

What is the limit for specified/unspecified/unknown impurities?



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Answer:

Unless otherwise prescribed or justified and authorised, organic impurities in active substances are to be reported, identified wherever possible, and qualified as indicated in the general monograph *Substances for pharmaceutical use (2034)* (Table 2034.-1 or Table 2034.-2).

Generally, specified impurities have their own specific acceptance criterion in the individual monograph. For other impurities, the decision tree in general chapter 5.10. *Control of impurities in substances for pharmaceutical use* may be used to determine the applicable acceptance criterion.