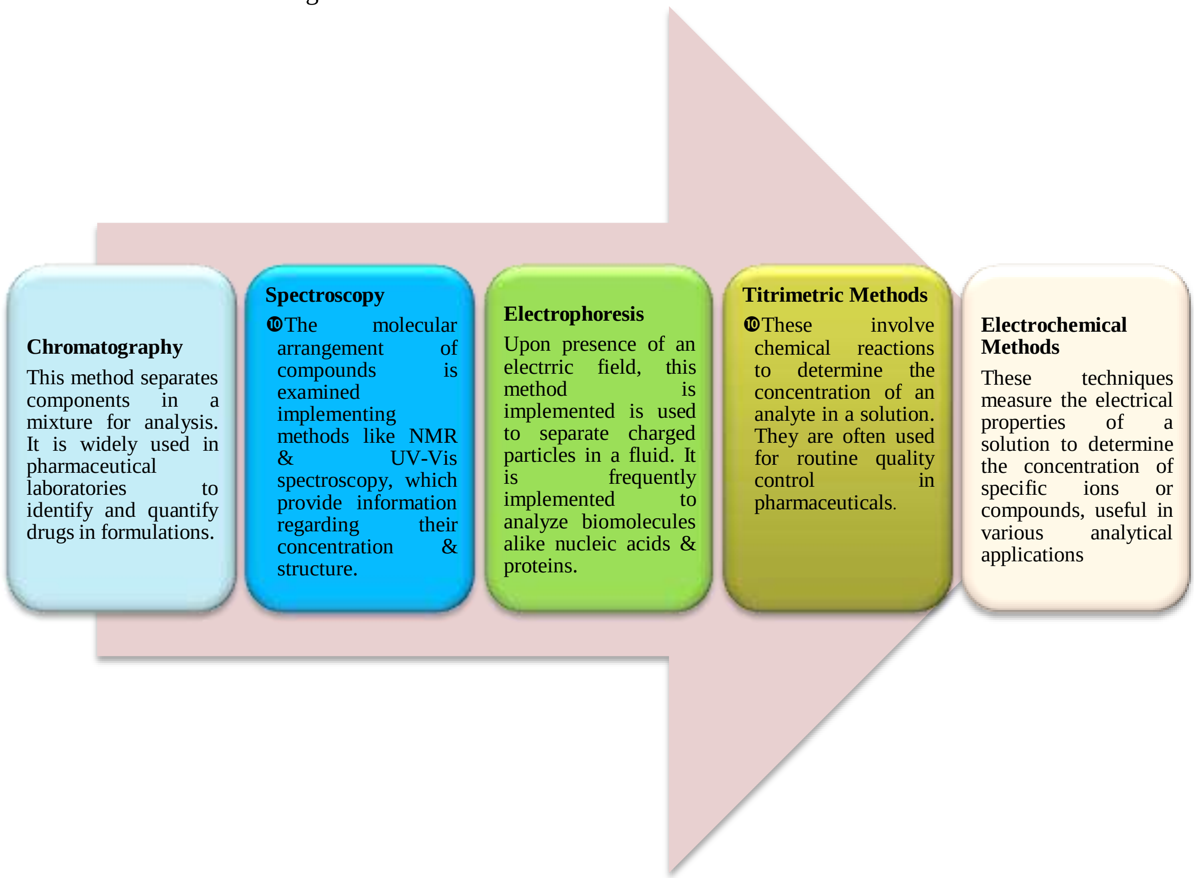

Fig 2. Different techniques for Analysis

The choice of analytical technique for estimation depends on the specific requirements of the project or analysis being conducted. Every approach has advantages and disadvantages, and frequently a mix of both of techniques is employed to achieve the most accurate and reliable results [17, 18]. Understanding these techniques is crucial for effective project management, data analysis, and pharmaceutical research in Table 2 and 3.

Chromatographic Techniques

Table 2. Analysis of medications containing Imeglimin involves the use of different columns with different mobile phases.

