

# Bibliometric Study of Trends in Chemometrics Applied to Drug Dissolution Testing

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## ABSTRACT

This bibliometric study explores the multifaceted domain of the dissolution of solid oral pharmaceutical forms, focusing on key aspects such as dissolution testing, dissolution profiling and modeling, and comparative dissolution tests for therapeutic equivalence over the past 40 years (1982–2025). The pharmaceutical quality system hinges on controlling the product and process elements. Dissolution tests are critical for bioperformance and therapeutic equivalence, necessitating mastery of this domain and the influencing factors. Traditionally, these procedures rely on liquid chromatography and UV-visible spectroscopy, which are often cumbersome and generate significant waste. However, innovative techniques such as artificial intelligence, machine learning, and chemometrics are gaining prominence, especially in research laboratories and institutions involved in pharmaceutical development. Pharmacopoeias contain general chapters on chemometrics and associated guidelines, including those from the Official Medicines Control Laboratories (OMCL) network, which develops chemometric tools for quality control, even for counterfeit products. Regulatory bodies like the ICH and authorities in developed countries encourage the pharmaceutical industry to adopt next-generation practices, including quality by design (QBD), process analytical technology (PAT), and continuous manufacturing. The development of increasingly complex drugs drives the adoption of new tools to address performance, structural complexity, excipient effects, and multicomponent formulations. These innovations aim to enhance the precision and efficiency of dissolution methods while reducing environmental impact and associated costs. Integrating advanced tools like chemometrics allows researchers to obtain more reliable results and optimize drug development processes. The future of the pharmaceutical industry relies on adopting these cutting-edge technologies to ensure superior product quality and meet growing regulatory demands.

**KEYWORDS:** chemometrics, dissolution testing, bibliometric analysis, pharmaceutical quality control

## INTRODUCTION

The field of dissolution of solid oral dosage forms encompasses several key aspects essential to ensuring drug quality and efficacy. These aspects include dissolution testing, dissolution profile modeling, and comparative dissolution testing in the context of therapeutic equivalence (1, 2).

Traditionally, dissolution testing has relied primarily on liquid chromatography and UV-visible spectroscopy.

These methods, while robust and widely used, can be procedurally intensive and generate significant amounts of waste. This poses environmental and logistical challenges for laboratories (3).

However, innovative techniques such as artificial intelligence (AI), machine learning, and chemometrics have started gaining importance. These technologies offer new opportunities to improve the efficiency of dissolution testing, reduce waste, and optimize

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processes. Chemometrics is the science of extracting relevant information from chemical systems by using data-driven mathematical and statistical methods. AI and machine learning can analyze large datasets to identify trends and predict drug behavior, improving the accuracy and efficiency of dissolution methods (4–8).

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and authorities in developed countries are encouraging manufacturers to adopt the next generation of pharmaceutical manufacturing. This includes concepts such as quality by design (QBD), process analytical technology (PAT), and continuous manufacturing. Dissolution testing is a key element of bioperformance and therapeutic equivalence, making mastery of this area and the factors that influence it crucial (9–13).

It is important to note that pharmacopoeias contain general chapters on chemometrics and associated guidelines. In particular, the Official Medicines Control Laboratories (OMCL), which is a network of control laboratories, is developing the application of chemometrics tools for quality control, including for counterfeit products. These guidelines provide frameworks for the rigorous and systematic application of these innovative methods (14).

The development of increasingly complex drugs is driving the adoption of new tools to address issues of performance, structural complexity, the effect of excipients, and management of multicomponent formulations. These innovations aim to improve the precision and efficiency of dissolution methods. Advanced techniques such as Raman spectroscopy and artificial neural networks offer more sophisticated and precise means of analysis. These tools allow researchers to obtain more reliable results and better understand the interactions between the different components of formulations (4, 15–18). By integrating advanced tools such as chemometrics, researchers can reduce the environmental impact of dissolution testing by minimizing the waste generated. Additionally, these technologies can help reduce testing costs by automating and optimizing processes (19).

