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COMPARATIVE ANALYSIS OF PHYSICOCHEMICAL AND PHARMACOKINETIC PROPERTIES OF PHARMACEUTICAL DRUGS ACROSS BIOPHARMACEUTICS CLASSIFICATION SYSTEM CLASSES

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ABSTRACT-

This study comparatively evaluated the physicochemical and pharmacokinetic characteristics of pharmaceutical drugs across Biopharmaceutics Classification System (BCS) Classes I–IV. A secondary cross-sectional analytical approach was used, and drugs with unambiguous BCS classifications were compared using descriptive statistics, Kruskal–Wallis tests, and Spearman correlation analysis. Among 799 classified drugs, Class II represented the largest group, followed by Classes III, I, and IV. Significant differences were identified among BCS classes for molecular weight, Log P, bioavailability, and plasma protein binding. Class II compounds demonstrated the highest median Log P, whereas Class IV compounds showed the highest median molecular weight and the lowest median bioavailability. No statistically significant class-wise differences were observed for melting point, elimination half-life, or Tmax. Molecular weight and Log P exhibited a moderate positive correlation, indicating that compounds with greater molecular weight tended to display higher lipophilicity. Overall, the findings demonstrate that BCS classes differ not only in their conventional solubility and permeability characteristics but also in several broader physicochemical and pharmacokinetic properties. Integrating these parameters can improve pharmaceutical characterization, support formulation development, and provide a more comprehensive understanding of drug disposition across BCS categories.

Keywords – Biopharmaceutics Classification System; Physicochemical Properties, Pharmacokinetics; Bioavailability; Lipophilicity

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1. Introduction

The Biopharmaceutics Classification System (BCS) classifies drugs according to their aqueous solubility and intestinal permeability properties. The biopharmaceutics classification system underpins much pharmaceutical industry activity as it can help anticipate formulation challenges such as dissolution and permeability issues during oral drug development (Agnihotri et al., 2024).

Compounds within BCS Class I are generally characterized by high solubility and high permeability, with Class II drugs having low solubility despite relatively high permeability. Compounds within Class III are characterized by high solubility but low permeability, while compounds within Class IV have low solubility and low permeability, presenting the most biopharmaceutical challenge. Variability in regional intestinal permeability can also influence the absorption of poorly soluble compounds such as Class IV (Markovic et al., 2020).

The physicochemical properties of a drug are intimately linked to its pharmaceutical performance. Factors such as molecular weight, lipophilicity, ionization, melting properties, particles, and solubility can all impact on its dissolution rate, permeation, distribution, and overall systemic exposure, highlighting the importance of a systematic assessment of these characteristics during drug candidate screening and formulation development (Khojasteh et al., 2022). Physicochemical profiling can identify whether a molecule appears to possess qualities that are compatible with acceptable oral absorption and developability (Reese et al., 2024).

Lipophilicity (commonly defined by Log P), in particular, is significant as it indicates a molecule's affinity for aqueous or lipid environments. Molecules with optimal lipophilicity can readily assist passive permeation through membranes but those that are too lipophilic can be associated with reduced aqueous solubility and be difficult to formulate. Solubility, permeability, and physicochemical properties should be evaluated collectively and integrated rather than independently, providing more meaningful data to inform drug development (Cviji et al., 2020).

Biopharmaceutical characteristics also guide formulation decisions. Poorly aqueous soluble agents may require methods such as particle size reduction, solid state engineering, and lipids-based formulations as solubility enhancing strategies. This information is most relevant in early formulation design, where knowledge of drug properties can inform technology selection (Zarmpi et al., 2022). The development process is reliant upon the combination of molecule design and identifying acceptable absorption and pharmacokinetics (Ruston, 2022).

