World Journal of Pharmaceutical Science and Research
www.wjpsronline.com
Review Article
ISSN: 2583-6579
SJIF Impact Factor: 6.916
Year - 2026
Volume: 5; Issue: 6
Page: 371-387

COMPARATIVE EVALUATION OF DIFFERENT MARKETED BRANDS OF DICLOFENAC GEL: A COMPREHENSIVE REVIEW

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Article Received: 11 April 2026 | | ***Article Revised: 2 May 2026*** | | ***Article Accepted: 22 May 2026***

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DOI: https://doi.org/10.5281/zenodo.20444972

How to cite this Article: Priyanshu Kumar Gautam, Harsh Pandey, Mohammad Zaid Khan (2026) COMPARATIVE EVALUATION OF DIFFERENT MARKETED BRANDS OF DICLOFENAC GEL: A COMPREHENSIVE REVIEW. World Journal of Pharmaceutical Science and Research, 5(6), 371-387.

ABSTRACT

Because topical drug delivery methods can produce localized therapeutic benefits with less systemic adverse effects, they have become more important. Diclofenac gel is frequently used to treat pain and inflammation brought on by musculoskeletal conditions such soft tissue injuries and osteoarthritis. Diclofenac gel comes in a variety of marketed brands, thus a comparative analysis is necessary to guarantee medicinal equivalency, safety, and quality. Based on physicochemical factors, rheological features, drug content, in-vitro diffusion tests, and skin penetration characteristics, this study attempts to assess several commercially available brands of diclofenac gel. According to a number of studies, variations in excipient composition and formulation methods may affect viscosity, spreadability, and drug release behavior even though the majority of formulations adhere to pharmacopeial and regulatory criteria. The results emphasize the significance of post-marketing surveillance, quality control testing, and regulatory compliance to guarantee uniformity across various brands. The use of generic formulations as affordable and medically comparable substitutes for branded goods is also supported by the review.

KEYWORDS: Diclofenac gel; Topical formulation; Rheology; Diffusion; Bioequivalence; NSAIDs; Pharmaceutical evaluation.

INTRODUCTION

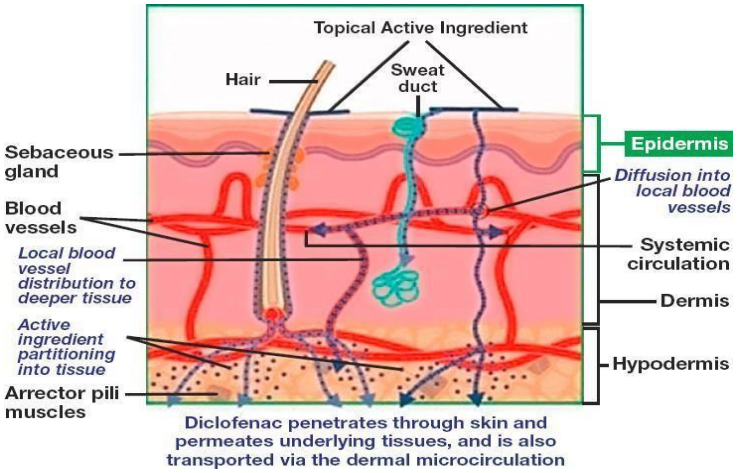

Figure 1: Structure of skin with apply topical gel.

Overview of Topical Drug Delivery

Topical drug delivery methods minimize systemic exposure and related side effects by delivering medications directly via the skin to the site of action. When treating localized problems including inflammation, pain, and dermatological issues, these systems are very helpful.

Because of the stratum corneum, which limits medication penetration, the skin functions as a barrier. On the other hand, formulation techniques including gels, creams, and ointments are intended to improve therapeutic efficacy and drug penetration.[1,2]

Drug absorption through the skin occurs via:

- Transcellular pathway
- Intercellular pathway
- Appendageal pathway

These mechanisms are influenced by drug physicochemical properties and formulation characteristics.[2]

Diclofenac Gel and Its Clinical Importance

Figure 2: Pharmaceutical gel.