Slno	StationayPhase (Column)	Mobile Phase (with ratio)	Wavelength	Flowrate	Reference
1	Purospher Star RP C18 Endcapped (250 mm X 4.6 mm), 5µm	H_2O:MeOH (80:20)	234 nm	0.8 mL/min	[19]
2	Purospher Star RP C18 Endcapped (250 mm X 4.6 mm), 5µm	H_2O:MeOH (80:20 v/v)	234 nm	0.8 mL/min	[20]
3	HypersilC18 (150 mm X 4.6 mm), 5µm	Buffer pH 3.0 and MeOH(80:20 v/v)	234 nm	0.8 mL/min	[21]
4	HypersilC18 (150 mm X 4.6 mm), 5µm	Buffer pH 3.0 and MeOH(75:25 v/v)	234 nm	1.0 mL/min	[22]
5	Inertsil ODS-3V C18 (250 mm X 4.6 mm), 5µm	Buffer:MeOH (50:50 v/v)	261 nm	1.0 mL/min	[23]
6	Agilent Zorbax Eclipse XDB-C18 (150 mm X 4.6 mm), 5µm	Acetonitrile:H_2O (60:40 v/v)	254 nm	0.9 mL/min	[24]
7	Luna C18(2) (150 mm X 4.6 mm), 3µm	Acetonitrile:Phosphate buffer (70:30 v/v)	235 nm	1.2 mL/min	[25]
8	XTerra RP18 (150 mm X 4.6 mm), 5µm	MeOH:H_2O (50:50 v/v)	210 nm	0.7 mL/min	[26]
9	Symmetry C18 (250 mm X 4.6 mm), 5µm	Acetonitrile:Phosphate buffer (30:70 v/v)	280 nm	0.8 mL/min	[27]
10	Kinetex C18 (150 mm X 4.6 mm), 2.6µm	MeOH:H_2O (40:60 v/v)	225 nm	1.0 mL/min	[28]
11	Discovery HS F5 (250 mm X 4.6 mm), 5µm	H_2O:MeOH (30:70 v/v)	240 nm	1.0 mL/min	[29]
12	Accucore RP-MS (150 mm X 4.6 mm), 2.6µm	H_2O:Acetonitrile (90:10 v/v)	270 nm	0.6 mL/min	[30]
13	Zorbax SB-CN (150 mm X 4.6 mm), 5µm	Acetonitrile:Formate buffer (60:40 v/v)	250 nm	0.5 mL/min	[31]
14	Phenomenex Gemini C18 (150 mm X 4.6 mm), 5µm	MeOH:H_2O(80:20 v/v)	235 nm	1.2 mL/min	[32]

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Spectroscopic Techniques

Table 3. Determination of stability methods

Sl.No	Drug	Method	Description	Reference
1	Stability-Indicating Method Development and Validation of a UV Method for the Determination of Tablets of AVR in Solid dosageForm	SpectroscopicMethod	Detectionwavelength:252nmin0.1 NSodiumHydroxide Linearity range: 5- 30 µg/ml Co-relation Coefficient: 0.999 %Recovery:99.72% %RSD: ≤2%	[33]
2	UV Spectrophotometric Analysis and Validation of IMG in Solid Dosage Form	SpectroscopicMethod	Detection wavelength: 243 nmin0.2 distilled H_2O Linearity range: 5- 30 µg/ml Co-relation Coefficient: 0.999 %Recoveryrange:100.1-100.5% %RSD:≤2%	[34]

IV. APPLICATIONS OF ANALYTICAL TOOLS IN DRUG DEVELOPMENT

Analytical tools are an essential component of the process of developing a new drug, being used to enhance many of the different phases within that process, which are from initial discovery through to clinical testing. This overview of this section covers some of the primary applications of analytical approaches and technologies within the pharmaceutical sector[35].