The pharmacokinetic implications of variations in physiochemical properties are reflected in measures such as bioavailability, plasma protein binding, half-life, and time to peak plasma concentration. These measures provide corroborative information about extent and rate of drug exposure, systemic distribution, and duration of action, translating biopharmaceutic attributes into pharmacology. Biopharmaceutic classification then becomes the link between molecular attributes and pharmacology in vivo (Frijlink et al., 2023).

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Contemporary drug development integrates information on physiochemical properties with formulation and disposition metrics through the development phase. This can help focus formulate optimization on compounds that require special considerations, guide the development of dosage form design and administration routes (Charoo et al., 2024). Biopharmaceutical classification schemes have also been applied to specialist delivery systems (Hastedt et al., 2024). Oral absorption of immediate-release dosage forms is predicted to be driven by the interplay between dissolution, solubility, permeability, and the presence of gastrointestinal constituents rather than by the chemical structure of the drug (García Alcalde, 2022). Overall assessment of the similarities and differences among biopharmaceutic classes with respect to physicochemical and pharmacokinetic characterise can thus provide valuable information about the distinctions between these classes beyond their traditional perceived differences in aqueous solubility.

The present study aimed to comparatively evaluate physicochemical and pharmacokinetic properties of pharmaceutical drugs across BCS Classes I–IV. The scope included molecular weight, Log P, melting point, bioavailability, plasma protein binding, elimination half-life, and Tmax. The objectives were to characterize distribution of drugs across BCS classes, compare key physicochemical and pharmacokinetic variables across the four groups, identify statistically significant class-wise differences, and examine association between molecular weight and lipophilicity.

2. Methodology

2.1 Study Design and Data Preparation

A secondary cross-sectional analytical design was used to compare physiological and pharmacokinetic characteristics of the pharmaceutical drugs within and between Biopharmaceutics Classification System (BCS) categories. The initial dataset structured the physicochemical properties as rows and individual drug records as columns. Thus, the data were transposed to create a dataframe where individual drugs were rows and the drug properties were columns (Tawade et al., 2024).

Physiological and pharmacokinetic characteristics of 938 pharmaceutical drugs were identified. The BCS category included different forms of Roman numerals, Arabic numbers, class designations (Class II), mixed forms (“II”), or additional descriptions (“BCS Class II”). Four standardized categories of BCS were created (BCS Class I, II, III, IV). Drug records with inconsistent, mixed, or unavailable BCS information were excluded from the BCS analyses. Other variables were analyzed with available cases; no data were imputed for missing values or records. Following the standardization procedure, 799 drugs had clear BCS classification information and served as a denominator for further analysis. Each of the remaining variables was analyzed in terms of availability and variability.

2.2 Study Variables and Operational Definitions

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The main outcome variable was the drug's BCS category (I-IV). Physiological variables included molecular weight (Da), Log P, and melting point (°C). The pharmacokinetic characteristics of the drug included bioavailability (%), plasma protein binding (%), elimination half-life (h), and the time to maximum plasma concentration, Tmax (h). No qualitative variables were analyzed; only measurements with an extractable numeric value were included in the analysis. For continuous variables, the median and interquartile range (25th-75th percentiles) were reported. Variable descriptive statistics were reported for valid samples. The number of drug records for each variable ranged from 266 to 540.

2.3 Statistical Analysis and Data Visualization

The descriptive statistics were reported for the whole sample for each of the four standardized BCS categories. The median and interquartile range (25th-75th percentiles) were selected as the most appropriate descriptive statistics for continuous variables since they appeared to have a different distribution range and dispersion. For categorical variables, the frequencies and percentages were reported with the total number of drugs (n=799) serving as a denominator for all calculations.

For the same reason, no logistic or linear regression models were estimated. To explore the associations between physiological and pharmacokinetic characteristics of the drug and its BCS classification, the Kruskal-Wallis H test was used for all continuous variables. For all the variables, pairwise comparisons were not performed since an initial test focuses on exploring the difference between four groups. For the continuous variables, the test used the median, and the two-sided p-value served to indicate whether the difference was statistically significant at the alpha level of $p<0,05$.