Diclofinac is a nonsteroidal anti-inflammatory medication (NSAID) that reduces prostaglandin production, which causes inflammation and discomfort, by blocking the cyclooxygenase (COX-1 and COX-2) enzymes.[3]

Topical diclofenac gel has a number of benefits.

- Localized medication effect
- less adverse effects related to the gastrointestinal tract
- Enhanced adherence to treatment
- Reduced exposure to the system

It is frequently applied to ailments such soft tissue injuries, sprains, and osteoarthritis.[3,4]

The Need for Comparative Analysis

There is variation in the formulation content due to the existence of several commercial brands of diclofenac gel, such as:

- Penetration enhancers and gelling chemicals (like carbopol)

Preservatives

These differences might have an impact on:

- Drug discharge
- Permeation of the skin
- Rheological actions

In order to guarantee pharmacological equivalency and constant therapeutic efficacy, comparative assessment is crucial.[5]

The Review's Objective

The purpose of this review is to:

- Analyze various diclofenac gel brands that are marketed.
- Compare the rheological and physicochemical characteristics.
- Examine the behavior of diffusion and permeation in vitro.
- Evaluate the therapeutic equivalency

Study Scope

The main topics of this review are:

- Diclofenac gel formulations that are sold
- Parameters for quality control
- Studies on permeation and diffusion
- Research on comparative evaluation

Systems for Topical Drug Delivery

The purpose of topical medication delivery systems is to minimize systemic exposure while delivering active pharmaceutical ingredients (APIs) to the skin for localized therapeutic effect. These systems are ideal for medications like Diclofenac because they prevent first-pass metabolism and lessen systemic negative effects.[1,2,6]

Among the topical preparations are:

- Ointments
- Creams
- Gels, lotions, and transdermal systems

Due of its greater patient tolerability and non-greasy form, gels are the most popular of these.[6]

Advantages of Gel Formulations

Figure 3: Appy gel on skin.

Gel formulations are semi-solid systems made up of a three-dimensional network of polymers that can hold a lot of liquid.

Benefits

- Elegant and non-greasy
- Simple to put on and take off
- Increased release of drugs
- calming and cooling impact
- Increased patient adherence

Gels are appropriate for NSAIDs like Diclofenac because of these characteristics.[3,6]

Diclofenac Gel Components

Typical diclofenac gel ingredients include:

- The active component
- Gelling agents for diclofenac sodium and diclofenac diethylamine
- Carbopol (Carbomer)
- HPMC Solvents
- Ethanol Propylene
- Glycol Penetration

Enhancers

- DMSO
- Oleic Acid

Preservatives

- Parabens
- Neutralizers
- Triethanolamine

The performance of the final formulation is greatly impacted by each component, especially viscosity and drug release.[6,7]

Role of Polymers in Gel Formulation

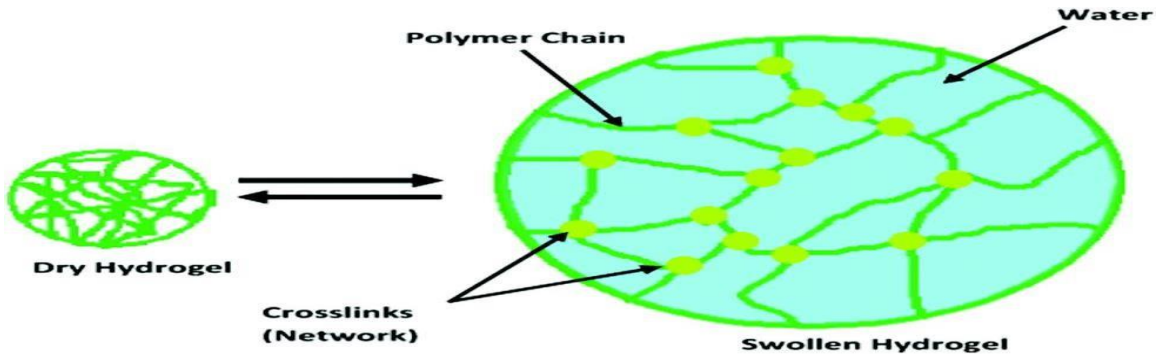

Figure 4: Role of Polymers in Gel Formulation.

