Dissolution test for solid dosage forms: I do not understand how to interpret the acceptance criteria. Could you provide an example?

Answer:

An example is provided below for a dissolution test of a conventional-release formulation.

If the *Q* value was set to 75% of the label claim dissolved within a specified time, the acceptance criteria would be interpreted as follows:

At acceptance level S_1: *6 dosage units are tested and each individual dissolution result is compared to Q+5%.*

At level S_1: each value of the 6 dosage units tested has to be more than 80% of the label claim dissolved within the specified time (i.e. 75%+5%=80%). If the results fulfil this requirement, the medicinal product complies with the test.

If the results do not comply, 6 additional dosage units are tested:

At acceptance level S_2: the average value of all 12 dosage units tested has to be equal to or greater than 75% of the label claim dissolved within the specified time and none of the values can be less than 60% (*Q*-15%: 75%-15%=60%). If the results fulfil this requirement, the medicinal product complies with the test at level S_2.

If the results still do not comply, 12 additional dosage units are tested:

At acceptance level S_3: the average value of all 24 dosage units tested has to be equal to or greater than 75% of the label claim dissolved within the specified time, no more than 2 values can be less than 60%, and no value can be less than 50%. If the results fulfil this requirement, the medicinal product complies with the test at level S_3.

If the results still do not comply, the medicinal product has failed the test and an out-of-specification investigation must be launched.

For more information, refer to Ph. Eur. general chapter *5.17.1*.