

What principles apply to disintegration tests described in medicinal product monographs?



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Answer:

The principles applied to disintegration mirror those applied to dissolution in the *General Notices*.

Where appropriate, a disintegration test is described in an individual monograph on a medicinal product. In such cases, the applicant may either select the monograph disintegration test or develop an in-house disintegration test as the product-specific disintegration test. In any case, the applicant has to demonstrate the suitability of the selected test to the satisfaction of the competent authority.