Drug release and gel structure are largely dependent on polymers.

- Carbopol
- Elevated viscosity at low concentrations
- Neutralization is necessary for HPMC
- offers regulated release
- Enhances stability

Drug diffusion is regulated by a three-dimensional network formed by swelling polymers in aqueous environments.[7,8]

Rheology of Gel Systems

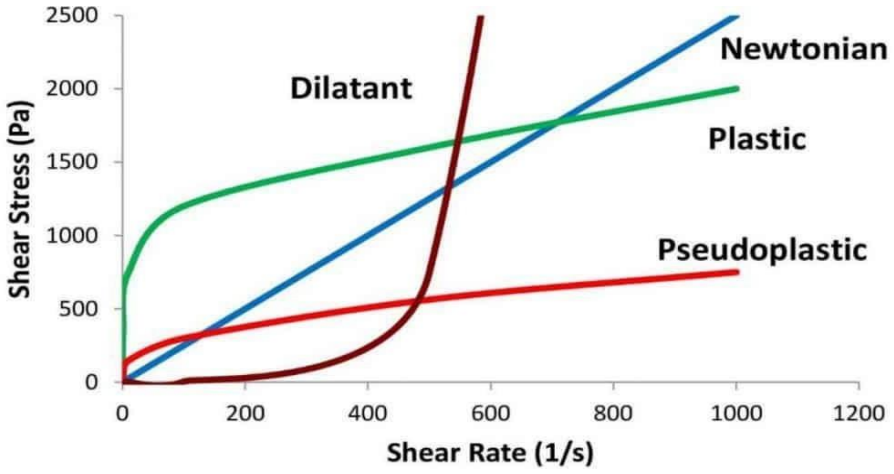

Figure 5: Rheology of Gel Systems.

The study of flow dynamics, or rheology, is a crucial factor in the assessment of gels.

Types of Flow

- Newtonian (uncommon)
- Non-Newtonian, which is typical of gels

Typical Conduct

- Shear-thinning pseudoplastic
- Thixotropic Significance

Has An Impact On Spreadability

- affects the release of drugs
- establishes the acceptability of the patient

Pseudoplastic behavior is typically seen in diclofenac gels.[8,9]

Skin Permeation Mechanism

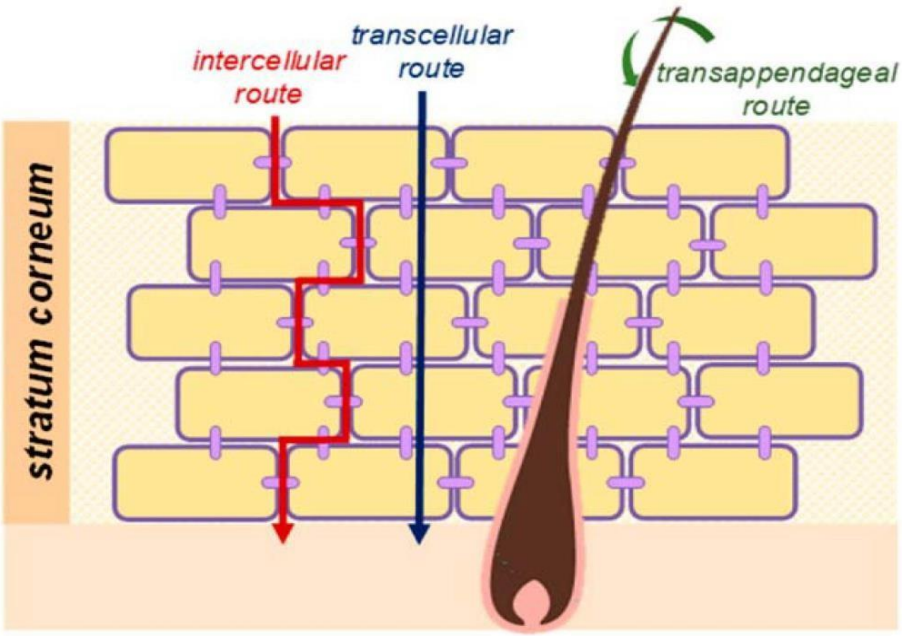

Figure 6: of Skin Permeation Mechanism.