Applications of Analytical Tools in Drug Development

A. ML; Machine Learning &AI; Artificial Intelligence

The Increasing presence of artificial intelligence; AI and machine learning; ML, are growing significantly in use within drug discovery & development processes[36]. These technologies facilitate in figure 3:

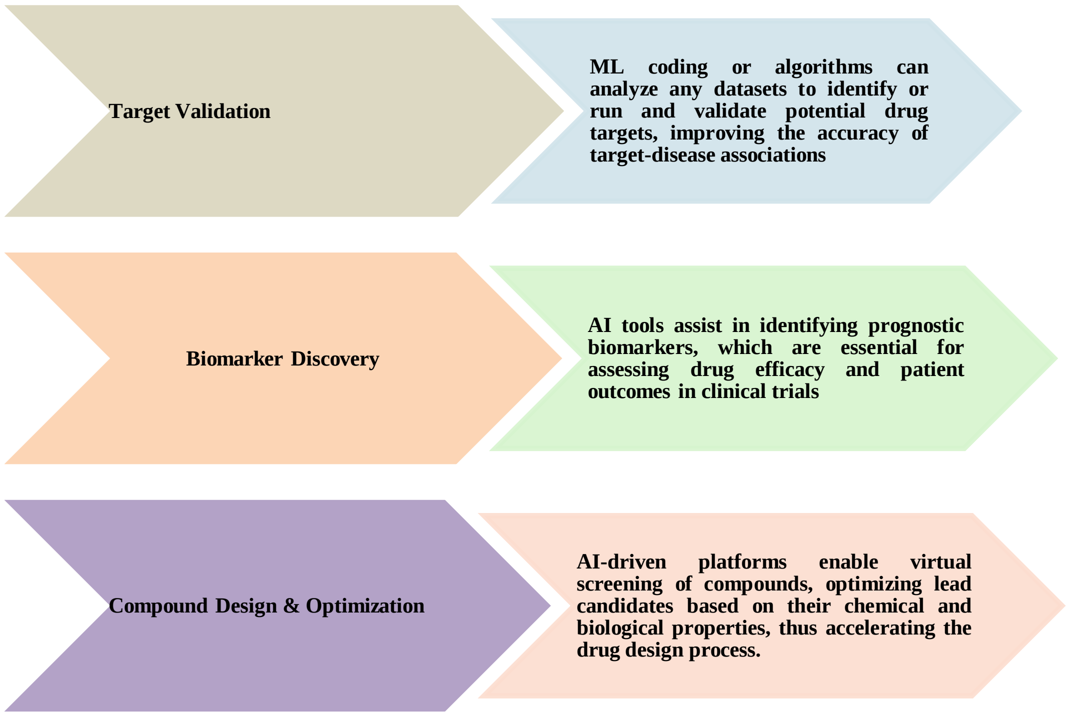

Fig 3. Analytical software are needed for know the quality and safety of drug.

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B. Analytical Method Development

Analytical methods are needed for confirming drug quality and safety. As shown in figure 4, key analytical methods include:

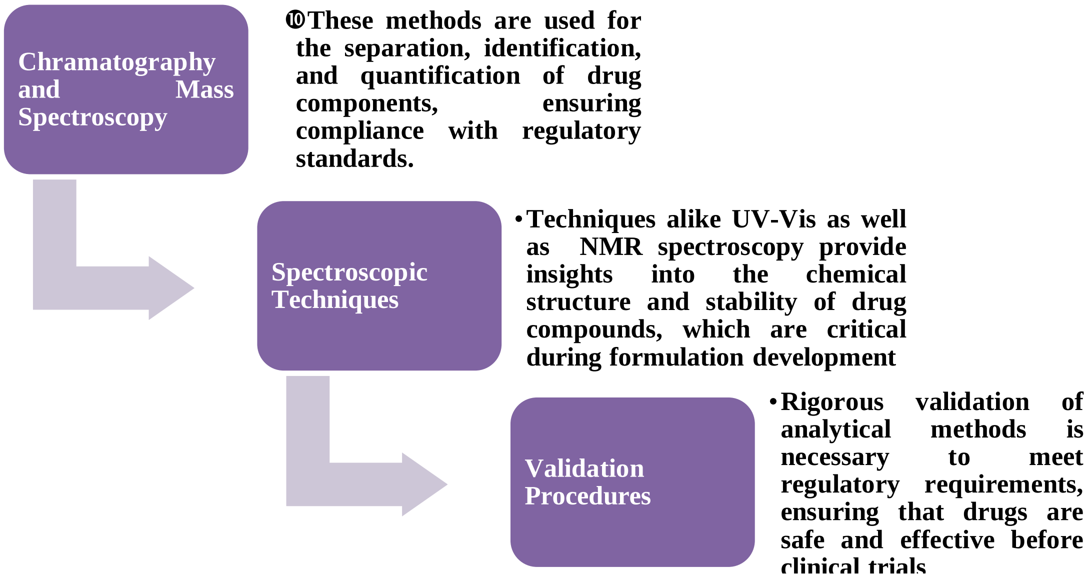

Fig 4. Key analytical methods ensure drug quality and safety.

