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Comment on the Importance of Data Transparency, Openness, and Reproducibility in Dissolution Science and Technology

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A recent editorial published in *Science* by Jeremy Berg emphasizes that "ideas supported by well-defined and clearly described methods and evidence are one of the cornerstones of science" (*1*). The broad importance of this topic is reflected by a current project entitled *Reproducibility and Replicability in Science* undertaken by the National Academies of Science, Engineering, and Medicine to "assess research and data reproducibility and replicability issues, with a focus on topics that cross disciplines"(*2*).

In the editorial, Berg notes that the key finding in a cancer biology article published in *Science* could not be reproduced and "this case reinforces the notion that reproducibility, certainly in cancer biology, is quite nuanced, and considerable care must be taken in evaluating both initial reports and reported attempts at extension and replication." The critical need for data reproducibility also applies to dissolution science and technology, where the results from dissolution studies have implications related to the safety and effectiveness of the drug and the dosage form. Irreproducible dissolution data can lead to out-of-specification test results, initiating costly and time-consuming root cause analysis.

Because dissolution is a physicochemical process, any lack of specificity with respect to the methodology, the dissolution medium, or the solubility of the drug compound can result in questions about reproducibility of the data. One example is incomplete specifications for buffered dissolution medium, described in one case as a pH 4.5 acetate buffer, but with incomplete information about the concentration of the buffer salts being provided. Therefore, the physicochemical properties of the buffer, including buffer capacity and ionic strength, are unknown to the reader and can lead to problems with data reproducibility given the sensitivity of some drug-excipient mixtures to buffer capacity and with cases where drug dissolution is sensitive to buffer concentration (*3, 4*). Another example involves the solid phase of the drug solute. Because different crystalline forms, such as solvates or polymorphs, affect the dissolution rate, then lack of information related to the structure of the solid phase may, in turn, influence the interpretation and reproducibility of the results (*5*).

Author guidelines for journals have been published to promote transparency, openness, and reproducibility (*6*). These guidelines include eight standards related to areas such as citations, data transparency, analytic methods, research materials, design and analysis, preregistration of studies, preregistration of analysis plans, and replication. Given the importance and relevancy of this topic to dissolution science and technology, it is timely for *Dissolution Technologies* Editorial Board to consider establishing a policy that follows the template provided in *Science*, where "all data, materials and methods necessary to understand and assess, and extend the conclusions of the manuscript must be available to any reader" (*1*).

CONFLICT OF INTEREST

The author disclosed no conflicts of interest.

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