The future of the pharmaceutical industry depends on the adoption of these cutting-edge technologies to ensure superior product quality and meet increasing regulatory requirements. Integrating AI, machine learning, and chemometrics into dissolution testing not only improves the accuracy and efficiency of existing methods but also creates new opportunities for innovation and the

development of more complex and personalized drugs. This evolution is essential to meet the ever-growing needs of both patients and the pharmaceutical industry (20, 21).

This bibliometric study aims to analyze and map the scientific literature to identify and visualize evolving trends, key research areas, and the collaborative landscape in the application of chemometrics to drug dissolution testing.

## METHODS

To achieve our research objective, we developed our keyword search to comprehensively cover the topic. The search key consists of three main components:

1. **Chemometrics Component:** ("Chemometric" OR "Chemometrics" OR "Multivariate" OR "Least Squares" OR "Partial least squares discriminant analysis" OR "Inverse Least Squares" OR "Principal Components Regression" OR "Partial Least Squares Regression" OR "Artificial Neural Networks" OR "Locally Weighted Regression" OR "Principal component analysis" OR "cluster analysis" OR "k-Nearest neighbors" OR "Multivariate curve resolution" OR "Soft independent modeling of class analogy" OR "Multiple linear regression" OR "Multiplicative scatter correction")
2. **Dissolution Component:** ("Drug release" OR "Dissolution" OR "Dissolution test" OR "Dissolution testing" OR "Dissolution profile")
3. **Analytical Methods Component:** ("Spectrophotometry" OR "spectroscopy" OR "Spectrometry" OR "Infrared" OR "Near infrared" OR "Raman" OR "fluorescence" OR "Nuclear magnetic resonance" OR "Fiber optic" OR "chromatography" OR "Electrochemical" OR "Voltammetry" OR "Electroanalytical")

This approach covers a wide range of relevant topics, including chemometric techniques, dissolution tests, and the various analytical methods used in this field. By including these three components, the search captured the most relevant studies (22).

The PRISMA flow diagram (Fig. 1) outlines the study selection process for the bibliometric review, beginning with 1449 articles identified through the Scopus database. Initial screening applied the following inclusion criteria: subject area = pharmacology, toxicology, and pharmaceuticals; document type = article; publication date between Feb 5, 1982 and Feb 22, 2025; and language = English. After excluding articles that did not meet these

criteria (966 articles), 483 articles underwent eligibility assessment, and 170 full-text articles were excluded due to insufficient information or irrelevance to the study focus. A total of 313 full-text articles were included in the final review.

The analysis was organized using the following structure: intellectual (publications, authors, and citations), social (institutions and countries), and conceptual (keywords).

## RESULTS AND DISCUSSION

Figure 2 illustrates the annual production of scientific articles over the 40-year period from 1982–2025, with a variation ranging from 0 to 25 articles per year. Over time, an increase in the number of published articles can

be seen, with a growing interest in the field of dissolution and chemometrics since 2020. This upward trend reaches a notable peak around 2020, when the number of published articles peaks. After 2020, the annual production of articles stabilized at around 20 articles per year. This stabilization can be interpreted as a sign of maturation of the field. Indeed, with the majority of basic concepts having been extensively explored, research is now focusing on more specific aspects or innovative applications of dissolution and chemometrics.

### Intellectual Structure

The analysis of the intellectual structure of the field of dissolution and chemometrics revealed a rich interconnectedness of contributions from influential