C. Process Analytical Technology (PAT)

PAT is a mathematical approach that improves the quality and efficiency of the manufacturing process in pharmacy. It is shown in figure 5.

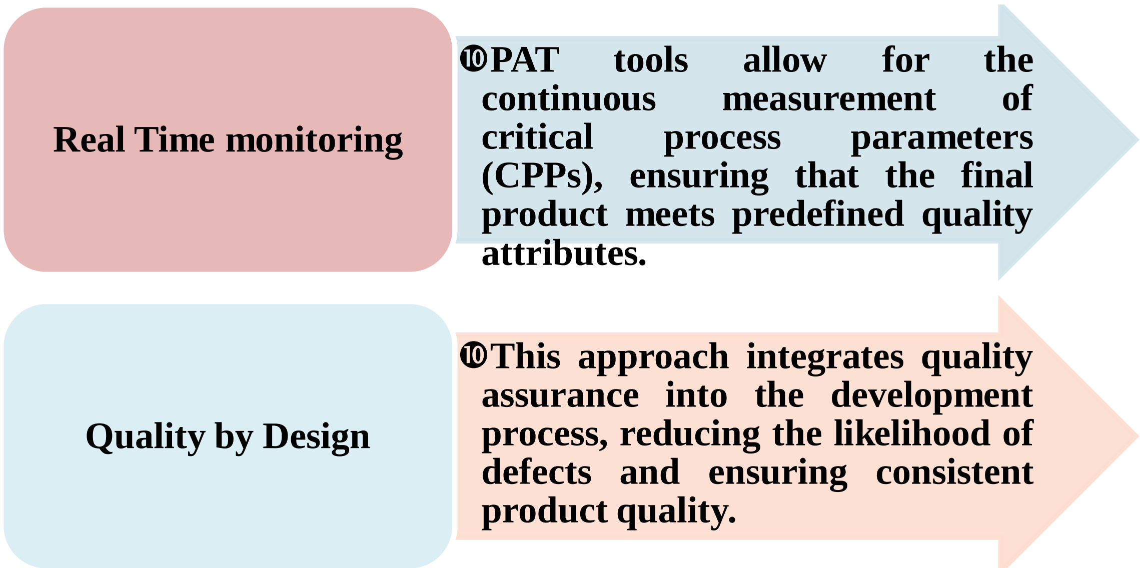

Fig 5. Enhances the quality and efficiency of pharmaceutical manufacturing

D. Data Analytics

The image below illustrates how data analytics is used to present various areas of a pharmaceutical company's drug development process by making use of APIs in figure 6.