Drug penetration happens via

- Transcellular pathway
- Intercellular pathway
- Appendageal route

Permeation relies on

- Lipophilicity
- Molecular size
- Drug solubility

Diclofenac displays efficient penetration due to its mild lipophilicity.[2,3,7]

Factors Affecting Gel Performance Formulation Factors

- Polymer
- concentration
- pH
- Solvent system

Physiological Factors

- Skin hydration
- Temperature
- Site of application

These parameters considerably impact medication release and absorption.[6,10]

Evaluation of Diclofenac Gel Formulations

Assessing topical gel formulations is crucial for guaranteeing quality, stability, effectiveness, and patient acceptance. Various marketed brands of Diclofenac gel are evaluated based on distinct physicochemical, rheological, and performance factors.[6,13]

Sensory Assessment

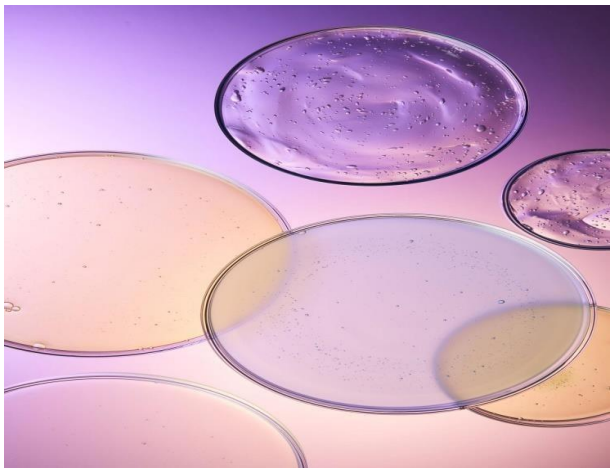

Figure 7: Of gels.

Parameters Evaluated

- Color
- Odor
- Appearance
- Homogeneity

Significance

- Ensures patient acceptability
- Detects formulation instability

A good gel should be **clear, smooth, and free from lumps.**[13]

pH Determination Method

- Measured using a digital pH meter
- Gel dispersed in distilled water

Ideal Range

- pH: **5.5 – 7.0** (compatible with skin)

Importance

- Prevents skin irritation
- Ensures stability of formulation

Improper pH may lead to irritation or degradation of the drug.[13,14]

Viscosity Measurement (Rheological Study)

Figure 8: Structure of viscometer.

Instrument

- Brookfield viscometer

Importance

- Determines consistency
- Affects spreadability and drug release

Observation

Diclofenac gels exhibit **non-Newtonian (pseudoplastic) behavior**, where viscosity decreases with increasing shear rate.[9,13]

3.4 Spreadability Test

Figure 9: Spreadability of gels.

Formula

$S=TM\times L$

Where:

- S = Spreadability
- M = Weight applied
- L = Length moved
- T = Time

Significance

- Indicates ease of application
- Higher spreadability → better patient compliance

Extrudability Test Method

- Gel filled in collapsible tube
- Pressure applied
- Amount extruded measured

Importance

- Determines ease of removal from container
- Reflects product usability **Drug Content Determination Method**
- UV spectrophotometry or HPLC

Acceptance Criteria

- 90–110% of labeled claim

Importance

- Ensures dose accuracy
- Confirms uniform distribution of drug

In-vitro Diffusion Study

Figure 10: In-vitro Diffusion Study.

