

What does 'Unless otherwise stated' mean in this context?



You are here:

[EDQM FAQs](#) / [EDQM FAQs in English](#) / [EUROPEAN PHARMACOPOEIA & INTERNATIONAL HARMONISATION](#) / [General Chapters and Monographs](#) / [GENERAL CHAPTER 2.2.46 \(11.0\)](#) / [PEAK SYMMETRY](#) / What does 'Unless otherwise stated' mean in this context?

Answer:

When elaborating a monograph, it may be noticed that the shape of the peak of interest fails to meet the default peak symmetry requirement (0.8-1.8). When this bears no detrimental impact on the performance of the analytical procedure and the results obtained, the provision of a specific peak symmetry requirement in the monograph is considered. As this phenomenon is unidirectional (either peak fronting or peak tailing), only the minimum or the maximum symmetry factor is stated (not a range), whereas the other end of the peak symmetry range remains as defined per default.

This approach has been followed by Ph. Eur. expert groups for decades and more than 100 monographs include a different minimum or maximum peak symmetry requirement.

This is further reinforced by the following sentence from general chapter 2.2.46 (see section *System suitability*): *'When specific requirements are stated in the monograph, they supersede the requirements mentioned in this chapter.'*