An approximate estimate of the association between molecular weight and Log P was performed with the Spearman's rank-order correlation coefficient (rho) for the subset of n = 267 drugs that had both measurements available. For rho, a value of $p < 0.05$ was considered statistically significant. To visualize the patterns in the data, a bar chart, boxplots for the Log P and drug bioavailability, and a scatter plot (BCS stratified) were created.

3. Results

3.1 Distribution of Pharmaceutical Drugs Across BCS Classes

Among the 799 drugs with a clearly identified BCS classification, Class II was the largest(n = 310;38.80%), followed by Class III(n = 202;25.28%), Class I(n = 196;24.53%), and Class IV(n = 91;11.39%) (Table 1). This distribution is depicted in Figure 1, which shows that there were significantly more Class II drugs than Class IV drugs.

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Table 1. Distribution of pharmaceutical drugs according to BCS classification

BCS Class	Number of drugs (n)	Percentage (%)
I	196	24.53
II	310	38.80
III	202	25.28
IV	91	11.39
Total	799	100.00

Figure 1 presents the number of pharmaceutical compounds belonging to each standardized BCS class.

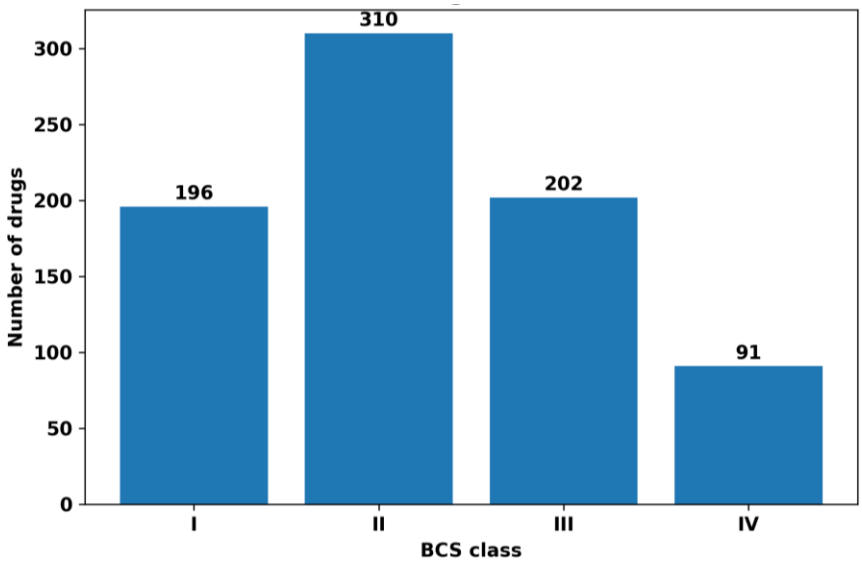


Figure 1. Distribution of pharmaceutical drugs across BCS classes

3.2 Physicochemical Characteristics Across BCS Classes

Physicochemical properties varied slightly among the four BCS groups (Table 2). Class IV compounds had the largest median molecular weight of 373.79 Da, whereas Class III had the smallest median value of 281.23 Da. Class II compounds had the highest median value of lipophilicity with a median Log P of 3.90, followed by Class IV compounds with a median Log P of 3.50. In comparison, Class I and III compounds had a lower median value of Log P of 2.02 and

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2.18, respectively. A relatively similar pattern of the median melting point was observed among Class I–III, ranging from approximately 163 to 175°C, whereas Class IV compounds had a higher median melting point of 207.50°C. Notably, significant differences were observed in the distribution of Log P, especially evident in Figure 2.