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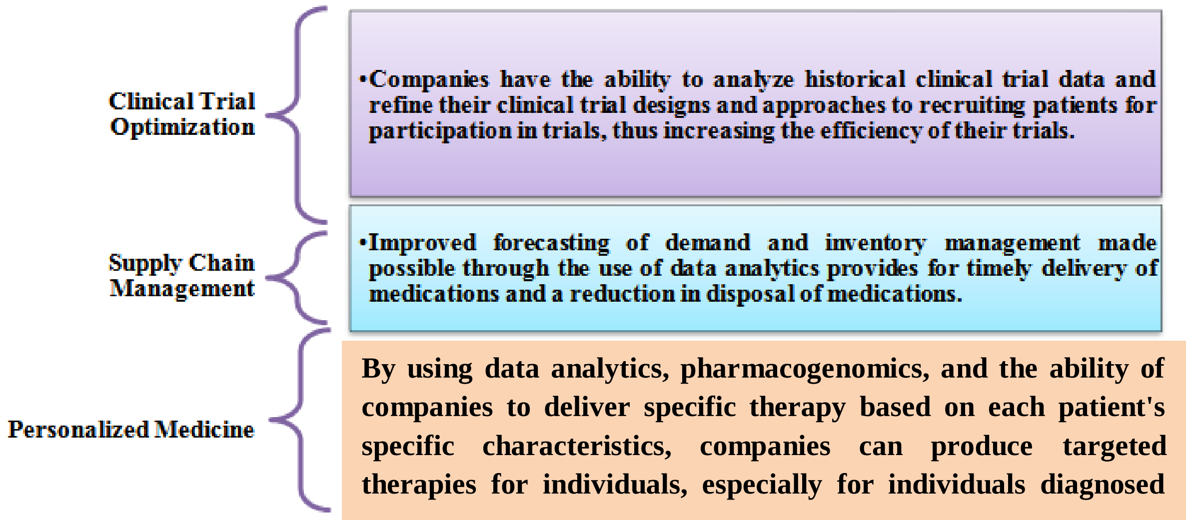

Fig 6. Leverage data analytics to inform various aspects for drug development

E. Quality Control and Compliance
Ensuring compliance with stringent regulatory standards is paramount in drug development. Analytical tools help in figure 7:

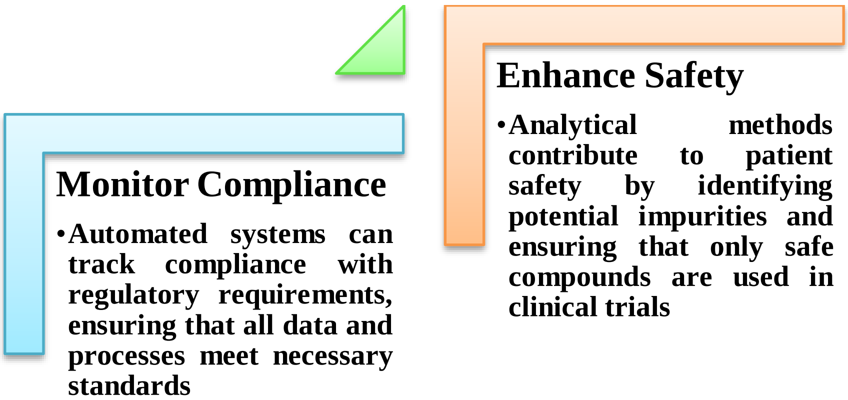

Fig 7. Stringent regulatory standards are paramount in drug development

Formulation Development
Importance of Analytical Method Validation in Formulation Development

❖ **Drug Quality Assurance:**

The main objective of pharmaceutical companies when developing their products will be to deliver superior quality. Analytical method validation allows us to analyze the chemical composition of drugs, which is a key element in developing these products [37, 38]. Validation also identifies the critical components (the characteristics that affect either the safety or efficacy of drugs) needed to produce a safe and effective medication.

❖ **Regulatory Compliance:**

The FDA and other authorities require that the analytical methods used to manufacture medications be validated prior to being used for conducting clinical trials or marketed as FDA approved medications. The lack of adequate CMC documentation will delay the verification and approval process of clinical trials [39-41]. As a result, validated analytical methods simplify regulatory compliance by providing clear, concise information regarding the quality of the medications.

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❖ **Patient Safety:**

As with all phases of drug development, patient safety is a critical priority. Analytical methods are used to ensure that only safe compounds will be used during clinical trials, thereby minimizing the risk to individuals participating in the early phase or clinical trial studies [42-44]. As well, validated analytical methods will ensure that the quality and potency of the drug(s) will be equal to the specifications of the clinical protocol.Steps in Analytical Method Validation

The validation procedure for analytical methods typically involves several key stepsin figure 8:

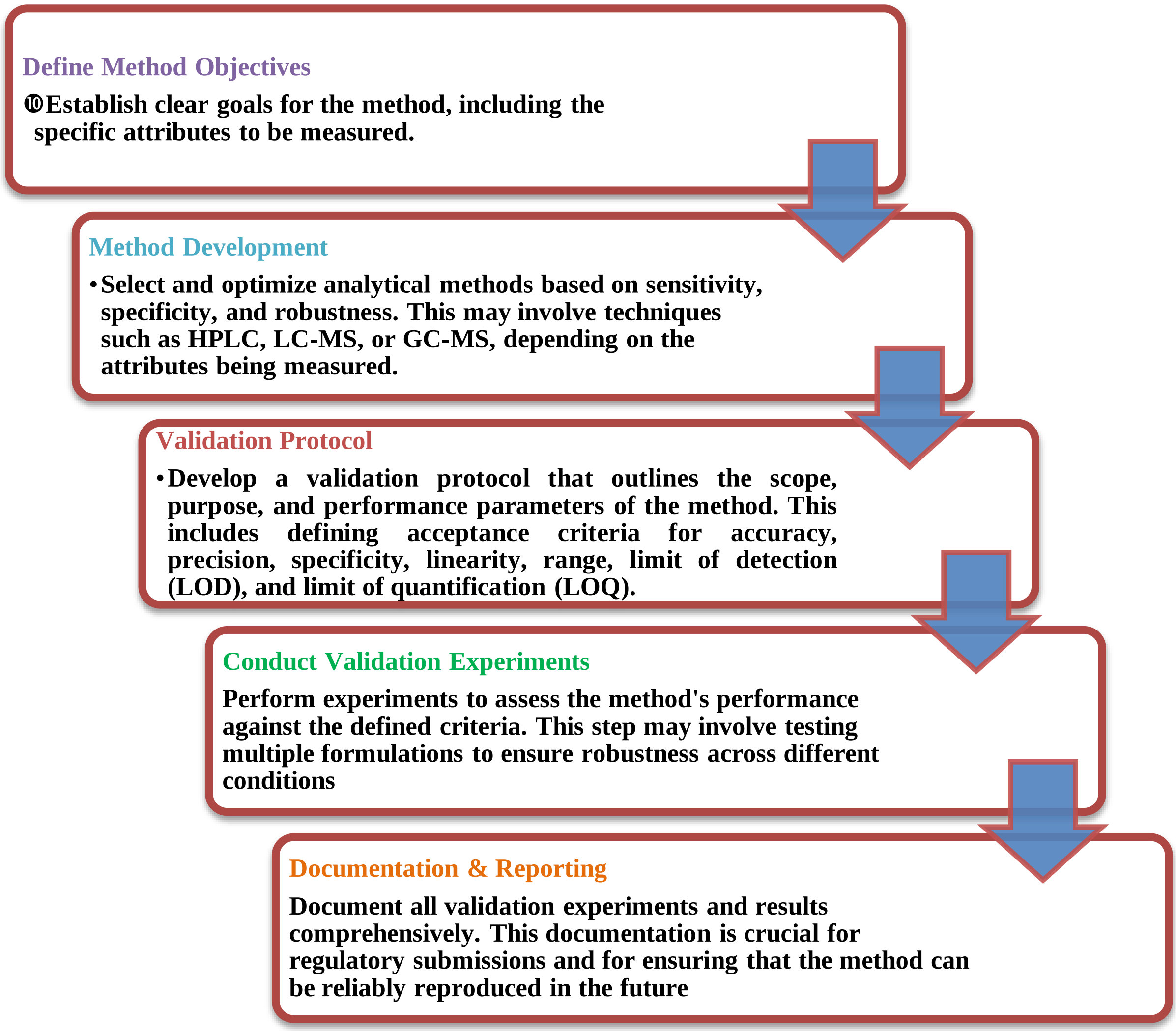

Fig 8. Validation procedure for analytical methods

V. CHALLENGES AND FUTURE PERSPECTIVES

A. Challenges

Drug formulation complexity

Developing analytical methods for pharmaceutical formulations is difficult because of their complex structure. Pharmaceutical formulations combine many different kinds of active and inactive ingredients, which can create difficulties when trying to ensure that you quantify accurately (specification and sensitivity) when quantifying active pharmaceutical ingredients (API's), such as CFP[45-47].