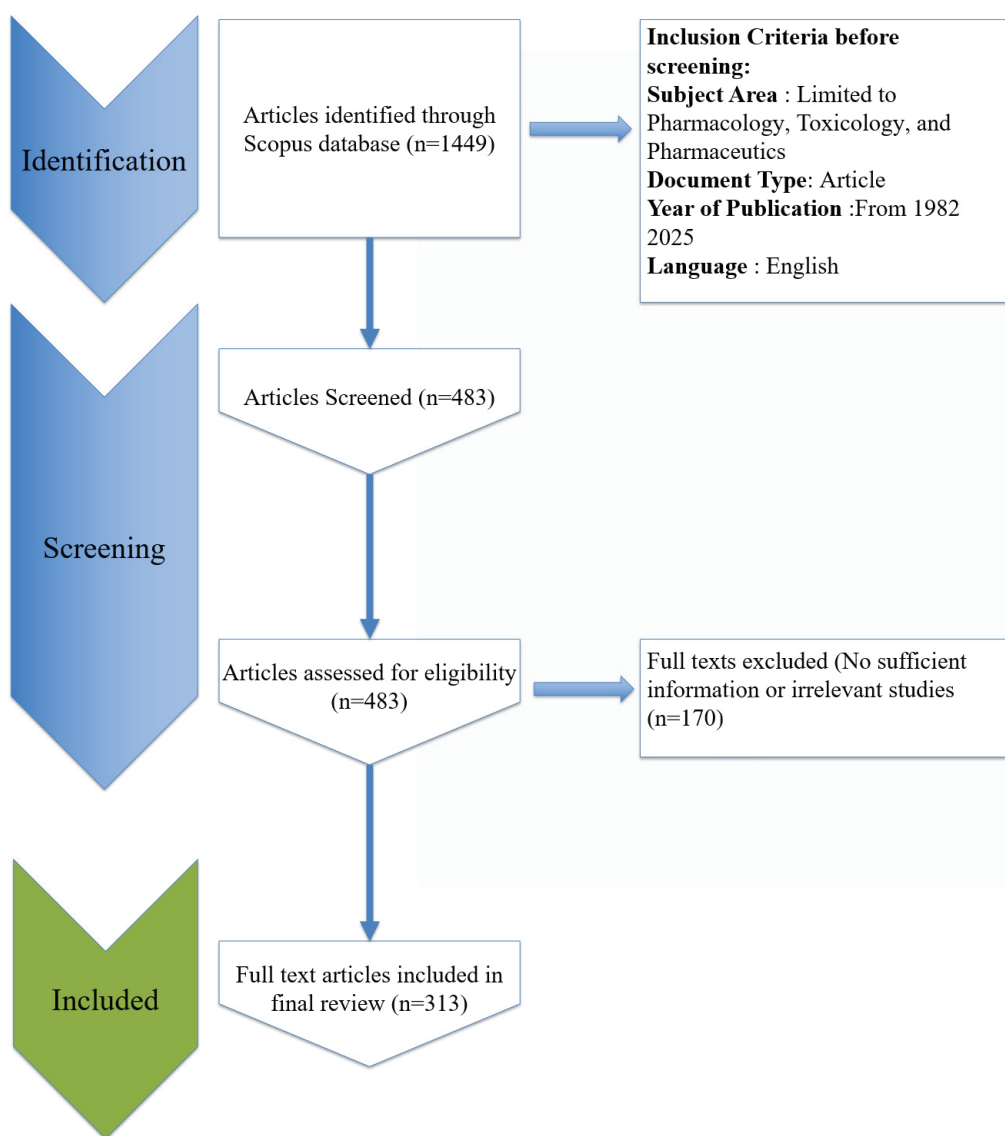


Figure 1. PRISMA Flow Diagram of Literature Search and Selection Process for Studies on Dissolution Testing of Solid Oral Pharmaceuticals (1982–2025).

authors, leading journals, and landmark articles. This sheds light on how knowledge has been developed and disseminated, and the findings identify the authors and journals that play a central role in advancing research.

