

# Why has the heavy metals test (2.4.8) been deleted from many Ph. Eur. monographs?



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## Answer:

### IMPLEMENTATION OF ICH Q3D:

With the publication of the 9<sup>th</sup> Edition of the European Pharmacopoeia, the reference to general chapter *Heavy metals* (2.4.8) has been deleted from individual monographs on substances for pharmaceutical use, except from those for veterinary use only. This completes the first step of the Ph. Eur. strategy for implementing the ICH Q3D guideline on elemental impurities.

For more information on the implementation of this guideline within the Ph. Eur., please see the following documents:

[Press release: Ph. Eur. on elemental impurities \(April 2015\)](#)

[Press release: Ph. Eur. policy on elemental impurities - clarification for products outside the scope of the ICH Q3D guideline \(August 2015\)](#)