Table 2. Physicochemical properties of pharmaceutical drugs across BCS classes

Parameter	Class I	Class II	Class III	Class IV
Molecular weight (Da)	305.91 [214.60–374.88] (n=70)	337.43 [241.50–465.53] (n=125)	281.23 [221.79–384.75] (n=82)	373.79 [309.64–487.16] (n=44)
Log P	2.02 [0.76–3.92] (n=95)	3.90 [2.44–5.50] (n=147)	2.18 [0.72–3.88] (n=106)	3.50 [1.38–5.50] (n=55)
Melting point (°C)	174.00 [127.50–206.75] (n=71)	175.25 [134.50–217.75] (n=100)	163.00 [132.88–209.38] (n=86)	207.50 [154.88–235.88] (n=36)

Values are median [interquartile range]. Valid n varies because some drug records did not contain extractable numerical values.

As shown in Figure 2, Class II compounds displayed the highest median Log P, while Classes I and III had comparatively lower lipophilicity.

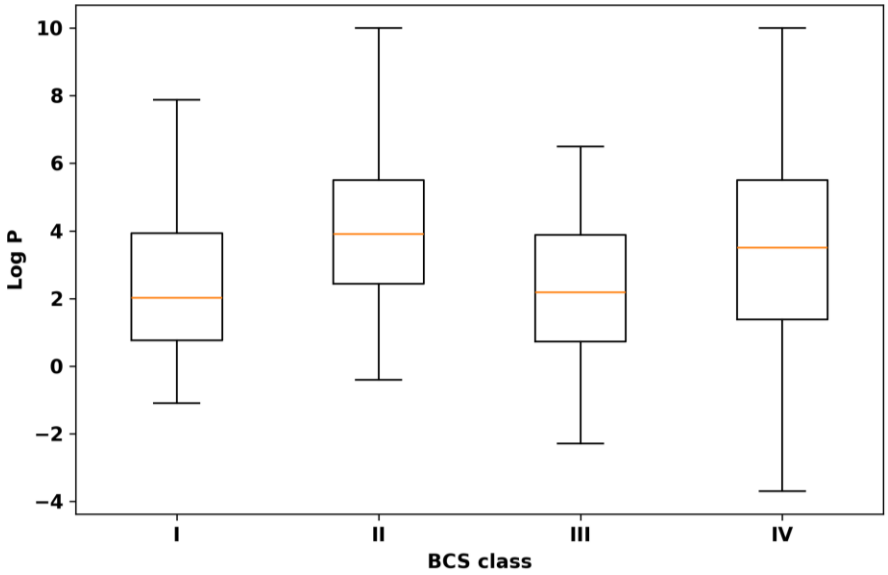


Figure 2. Distribution of Log P across BCS classes

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3.3 Pharmacokinetic Properties Across BCS Classes

Besides the described trends, marked variation was also observed in pharmacokinetic characteristics (Table 3) . Thus, the median bioavailability was highest for Class I compounds at 70.00%, followed by Class II at 60.00%, Class III at 59.00%, and Class IV at 38.00% (ranked from the largest to the lowest). At the same time, protein binding was found to be highest for Class II compounds (median: 90.00%), followed by Class IV (median: 87.50%) and Class I (median: 78.75%). Notably, Class III compounds had a considerably lower median value of 40.00%. By contrast, median half-life values were relatively comparable (ranging between 5.00 h for Class III and 7.50 h for Class IV), and median Tmax was also relatively similar (around 2.5-3.0 h). The gradual decrease in the median value of bioavailability from Class I to Class IV is illustrated in Figure 3 below.