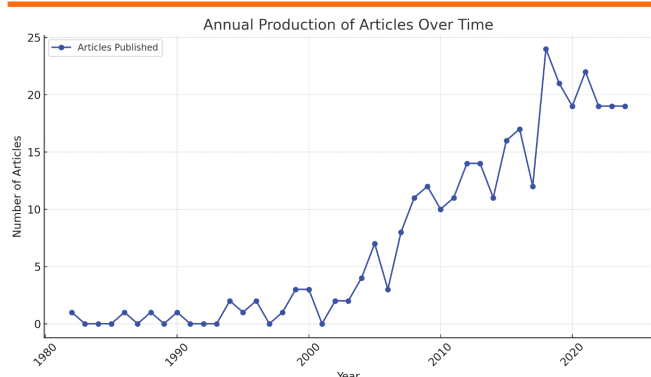


Figure 2. Number of relevant publications per year from Feb 1982–Feb 2025.

### Authors and Their Influence

The analysis of intellectual structure begins with the identification of influential authors. Analyzing their collaborations can also reveal important research networks and co-authorship dynamics. In this field, Zsombor Kristóf Nagy, Attila Farkas, and Mansoor A. Khan stand out, with a total of 14, 12, and 12 publications, respectively (Fig. 3). Their contributions reflect not only their influence but also their ability to mobilize and guide research in dissolution testing and chemometrics. Their work is frequently cited and forms a reference base for other researchers.

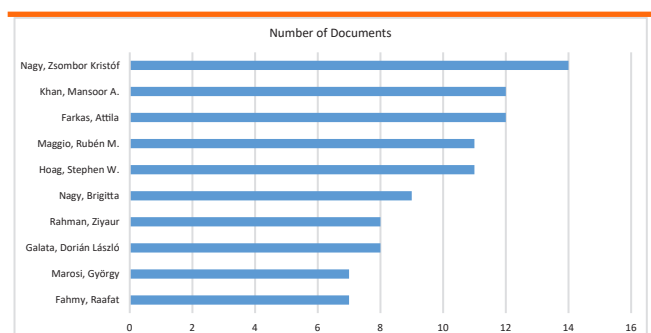


Figure 3. Most relevant authors based on cumulative number of publications in the field from Feb 1982–Feb 2025.

### Dominant Sources and Journals

Scientific journals play a crucial role as platforms for knowledge dissemination. Among the most influential sources in this field, the *International Journal of Pharmaceutics* stands out with a total of 55 published articles (Fig. 4). This journal is a key source for researchers, providing cutting-edge research and critical reviews that shape the understanding and practical applications of dissolution and chemometrics.

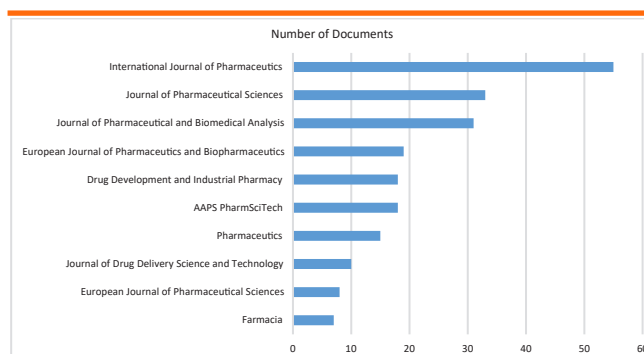


Figure 4. Most relevant journals based on cumulative number of publications in the field from Feb 1982–Feb 2025.

The *Journal of Pharmaceutical Sciences*, with 33 articles, and the *Journal of Pharmaceutical and Biomedical Analysis*, with 31 articles, are also leading journals (Fig. 4). Their significant contribution demonstrates their central role in disseminating knowledge and innovations in this field.