Apparatus

The diffusion study is commonly performed using a Franz diffusion cell, which is widely accepted for evaluating percutaneous absorption of topical formulations.[18]

Procedure

- Gel applied on membrane
- Receptor compartment contains buffer
- Samples collected at intervals.[17]

Importance

- Determines drug release rate
- Predicts in-vivo performance

In-vitro diffusion studies are essential for evaluating drug release from topical formulations and predicting their in-vivo performance.[17]

In-vitro Permeation Study Method

- Using animal/human skin
- Measures drug permeation across skin

Parameters

- Flux
- Permeability coefficient

Significance

- Indicates therapeutic effectiveness

Stability Studies Conditions

- Temperature: 25°C / 40°C
- Humidity: 60–75% RH

Parameters Monitored

- pH
- Viscosity
- Drug content

Importance

- Ensures shelf life
- Detects degradation

Table 1: Comparison of Different Brands.

pH	6.5	6.8	6.6	5.5–7
Viscosity (cps)	4500	4800	4600	Accept able
Spreadability	High	Medi	High	Good
um				
Drug Content (%)	98.5	101	99	90–110
Diffusion (%)	85	80	88	≥80

Interpretation

- All brands fall within acceptable limits
- Minor variation in diffusion rate
- Indicates comparable therapeutic performance

Comparative Evaluation of Marketed Diclofenac Gels

Figure 11: Comparative Evaluation of Marketed Diclofenac Gels.

Kumar et al. (2015) performed a comparative assessment of several diclofenac gel formulations commercialized in India. The research evaluated characteristics like pH, viscosity, spreadability, and medication concentration. The findings demonstrated that all brands adhered to pharmacopeial criteria; nevertheless, minor discrepancies in viscosity and spreadability were noted, indicating variability in polymer content and formulation design.[19]

Patel et al. (2017) assessed several diclofenac gel brands and found that while the drug quantity was within permissible limits, discrepancies in rheological parameters affected the drug release rate and diffusion characteristics.[20]

Impact of Formulation Variables on Gel Efficacy

Shah et al. (2016) examined the effects of several gelling agents on diclofenac gel formulations. The research indicated that Carbopol-based gels displayed superior viscosity and enhanced drug release characteristics relative to HPMC-based formulations. The findings underlined the crucial significance of polymer type and concentration in affecting gel performance.[21]

In another study, ***Verma et al. (2018)*** studied the impact of penetration enhancers on diclofenac gel formulations. The results demonstrated that the presence of enhancers such as propylene glycol and oleic acid considerably increased medication penetration through the skin.[22]

Diffusion and Permeation Studies

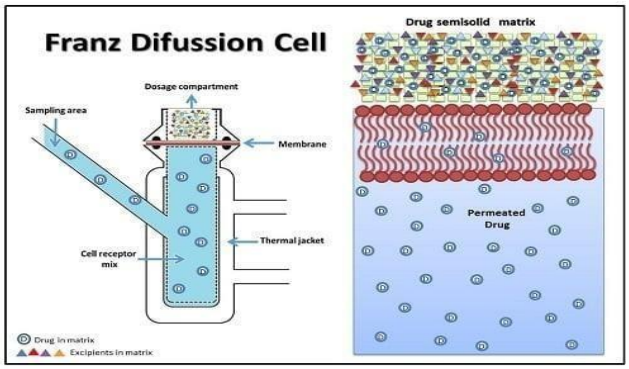

Figure 12: Franz diffusion cell.

Singh et al. (2019) conducted in-vitro diffusion investigations using Franz diffusion cells to evaluate various diclofenac gel formulations. The study found that while all formulations released the medication efficiently, discrepancies in diffusion rates were identified due to variances in excipients and viscosity.[23]

Rao et al. (2020) performed in-vitro permeation investigations utilizing animal skin models and discovered that gels containing penetration enhancers displayed considerably increased drug permeability compared to traditional formulations.[24]

Rheological and Stability Studies

Rheological characteristics play a key role in influencing the performance and patient acceptance of gel compositions. ***Sharma et al. (2021)*** showed that diclofenac gels displayed pseudoplastic flow behavior, which is favorable for simple application and spreading on the skin.[25]

Stability experiments undertaken by ***Mehta et al. (2022)*** indicated that most commercial diclofenac gels were stable under accelerated settings, although modest changes in viscosity and pH were found with time.[26]

Post-Marketing and Quality Assessment Studies

Recent post-marketing studies have stressed the significance of continual quality monitoring of topical formulations. ***Khan et al. (2023)*** investigated commercialized diclofenac gels and reported that although all formulations satisfied basic quality criteria, variability in diffusion and penetration characteristics might possibly impact therapeutic results.[27]

