Requesting withdrawal of drug dissolution apparatuses from FDA regulatory requirements.

A drug dissolution test is an analytical test used to assess the quality of pharmaceutical products such as tablet and capsule (both prescription and non-prescription types). These tests are extensively conducted during product development stages as well as later as a quality control tool for establishing quality of the manufactured products [1]. The tests are conducted using testers commonly known as drug dissolution apparatuses such as paddle and basket. The specifications and instructions to follow for the use of these apparatuses are provided in the USP General Chapter <711> [2].

There are numerous regulations and Guidance documents available from FDA which dictate the use of these apparatuses [e.g. see 3-5].

On the other hand, as per cGMP requirements every equipment, including apparatuses/testers, used for drug product manufacturing and evaluation must be validated [e.g. see 6-8] to demonstrate that the equipment or testers are qualified and validated for the intended use and purpose. However, the drug dissolution testers have never been validated for their intended use. Regulatory authorities (including US FDA), pharmacopeias (including USP), manufacturers and/or suppliers of the products and the testers ***do not*** maintain or provide any supporting documentation in this respect. Therefore, at present, if given a (blinded) product (tablet/capsule) sample, a common practice in evaluating the capability of a tester/apparatus, it is not possible for an analyst to obtain valid or accurate dissolution results/characteristics of any product, hence its quality. Thus, the consumers/patients have been receiving false assurance about the quality of the manufactured products.

It is, therefore, requested that the current requirements of using FDA recommended drug dissolution apparatuses (basket/paddle and others) be withdrawn from the regulatory requirements to address the false claims concerning the product quality.

Looking forward to a favourable consideration of this request.

Sincerely,

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References:

1. FDA Dissolution Methods (<https://www.accessdata.fda.gov/scripts/cder/dissolution/>)
2. U.S. Pharmacopoeia-National Formulary. Rockville, MD: United States Pharmacopeial Convention, Inc.; General Chapter <711> Dissolution.
3. Dissolution Testing of Immediate Release Solid Oral Dosage Forms (<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070237.pdf>)
4. Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070239.pdf>)
5. Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System (<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070246.pdf>)
6. CFR - Code of Federal Regulations Title 21 [[21 CFR 111.320](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=111.320)]: What requirements apply to laboratory methods for testing and examination?
7. CFR - Code of Federal Regulations Title 21 [[21 CFR 820.72](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.72)]: Inspection, measuring, and test equipment.
8. CFR - Code of Federal Regulations Title 21 [[21 CFR 211.194 (a) (2)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=211.194)]: Laboratory records.

**Some relevant articles from the blog with links** ([www.drug-dissolution-testing.com](http://www.drug-dissolution-testing.com))

1. Validation – what it really means! (<http://www.drug-dissolution-testing.com/?p=2988>)
2. Impact of the revised USP Chapter <1058> [Analytical Instrument Qualification - AIQ] on the pharmacopeial drug dissolution testing – the beginning of the end of the use of current dissolution apparatuses including Basket/Paddle! (<http://www.drug-dissolution-testing.com/?p=2933>).
3. Response to a recent query: Scientifically all dissolution results obtained using currently recommended apparatuses would be null and void and non-GMP compliant! (<http://www.drug-dissolution-testing.com/?p=2731>).
4. Addressing the issue of failing calibration/PVT of dissolution testers (paddle/basket), (<http://www.drug-dissolution-testing.com/?p=2281>)

**PS:** ***For convenience, a Word document is provided as an attachment as well.***