### Key Articles and Their Impact

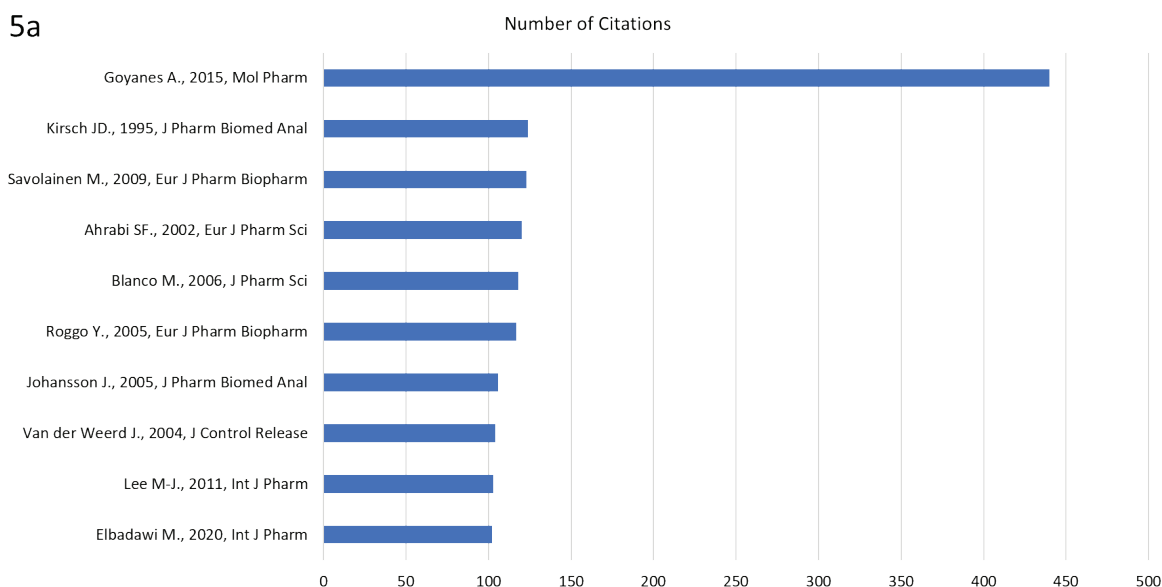
Some publications have a particularly strong impact and mark significant advances in the field. For example, the article by Goyanes A, published in 2015 in the journal *Molecular Pharmaceutics*, has been cited 440 times (Fig. 5a), demonstrating its influence and importance in subsequent research (23). This article appears to have introduced innovative concepts or crucial methodologies that have been widely adopted and cited by other researchers. Similarly, Kirsch JD's 1995 article in the *Journal of Pharmaceutical and Biomedical Analysis*, with 134 citations (Fig. 5a), is another pillar of the field (24). These key articles demonstrate how certain research projects can define paradigms and influence generations of scientific work.

Figure 5b provides a comprehensive overview of the cumulative number of publications in the field for the top five pharmaceutical journals from 1982–2025. Over the years, there has been a noticeable increase in publications, particularly after 2000. The *International Journal of Pharmaceutics* has the most publications, followed by the *Journal of Pharmaceutical and Biomedical Analysis*. The other journals—*AAPS PharmSciTech*, *European Journal of Pharmaceutics and Biopharmaceutics*, and *Journal of Pharmaceutical Sciences*—also show an upward trend, but with fewer publications than the top two journals. These data highlights the growing productivity and publication trends in pharmaceutical research over the past 20 years.

### Social Structure

The social structure in the field of dissolution and chemometrics focuses on examining the relationships and