Table 3. Pharmacokinetic characteristics of drugs according to BCS class

Parameter	Class I	Class II	Class III	Class IV
Bioavailability (%)	70.00 [45.00–90.00] (n=59)	60.00 [31.12–85.00] (n=116)	59.00 [25.00–80.00] (n=83)	38.00 [6.75–72.50] (n=38)
Plasma protein binding (%)	78.75 [27.50–90.50] (n=58)	90.00 [57.25–98.00] (n=104)	40.00 [16.75–85.25] (n=71)	87.50 [45.00–95.50] (n=33)
Half-life (h)	6.00 [2.50–35.00] (n=119)	7.00 [2.50–30.00] (n=223)	5.00 [2.00–18.40] (n=141)	7.50 [3.00–30.00] (n=57)
Tmax (h)	2.50 [1.50–3.00] (n=69)	2.50 [1.50–3.88] (n=106)	2.50 [1.50–4.00] (n=76)	3.00 [1.50–3.62] (n=36)

Values are median [interquartile range].

As illustrated in Figure 3, Class I compounds tended to have higher bioavailability, whereas Class IV displayed the lowest median and considerable dispersion.

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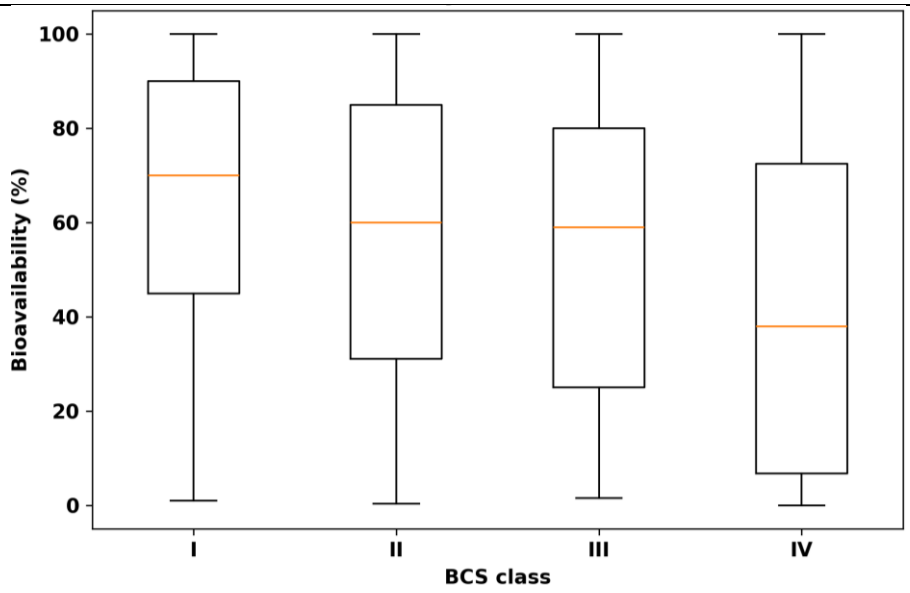


Figure 3. Bioavailability across BCS classes

3.4 Statistical Comparison and Relationship Between Physicochemical Properties

Kruskal–Wallis tests revealed significant differences among the BCS classes in terms of molecular weight ($H = 13.770$, $p = 0.003$), Log P ($H = 35.942$, $p < 0.001$), bioavailability ($H = 10.624$, $p = 0.014$), and plasma protein binding ($H = 24.738$, $p < 0.001$), while melting point, half-life, and Tmax were not significantly different among the four groups (Table 4).

Table 4. Comparison of physicochemical and pharmacokinetic parameters across BCS classes

Variable	Valid n	Kruskal–Wallis H	p-value
Molecular weight (Da)	321	13.770	0.003
Log P	403	35.942	<0.001
Melting point (°C)	293	6.515	0.089
Bioavailability (%)	296	10.624	0.014
Plasma protein binding (%)	266	24.738	<0.001
Half-life (h)	540	2.348	0.503

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Tmax (h)	287	1.193	0.755

The relationship between molecular weight and lipophilicity is presented in Figure 4. Across drugs with available data for both variables, a moderate positive

