A simple approach to assess the validity of a dissolution tester/method

Saeed A. Qureshi, Ph.D. (www.drug-dissolution-testing.com)

Before one uses a tester/method, it is mandatory, in particular in a GMP environment, that the validity of its use be established i.e. does the tester/method measure the expected characteristics of the product? In the case of a dissolution tester/method, one expects that it should measure the drug dissolution/release characteristics of a product and should be able to differentiate between products having different dissolution/release characteristics. In addition, a tester/method should not just measure and/or show such differences but these measurements and differences have to be relevant and useful.

The dissolution tests are conducted for products for human use, therefore, for validation purposes one should use products which are expected to behave differently in humans. Immediate-release (IR) and extended-release (ER) products are such products which are commonly available and easy to evaluate. Therefore, one should use two products (IR and ER) having the same active ingredient and assess their dissolution characteristics. The tester/method should provide different dissolution profiles reflecting their IR and ER characteristics under the ***exactly same testing conditions***. A tester/method which provides such characteristics will be considered as a ñdissolutionò tester/method and should then be used to determine dissolution characteristics of a ñtestò product.

Thus, if one is looking for a dissolution tester/method or planning to develop one, a simple approach is to evaluate dissolution characteristics of IR and ER products having the same ingredient. If the tester/method provides expected release characteristics with differentiation, the tester/method should be considered valid for conducting dissolution testing.

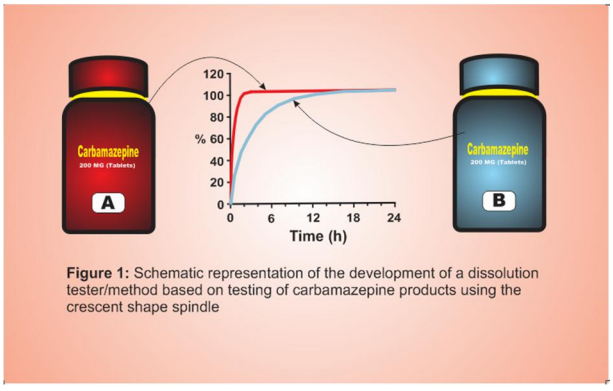

Figure 1: Schematic representation of the development of a dissolution tester/method based on testing of carbamazepine products using the crescent shape spindle

A schematic representation of this validation step is shown in Figure 1, where two carbamazepine products (approved and commercially available) were analyzed with crescent shape spindle set at 25 rpm using water containing 0.5% SLS, as a dissolution medium, where the products show expected drug release characteristics of the products. Now such a tester/method can be used for evaluating dissolution/release characteristics of a product. Any exercise of developing a dissolution method/tester has to go through such a step.

It is very important to note that a tester without its validation should not be used for testing/evaluating drug release characteristics of a ñtestò product. In addition, a tester/method must not be developed using a ñtestò product (or product underdevelopment) as often described in literature since it would lead to scientifically invalid results and conclusions.