5a



5b

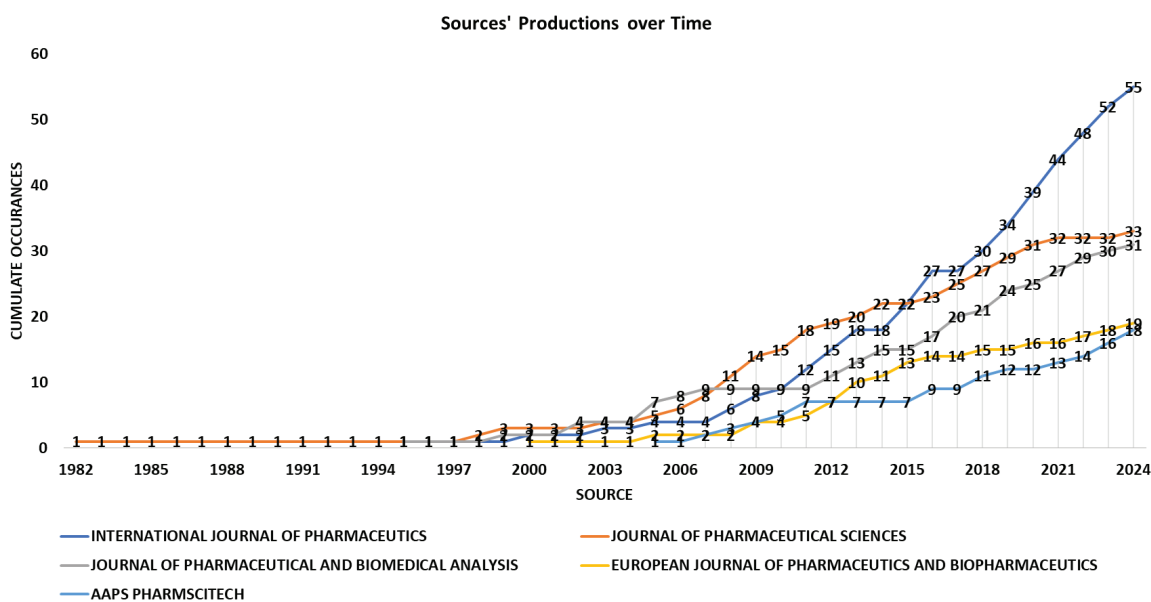


Figure 5. Most relevant publications and journals based on cumulative number of citations (a) and publications (b) in the field from Feb 1982–Feb 2025.

levels of scientific collaboration between institutions and countries. This analysis sheds light on how collaborative networks influence the production and dissemination of knowledge.

#### Collaborations Between Authors

Nagy, Zsombor Kristóf, and Farkas, Attila are prominent examples of authors with extensive collaborations, with 14 and 12 co-authored papers (Fig. 3), respectively. These collaborations reflect well-established networks, where authors share their expertise and work together to advance the field. Such networks are essential for

stimulating innovation and facilitating the resolution of complex problems through a synergy of ideas and skills.

#### Institutional Networks

In terms of institutional networks, collaborations between various research institutions reveal the most influential centers in the field. These interinstitutional collaborations are often the result of strategic partnerships aimed at combining resources and expertise for ambitious research projects. Leading institutions serve as hubs of innovation and training, attracting researchers from diverse backgrounds and strengthening their global influence.

### **Collaborations Between Countries**

At the country level, some nations stand out for their international collaborations. The United States, for example, demonstrates close collaborations with the United Kingdom, Canada, and Australia. These partnerships reflect cultural and linguistic affinities, as well as shared scientific interests. In Europe, countries such as Germany, France, Italy, and Spain also demonstrate strong regional collaborations, often supported by European funding programs.

In Asia, countries such as China, Japan, South Korea, and India demonstrate growing collaborations both regionally and internationally. These collaborations demonstrate the growing importance of scientific research in Asia and the integration of these countries into the global network of dissolution and chemometrics research.

Overall, the analysis of the social structure in the field of dissolution and chemometrics highlights the importance of collaborative networks at different levels. Relationships between authors, institutions, and countries play a crucial role in the production and dissemination of knowledge, and these collaborations are essential for the continued advancement of the field.

### **Conceptual Structure and Gaps**

The conceptual framework aims to map the landscape of dominant concepts, theories, and paradigms in the field of dissolution and chemometrics. It examines the relationships between different keywords that appear in the literature to structure knowledge and identify potential gaps.

Several concept clusters were identified (Fig. 6). These include pharmaceutical technology and process control, advanced methods to improve drug solubility, physiochemical properties of drugs, and emerging technologies such as 3D printing.

Analysis of the conceptual structure (Fig. 6) also helps identify gaps in current research. For example, there is a need for additional research on the application of artificial intelligence (AI) in pharmaceutical processes. Furthermore, excipient variability is another area requiring in-depth study to better understand and control their impact on drug quality and efficacy.