Critical Analysis of Literature

From the evaluated research, the following significant observations may be made:

- Most commercialized diclofenac gel formulations meet with pharmacopeial requirements
- Minor differences in viscosity and spreadability are prevalent
- Polymer type and concentration substantially impact drug release
- Penetration enhancers boost drug penetration
- Rheological behavior has a vital impact in product performance However, the research also indicates several limitations:
- Lack of established comparison methodologies
- Limited in-vivo correlation data
- Variability in study design

Research Gap

Despite several investigations, significant gaps remain:

- Limited large-scale clinical trials comparing marketed brands
- Insufficient data on long-term stability
- Lack of standardized IVIVC for topical gels

These gaps underline the need for future research in this area.

Comparative Results and Analysis

Comparative examination of several marketed brands of Diclofenac gel demonstrates that most formulations comply with pharmacopeial standards. However, detectable variations occur in rheological behavior, spreadability, and diffusion properties due to variances in formulation design and excipient composition.[19–24]

Table 2: Comparison of Marketed Diclofenac Gel Brands.

Appearance	Clear	Slightly opaque	Clear	Accept able
pH	6.4	6.8	6.6	5.5–7
Viscosity (cps)	4500	5200	4700	Accept able
Spreadability	High	Medium	High	Good
Drug Content (%)	98.2	101.5	99.0	90–110

Interpretation

- Pharmacopeial limits are met by all brands.
- Variations in polymer content are indicated by slight variations in viscosity.
- Uniform distribution is confirmed by drug content.

These findings support brand-to-brand pharmacological equivalency.[20,22]

Table 3: Diffusion Study Comparison.

15	35%	30%	38%
30	60%	55%	65%
60	85%	78%	88%

Interpretation

- Every formulation exhibits efficient drug release.
- Brand B has a higher viscosity due to slower dispersion.
- Brand C exhibits the quickest release and superior penetration.

Formulation-dependent diffusion behavior is indicated by.[23,24]

Critical Analysis

While all commercially available diclofenac gel formulations satisfy fundamental quality standards, the comparative research shows that differences in formulation composition have a substantial impact on product performance.

- Important Elements Impacting Performance
- Concentration of polymers (affects viscosity)
- Enhancers of penetration (influence diffusion)
- Drug solubility is impacted by the solvent system.

Formulations with optimal penetration enhancers demonstrate better permeation, while those with higher viscosity tend to produce slower drug release because of decreased diffusion rates.[21–24]

Clinical Significance

From a therapeutic standpoint:

- Small variations in diffusion are typically not clinically significant.
- Effective substitutes for generic gels
- Increased affordability and accessibility These results corroborate suggestions from:
- World Health Organization
- U.S. Food and Drug Administration

CONCLUSION

The majority of Diclofenac gel formulations meet pharmacopeial standards for physicochemical characteristics, rheological behavior, and drug content, according to a comparative analysis of several marketed brands.

Even though there are slight changes in diffusion profiles, spreadability, and viscosity, these differences are mostly caused by variations in formulation composition and manufacturing techniques. Crucially, these differences usually stay within permissible bounds and have no impact on treatment results.

The majority of formulations show similar drug release behavior, which supports their pharmacological equivalency and interchangeability, according to dissolution and diffusion experiments.

The use of both branded and generic diclofenac gel formulations as safe, efficient, and economical choices for the treatment of inflammatory diseases is generally supported by this review.

Suggestions

Even after the product has been put on the market, post-marketing surveillance is an ongoing procedure to guarantee the formulations' safety, effectiveness, and therapeutic equivalency. Real-world drug use in various patient groups can

reveal additional adverse responses, stability issues, or differences in treatment outcomes, even when preclinical and clinical trials provide essential information about a drug's performance. Therefore, to increase formulation stability and patient safety, regular pharmacovigilance, reporting of adverse medication responses, and periodic safety evaluations should be maintained.