Information related to regulatory

Compliance with the requirements of regulatory bodies such as the FDA and ICH is another guideline for developing analytical

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methods. Additionally, as regulations change, analytical methods must continuously be updated to meet the new legal requirements in order to maintain compliance, which requires significant resources.

Validation with transfer of methods

Method transfer from R&D to QC laboratories often introduces variability in analytical results. Establishing those analytical methods yield consistent results in all environments can be challenging [48] and requires an appropriate level of validation and documentation. Both of which can take considerable time and resources to complete.

Limits of Technology:

Advances in analytic instruments such as UHPLC and MS have allowed for greater utilization of analytical methods than ever before; however, there remains limitations and limitations regarding sensitivity and specificity when using commonly used analytical techniques with extremely complex biological matrices (e.g. urine and blood) [49]. It is also possible that performing analytical methods on complex biological ingredients or-formulations containing low levels of poisonous compounds or degradation products, may result in being unable to detect the presence of analytes.

Sample Prep Issues:

The need for sample preparation methods that are capable of producing results that have little or no effect from the matrix, while at the same time achieving maximum quantification of the analytes is critical, as a failure to adequately prepare a sample may result in the failure of the method to yield results and would require additional optimization of the method [50, 51].

B. Future Perspectives

Analytical Methodologies of the Future Will Depend on the Adoption and Use of Innovative Technologies Ever Increasingly:

Advances in analytical methodology will rely heavily on new technologies such as artificial intelligence (AI) and machine learning (ML) to optimize how analytical methods are developed, analyze data efficiently through the use of analytical methods, and provide better predictability regarding the performance of analytical methods in the future[52].

Emphasis on Developing Analytical Methods That Are Both Robust and Flexible:

Education and modification of analytical methods are both necessary due to the evolution of regulations and changing regulatory standards. A major piece of this evolution is the validation of analytical methods for biopharmaceuticals versus small molecules[53, 54].

Changes in Regulation:

Ongoing education and changes in regulatory standards require continuing adjustments in the technique of analysis. One area will be focusing on the validation of analytical procedures for biopharmaceuticals since they might differ from those used to evaluate small molecules[55, 56].

Cross-Disciplinary Collaboration:

It will be critical to enhance collaboration among analytical chemists formulation scientists and regulatory affairs using an interdisciplinary approach in order to develop safe and effective compliant analytical methods which meet the requirements of the drug development process[57-59].

Sustainability Issues:

In the future, new analytical methods will be developed with an emphasis on sustainability by reducing waste and energy used in producing the thousands of analytical results that are produced as a result of using pharmaceuticals. This trend aligns with the much larger effort being made toward greater environmentally sustainable practices in both the pharmaceutical and biopharmaceutical industries[60].

VI. CONCLUSION

IMG may be an exciting new treatment option for people with Type 2 diabetes. It has several different ways of working, including improving mitochondrial function, reducing oxidative stress, and increasing sensitivity to insulin. Thus, it offers a new solution to the complex biological problems associated with Type 2 Diabetes that no other medications currently provide. The article reviews animal and human studies conducted to date that suggest that IMG has the potential to lower blood glucose and improve health profiles in people with diabetes, as well as reports that the development of bioanalytical tools for measuring IMG concentration using LC-MS will allow for accurate assessment of

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pharmacokinetics and pharmacodynamics. More work is needed to determine the long-term safety and efficacy of this drug. Continued development of analytical methods will be crucial in advancing the development and further study of this compound throughout clinical trials and bringing it one step closer to possible regulatory approval as a new medication to help treat diabetes.

ABERRATION

IMG: Imeglimin
VZV: varicella-zoster virus
HSV: herpes simplex virus
LC&MS: liquid chromatographic techniques coupled with mass spectrometry
AMDV: Analytical method development and validation
LOD: Limit of Detection
LOQ: Limit of Quantification
ML: Machine Learning
MeOH: Methanol
H_2O: Water
AI: Artificial Intelligence
CMC: chemistry, manufacturing, and controls
APIs: active pharmaceutical ingredients
R&D: research and development
QC: quality control

CONFLICT OF INTERESTS

The authors admitted that there is no conflict of interest between the authors.

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