### **Future Directions**

The future of the field of dissolution and chemometrics relies on the integration of new technologies and innovative approaches. These advances promise not only to optimize manufacturing processes but also

to revolutionize the personalization and efficiency of pharmaceutical treatments.

### **Artificial Intelligence and Machine Learning**

The use of AI and machine learning is a promising avenue for optimizing pharmaceutical manufacturing processes. AI can analyze large data sets to identify trends and anomalies, enabling better quality management and reduced production costs. Machine learning algorithms can also predict the behavior of drugs and excipients, facilitating the development of more effective and safer formulations (25–30).

### **Personalization and 3D Printing of Drugs**

Innovation in drug personalization, particularly through 3D printing, offers tailor-made solutions to meet individual patient needs. 3D printing makes it possible to manufacture drugs with specific dosages, shapes, and controlled releases, tailored to each patient. This technology could transform the way treatments are prescribed and administered, offering unparalleled precision and personalization (31–35).

### **Development of New Excipients**

The development of new excipients is essential to improve the stability and bioavailability of drugs. Excipients play a crucial role in drug formulation, influencing their dissolution, absorption, and efficacy. Innovation in this area can lead to more stable formulations with improved release of active ingredients, and to more effective and safer drugs (36).

### **Advanced Techniques**

The adoption of advanced techniques, such as Raman spectroscopy and artificial neural networks, is also a promising direction for the future of this field. Raman spectroscopy can provide detailed information on chemical composition and molecular interactions, and artificial neural networks can model complex systems and predict formulation outcomes. These advanced technologies offer new perspectives for pharmaceutical research and development (4, 7, 14–16).

By integrating these new technologies and approaches, the field of dissolution and chemometrics is poised to enter a new era of innovation and efficiency. The future promises personalized solutions, optimized processes, and safer and more effective drugs, meeting the ever-growing needs of patients and the pharmaceutical industry.