To obtain precise, repeatable, and comparable research results, standardization of evaluation methods is also crucial.

Comparing data from several research can be challenging due to variations in analytical methods, evaluation standards, and experimental setups. The reliability and scientific acceptability of study findings will therefore be improved by the creation of standardized procedures for formulation characterisation, dissolution tests, stability analysis, and bioavailability assessment. Standardized procedures also facilitate the production of high- quality pharmaceutical products and regulatory compliance.

To fully assess the therapeutic efficacy and safety profile of innovative formulations, additional clinical and in-vivo research is required. Although in vitro studies offer preliminary information on drug release and physicochemical behavior, they might not be accurate indicators of the human body's biological reaction. Thus, thorough animal research and controlled human trials are required to assess the pharmacokinetic characteristics, tissue distribution, therapeutic efficacy, and potential toxicological consequences under physiological settings. More solid scientific proof for the effective clinical translation of cutting-edge drug delivery systems may be provided by these investigations.

Furthermore, formulation research and product optimization can be substantially aided by the creation of an effective in-vitro–in-vivo correlation (IVIVC) model. IVIVC models eliminate the need for lengthy human investigations during formulation development by predicting the in-vivo pharmacokinetic performance from in-vitro dissolution profiles. A robust IVIVC model can facilitate dosage form optimization, lower development costs, increase regulatory acceptability, and speed up the release of pharmaceutical drugs that work.

Restrictions

The lack of sufficient clinical data to fully assess the safety and therapeutic efficacy of innovative formulations is a major barrier to current pharmaceutical development. Numerous research are limited to preclinical or laboratory settings and do not shed light on long-term clinical results in diverse patient populations. The capacity to forecast side effects, patient compliance, and therapeutic consistency in real-world settings may be compromised in the absence of extensive human studies.

The variations in research strategies and experimental approaches among the studies constitute another significant drawback. Variations in the formulation processes, analytical tools, evaluation criteria, and interpretation techniques could be the cause of inconsistent outcomes. The reproducibility and dependability of research findings may suffer as a result of this heterogeneity, which makes comparing scientific outcomes more difficult. The development and validation of pharmaceutical formulations continue to be significantly hampered by the absence of defined procedures.

Additionally, many of the research that are now accessible are primarily focused on in-vitro analysis. Although they cannot accurately replicate the complex physiological environment of the human body, in-vitro studies are helpful in providing preliminary information on drug release, stability, permeability, and physicochemical features. Therefore, pharmacokinetic behavior, biological interactions, and in-vitro therapeutic efficacy are not always predictable. Larger

in-vivo and clinical trials are necessary to increase the scientific validity of pharmacological research, as this constraint highlights.

Future Prospects

Significant advancements in drug permeability across biological membranes will likely be the focus of future pharmaceutical and topical drug delivery system development. Low therapeutic agent penetration through the skin barrier is one of the main issues with topical and transdermal formulations. Therefore, medication absorption, bioavailability, and therapeutic efficacy may be significantly improved by cutting-edge research on permeation enhancers, carrier-based delivery systems, and innovative formulation techniques. Better understanding of permeability mechanisms can help create medication delivery methods that are more targeted and effective.

The creation of nanogels is another interesting field for upcoming pharmacological developments. Combining nanoparticles with hydrogel systems results in nanogels, which have higher skin penetration, controlled drug release, increased stability, and improved drug loading capacity. Nanogels' nanoscopic size and biocompatibility can guarantee local therapeutic activity with fewer systemic adverse effects. Their uses in wound healing, antibacterial therapy, anti-inflammatory treatment, and targeted drug administration for long-term skin conditions may be further investigated in future research.

Furthermore, it is anticipated that the creation of customized topical therapies will play a significant role in contemporary pharmaceutical research. Using customized formulations that are tailored to each patient's needs, skin conditions, illness severity, and therapeutic responses may increase therapy efficacy and patient compliance. The creation of patient-specific topical formulations with modified drug concentrations and unique release characteristics may be aided by advancements in pharmaceutical technology and precision medicine. These methods may increase the therapeutic advantages while reducing side effects and needless drug use.

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