Advantages of using the crescent shape spindles for drug dissolution testing

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It is a well established fact that the currently used dissolution testers, in particular the paddle and basket, are not qualified and validated apparatuses, thus cannot be used for appropriate and accurate evaluation of dissolution characteristics of the products. To address these deficiencies a new spindle, known as the crescent shape spindle, has been suggested as a substitute for the paddle and basket in the vessel based apparatuses. This substitution not only addresses the flaws of the paddle and basket apparatuses, as described below, but also provides a number of additional advantages for easier, scientifically valid and superior product evaluation. For example:

1. The use of crescent shape spindles provides a product independent dissolution testing approach.

2. As the experimental conditions are fixed and product independent, no further dissolution method development steps or exercises would be necessary. Freedom from method development requirements would result in significant time and resource savings for the user.

3. As the use of crescent shape spindles provides a product independent testing environment, thus it provides true dissolution characteristics of a product which results in appropriate and valid comparison between products having the same or different drugs.

4. A single method should be applicable for the evaluation of both types of products i.e. immediate release (IR) and extended release (ER).

5. Physiological or bio-relevant testing requires that the testing environment must be linked to the human GI tract environment which is product independent thus apparatuses using the crescent shape spindles are considered physiologically relevant dissolution testers.

6. The suggested experimental conditions are simple and are as follows: 900 mL of water as a medium maintained at 37 °C with spindle rotation speed set 25 rpm. Small amounts of solubiliser, such as SLS, may be added for those drugs that have lower aqueous solubility.

7. There are no requirements of de-aeration of the medium. This removes a time consuming practice, which also is often considered to add variability in dissolution testing. The medium should however be equilibrated at 37 °C, as usual, prior to the testing. This further aligns testing with a physiological environment, where the liquid phase is not de-aerated but equilibrated at body temperature (37 °C).

8. As the crescent shape spindle forces the product and/or its aggregates to move, product/medium interactions occurs on all sides, resulting in improved characterization of products.

9. Since the crescent shape spindle fits at the bottom of the vessel, it is free from sensitivities of normal and expected variations in the curvature of the vessel, resulting in improve ruggedness of the tester.

10. The use of the crescent shape spindle moves the product around at the bottom of the vessel, thus its use is free from the sensitivities of usual and expected vibrations in and around the apparatuses resulting in further improvement in the ruggedness of the tester.

11. The crescent shape spindle sits snugly and tightly in the vessels because of the spring effect of the curved wired brush thus is free from sensitivities of usual and expected variations in vessel/spindle alignments.

12. The use of the crescent shape spindle provides highly efficient stirring and mixing or product/medium interaction. The tester is free from unstirred and stagnant areas, within dissolution vessels, thus is free from the artefacts of the "cone" formation and/or positioning effects of the product. This leads to higher consistency (repeatability and reproducibility) of dissolution results.

13. Because of efficient product/medium interactions, the use of the crescent shape spindle provides complete extraction and dissolution of the drug from the product. This leads to dissolution results matching those obtained from assay and content uniformity tests. Therefore, dissolution tests using crescent shape spindle would make the separate assay and content uniformity testing unnecessary, thus providing further savings of time and resources.

14. As the suggested experimental conditions of dissolution tests are similar to those often used for routine quality control tests, the same tests which are used for product development will also be used directly as quality control tests. There is no need for developing separate quality control tests.

15. Moreover, as the experimental conditions are linked to a physiological environment, these quality control tests will be bio-relevant as well, thus enhancing the credibility of the QC tests.