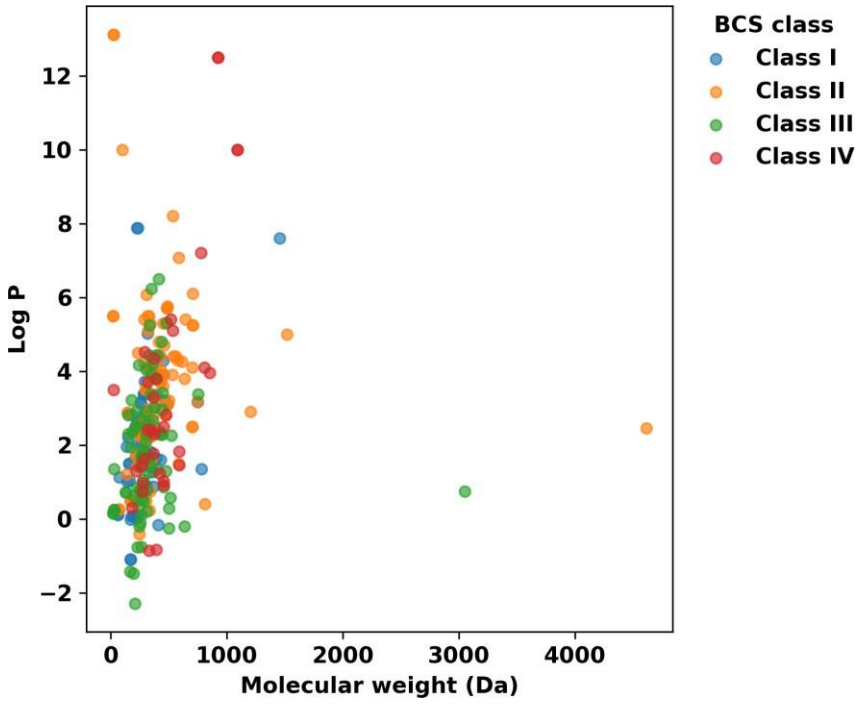


Figure 4. Relationship between molecular weight and Log P according to BCS class

Spearman correlation was observed between molecular weight and Log P ($\rho = 0.422$, $n = 267$, $p < 0.001$), indicating that compounds with greater molecular weight generally tended to exhibit higher lipophilicity. Figure 4 additionally demonstrates substantial overlap among the BCS groups, although Class II and Class IV compounds were more frequently represented at higher Log P values.

4. Discussion

The present analysis revealed physicochemical and pharmacokinetic heterogeneity of drugs within BCS Classes I–IV. Of the 799 drugs with a defined BCS classification, the largest percentage belonged to Class II, followed by Classes III, I, and IV. The values of the majority of the parameters analyzed differed significantly between the BCS classes. In particular, there were significant differences in molecular weights, Log P, levels of bioavailability, and protein binding capacity. At the same time, no significant differences were found for the melting point, half-life, and Tmax. The obtained results highlight the importance of considering multiple factors in the

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physicochemical and pharmacokinetic characterization of drugs and the insufficient validity of dividing drugs into classes based only on their solubility and permeability properties.

Compounds in Class II displayed the maximum Log P median value, whereas Class IV compounds were comparatively highly lipophilic. This trend appears to be physiologically sound as higher lipophilicity can help partitioning across membranes at the same time decreasing water solubility. Modern-day physiochemical evaluation in drug discovery focuses on finding a balance between lipophilicity and other physiochemical properties such as solubility, ionization, and size in order to create appropriate drug developability characteristics (Çevik et al., 2025). Medicinal chemistry studies in general also indicate that physiochemical property balance plays a significant role in drug development success (Davis & Leeson, 2023).

The observed positive correlation between the molecular weight and Log P also implies that large molecules were more lipophilic. While the correlation is not very strong, it shows that the physicochemical descriptors can be associated with each other and cannot be considered separately. It has been shown before that in predictive pharmaceutical studies, the combination of certain molecule properties can yield important information concerning solubility and metabolism (Ashrafi et al., 2024). In the current study, though, the correlation was calculated in the traditional way, without the use of machine learning modeling.

