Research and Reviews: Drug Delivery

Note on Current Perspectives on Dissolution Testing

Vellian Kook*

Department of Pharmaceutical Sciences, Southwest Medical University, Luzhou, China

Editorial

Received: 07-Mar-2022, Manuscript No. DD-22-56374;
Editor assigned: 09-Mar-2022, PreQC No. DD-22-56374(PQ);
Reviewed: 21-Mar-2022, QC No. DD-22-56374;
Accepted: 23-Mar-2022;
Manuscript No. DD-22-56374(A);
Published: 30-Mar-2022, DOI : 10.4172/resrevdrugdeliv.6.1.e001

***For Correspondence:**
Vellian Kook, Department of Pharmaceutical Sciences, Southwest Medical University, Luzhou, China

E-mail: Kook397V@gmail.com

ABOUT THE STUDY

This type of testing is commonly used in R and D and quality control. QC stresses dissolution testing of each product to ensure uniformity in subsequent batches of the product produced by the production department. In terms of QC, the test should show that dosage forms are formulated according to specifications with significant steps of simulation to deliver a reliable product, whereas the emphasis of dissolution testing in the R and D division is on providing some prognostic evaluation of drug release with respect to *in vivo* performance of a drug product. With the increasing complexity of drug delivery for novel dosage forms, a prerequisite for the development of modified dissolution testing methods for characterization of *in vitro* release of these dosage forms should be considered.

Dissolution testing has come a long way in the field of *in vivo* drug product testing, and it has now established itself as a preeminent instrument for the characterization of any therapeutic product and it's *in vivo* performance. It was discovered that medication products failed the dissolution test by analyzing the profile of numerous factors at the same time. During the stability research, the generic products failed the dissolution

test more frequently than the branded products. On the one hand, FDA uses pharmacokinetic stimulation and modeling, in-house dissolution testing, and post market surveillance methods to guide risk based assessment. Meanwhile, the draught report will outline the basic scheme for evaluating solid oral dosage form disintegration failures as a pharmaceutical quality indicator used intrinsic dissolution criteria to examine the impact of processing parameters on drug release. They investigated and validated an atenolol technique using validated USP-recommended dissolving media [1-5].

Three degrees of optimization were applied to the experimental variables such as disc rotation speed and compaction pressure. Wet granulation was used to granulate atenolol, with binder concentration and granulation time serving as process factors and dis-solution rate serving as the response variable. Intrinsic dissolution was given 1.84 0.13 mg/ (cm^2 min) for atenolol; it was high due to increased solubility in the dissolving medium, and it was reduced by granulation with PVP under various conditions. As a result, it's been stated that pre-compression intrinsic dissolution tests might be used to assess the effect of processing parameters on the rate of dissolution of API. This strategy will save time and resources by reducing the amount of trial required to optimize the dissolving rate. Anselmo also created a novel approach for analyzing the composition and bioavailability of formulations. They assessed intestinal permeability using a converted rat intestinal sac model in water and USP apparatus II with P80 at 1%, 2%, and 5% (w/v) with rotations at 50, 75, and 100 rpm. At biased circumstances, the notable differences between the two formulations were 100 rpm in water with 2% polysorbate 80. This article's main finding in the intestinal permeation experiments of highly permeable medicines was lag time and apparent permeability [6-10].

They concluded that the dissolution test could be used as an important QC tool for formulations containing compounds such as leutin, despite the fact that it is not required by the regulatory agency. They investigated easily available solid dosage forms of mefenamic acid for their dissolution profiles in three different mediums: PPRC, USP, and Fasted Stimulated Small Intestinal Fluid (FaSSIF). They compared a generic product (available as a capsule or caplet) to a product developed by an inventor (available in FN caplet and caplet dosage form).

At a temperature of 37°C and a rotation speed of 75 rpm, the dissolving test for drug products was performed using 900 mL dissolution media and equipment II (paddle). Both of these tests were performed using apparatus I (basket) at a rotation speed of 100 rpm, with the exception of the capsule product and USP medium. The results showed that mefenamic acid had the highest solubility in USP dissolving media when heated to 37°C, followed by PPRC medium (0.5 mg/mL), and then FaSSIF medium (approx. 0.06 mg/mL).

After 45 minutes of dissolving testing, the percentage of dissolved medication in PPRC and USP reached more than 75%, but it was only 44% in USP medium. Meanwhile, the percentage of drug dissolved in the biorelevant medium for all products did not surpass 16 percent, and the capsule dosage had the highest dissolving rate in all dissolution media. Bredael devised a precise dissolve procedure for QC purposes that took into account a variety of parameters. For the logic of process development, their article provided extensive guidelines for building a quality-controlled dissolution procedure for IR solid dosage forms.

REFERENCES

1. Abdel-Mottaleb MM, et al. 2011. Standardized in vitro drug release test for colloidal drug carriers using modified USP dissolution apparatus I. Drug Dev Ind Pharm. 2011;37:178-184.
2. Anand 0, et al. Dissolution testing for generic drugs: an FDA per-spective. AAPS J. 2011;3:328-335.
3. Babu NJ, et al. Solubility advantage of amorphous drugs and pharmaceutical cocrystals. Cryst Growth Des.

2011;7:2662-2679.

4. Bai G,et al. Velocity profiles and shear strain rate variability in the USP dissolution testing apparatus 2 at different impeller agitation speeds. Int J Pharm. 2011; 1:1-14.
5. Bala R, et al. Orally dissolving strips: a new approach to oral drug delivery system. Int J Pharm Invest. 2013;2:67.
6. Bartosova L, et al. Transdermal drug delivery in vitro using diffusion cells. Curr Med Chem. 2012;27:4671-4677.
7. Sidney S, et al. Recent trends in cardiovascular mortality in the United States and public health goals. JAMA Cardiol. 2016;1:594-599.
8. Hansen PB, et al. Adenosine induces vasoconstriction through Gi-dependent activation of phospholipase C in isolated perfused afferent arterioles of mice. J Am Soc Nephrol. 2003;14:2457-2465.
9. Hansen PB, et al. Vasoconstrictor and vasodilator effects of adenosine in the kidney. Am J Physiol Renal Physiol. 2003;285:590-599.
10. Harder DR, et al. Role of cytochrome P-450 enzymes and metabolites of arachidonic acid in the control of vascular tone. J Vasc Res. 1995;32:79-92.