### **Research Limitations**

This study has limitations. First, although the Scopus

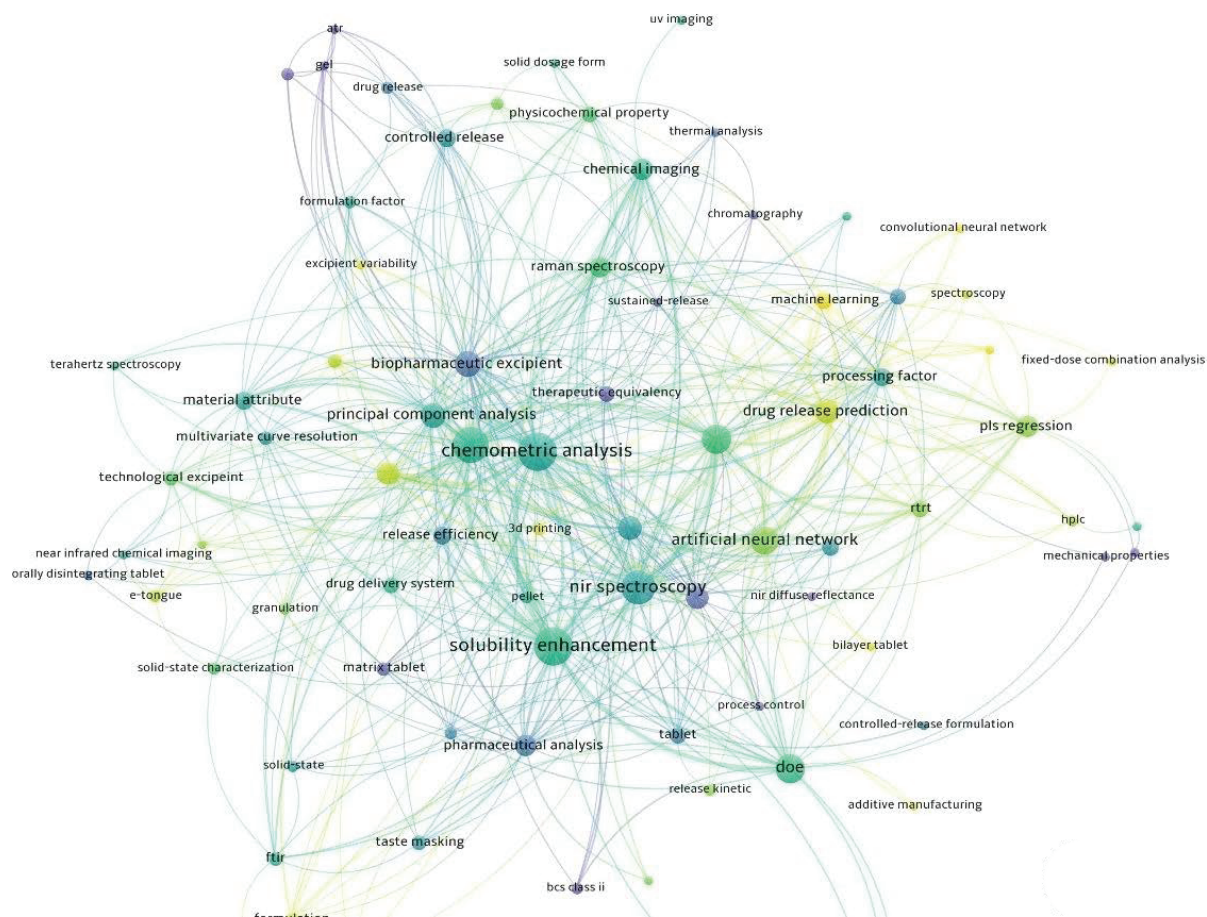


Figure 6. Network diagram of authors' co-occurring keywords in dissolution testing over time based on literature analysis (1982–2025).

- **Blue:** The blue cluster includes terms such as "release testing" and "tablet" and focuses primarily on pharmaceutical technology and process control. This cluster explores the methods and practices used to test drug release and ensure the quality of pharmaceutical products.
- **Green:** The green cluster is characterized by keywords such as "solubility enhancement" and "chemometric analysis." It highlights pharmaceutical analysis and the use of advanced methods to improve drug solubility. This cluster underlines the importance of chemometric analysis in understanding and optimizing the pharmaceutical properties of compounds.
- **Yellow:** The yellow cluster focuses on the physicochemical properties of drugs and emerging technologies, such as 3D printing. This cluster explores new technologies and methods for manufacturing drugs with specific properties, as well as the challenges associated with these innovations.

database covers the majority of studies concerning our topic, other databases such as Medline (PubMed) and Web of Science may contain additional publications. Therefore, although this study represents a robust and significant image of the literature on the topic, it may not represent entirety the research in the field of chemometrics applied to dissolution testing.

## CONCLUSION

The study highlights the evolution and future directions in the field of dissolution and chemometrics. Traditional methods, though effective, present environmental and logistical challenges. The introduction of AI, machine learning, and chemometrics provides new opportunities to improve efficiency, precision, and sustainability in dissolution testing. Regulatory encouragement for

practices such as QbD, PAT, and continuous manufacturing underscores the need for a robust pharmaceutical quality system. Mastery of dissolution testing remains crucial for ensuring bioperformance and therapeutic equivalence. The role of pharmacopoeias and guidelines in standardizing these advanced techniques cannot be overstated. The development of complex drugs requires innovative approaches to address various challenges, from performance to structural complexity and excipient variability. By integrating advanced tools, researchers can achieve more reliable outcomes, optimize drug development processes, and reduce environmental impact. The future of pharmaceutical research and manufacturing will undoubtedly be shaped by the adoption of these technologies, ensuring superior quality products and compliance with stringent regulatory

requirements. This study underscores the importance of continuous innovation and adaptation to meet the evolving needs of the industry and patients alike.

## DISCLOSURES

The authors received no financial support for this work and have no conflicting interests.

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