The bioavailability was different among the four BCS classes, with the highest median value being observed for Class I drugs and the lowest one for Class IV drugs. The differences observed are a direct effect of the combined impact of solubility and permeability on systemic exposure of the drug. Dissolution variation due to gastrointestinal environment could affect the availability of drug for absorption, especially in the case of low-soluble drugs (Shawahna et al., 2023). Regulatory and formulation evaluations of drugs based on BCS also take into account the relationship between dissolution properties and absorption properties (Van Wyk et al., 2024).

The plasma protein binding also varied significantly among the four BCS classes. The maximum plasma protein binding was observed for Class II drugs, while the minimum value was observed for Class III drugs. Increased lipophilicity could lead to higher plasma protein binding, however, protein binding depends also on many factors such as ionization, molecular structure, binding affinity to proteins, etc. (Cvijić et al., 2023).

In contrast, half-life and Tmax values were not found to exhibit a statistically significant difference across BCS classes. This result is anticipated due to the fact that the majority of these parameters are governed by various processes, namely distribution, metabolic clearance, transport, elimination, formulation, and route-related mechanisms. The characteristics of drug delivery critically impact the absorption and exposure of drugs despite similar properties of a given pharmaceutical substance (Ghosh, 2020). Thus, the BCS categorization may not be adequate in explaining the differences in temporal pharmacokinetic patterns.

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Simultaneously, the absence of significant differences in Tmax values underscores the need to consider the importance of formulation-specific effects. Modified release can influence the in vitro/in vivo relationship, making it impossible to determine the pharmacokinetic performance based solely on the intrinsic characteristics of a drug (Tomic & Cardot, 2022). Therefore, in vitro/in vivo correlations must consider the impact of formulation, dissolution, and absorption in combination with physiological processes (Zhou & Qiu, 2023).

The low bioavailability of Class IV drugs partly explains the increased interest in optimizing formulations for poorly soluble and permeable compounds. The application of computational and formulation approaches enables the prediction of drug developability and the identification of design options for optimizing the properties of a given molecule with undesirable physicochemical characteristics (Bennett-Lenane, 2021). Physiologically based biopharmaceutics modeling has also been employed to explore formulation spaces and anticipate bioequivalence outcomes involving dissolution rate variability (Zhao et al., 2025).

Lastly, solubility and bioavailability can also be influenced by efflux transporter-protein interactions and formulation-specific factors. Indeed, P-glycoprotein substrates exhibit a fascinating interplay between solubility and efflux processes, which significantly impact absorption and exposure (Murakami et al., 2021). In summary, the study highlights the key differences between BCS classes in terms of physicochemical and pharmacokinetic characteristics and the general principles determining other attributes.

5. Conclusion

This study established that drugs from different biopharmaceutical classes have significant differences and similarities concerning their physicochemical and pharmacokinetic characteristics. Notably, there were several drugs that fell under class II of the BCS, while there were fewer drugs in class IV. On the other hand, there were significant differences among the four classes of BCS drugs in terms of the molecular weight, Log P, bioavailability, and plasma protein binding. The differences in these parameters can partly explain the differences in the biopharmaceutical classifications of the drugs. For example, there were drugs with the highest median lipophilicity in class II drugs, while class IV had the highest median molecular weight and the lowest median bioavailability. However, there were no significant differences among the four classes of BCS drugs in terms of melting point, half-life, and Tmax . These three parameters were likely to be influenced by other physiological and formulation variables beyond the BCS. Lastly, there was a moderate positive correlation between molecular weight and Log P, suggesting that the larger the drug is, the more lipophilic it tends to be. Physicochemical and pharmacokinetic properties are, therefore, useful in understanding the BCS classification of different drugs. Comparing and contrasting the properties helps in having an insight into the drug classification. Therefore, these properties should be used to supplement the information provided by the BCS of drugs to understand how they will behave in the body.

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