When should I apply general chapter 2.9.40. Uniformity of dosage units?



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Answer:

From a pharmaceutical quality point of view, the approach taken in the harmonised general chapter on uniformity of dosage units (2.9.40) is considered equivalent to the requirements in general chapters 2.9.5 and 2.9.6. Thus, the decision on which approach to take is left to the user. Either 2.9.40 or 2.9.5 and 2.9.6 may be applied to demonstrate compliance with the Ph. Eur. with regard to the uniformity of dosage units.

For more details, you can also consult the Questions & Answers provided by the Quality Working Party of the European Medicines Agency on their website.