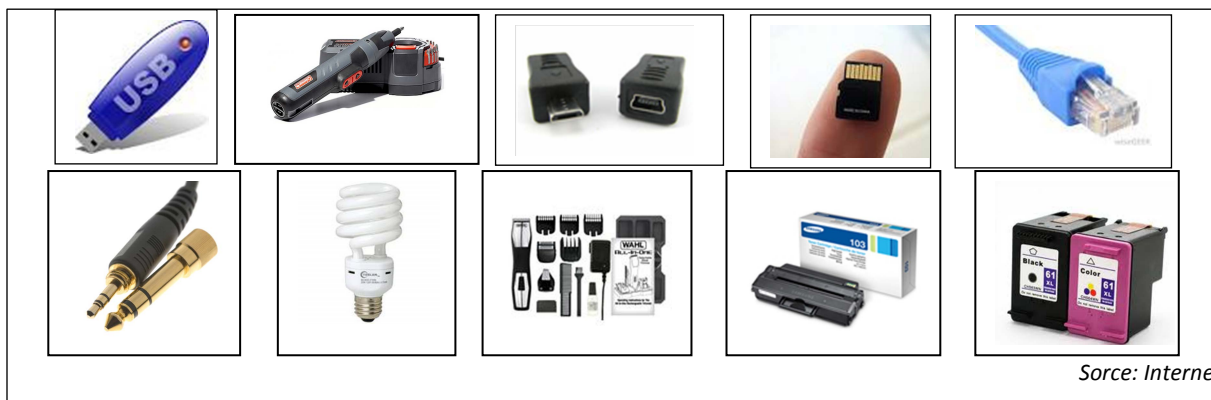


Drug dissolution testers: "A modern-day mystery" - Are people being fooled by promoters of (paddle/basket) dissolution testers? It appears so!

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Below are some examples of modern day, commonly used, electronics and/or their components. They require a fairly high level of precision for their operations. They are all examples of "plug & play" operations i.e. instant

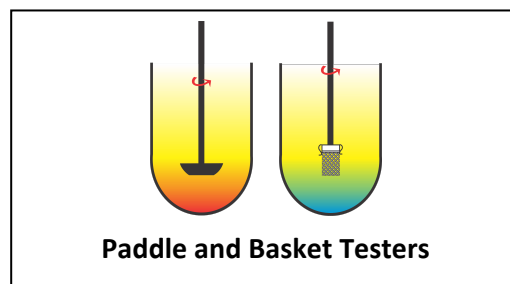
use without any calibration, performance verification and/or training on the users' part. In addition, these all often come with years of money back warranties.



Source: Internet

On the other hand, promoters of (paddle/basket) dissolution testers suggest that the main components of the testers, a 3/8" thick 316-stainless steel rod based stirrer with (thick) glass-wall beakers cannot be used, or replaced, as a "plug & play" but require extensive calibrations, performance verifications following sophisticated protocols (guidances) such as PVT or EMC (Enhanced Mechanical Calibration) for alignments and proper adjustments/operations. Furthermore, when the operation of these components (stirrer and vessel) still fails, which is frequent, then deficiencies in operation or lack of proper operator's training usually is blamed. Does this make sense?

product. So, then why does one buy or use these testers? A strange and weird modern day mystery! Are people (analysts/formulators) being fooled by marketing of such low-tech components which are promoted as "hi-tech and sophisticated components" and 21st century scientific wonders? It certainly appears so.



An even more interesting aspect is that although these testers are called dissolution testers, but given a product to the promoters/vendors, they cannot provide dissolution characteristics of any

There is no reason for a promoter or vendor to not be able to provide dissolution characteristics of some blinded sample/product to establish relevancy and credibility of the products they are

selling or promoting. This is an indirect indication (certainty) that dissolution testers, as available, are not really dissolution testers but something else.

So next time, when you are going to use these testers, and/or evaluate results obtained with such testers, beware that the testers and/or associated data is from testers which cannot be shown to provide dissolution results for any product. Something to keep in mind!