

The limit for unspecified impurities in the monograph is higher than the values defined in general monograph Substances for pharmaceutical use (2034) (Table 2034.-1) and general chapter 5.10. Control of impurities in substances for pharmaceutical use.



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Answer:

Some monographs are awaiting revision. However, the requirements of general monograph 2034 are binding and must be implemented by the user as described in general chapter 5.10. In some exceptional cases, the requirements of general monograph 2034 and general chapter 5.10 do not apply, and different thresholds can be prescribed. In this case, the following statement can be found in the related substances section: 'The thresholds indicated under Related substances (Table 2034.-1) in the general monograph *Substances for Pharmaceutical use (2034)* do not apply'.