

# How are limits for impurities defined in monographs?



You are here:

[EDQM FAQs](#) / [EDQM FAQs in English](#) / [EUROPEAN PHARMACOPOEIA & INTERNATIONAL HARMONISATION](#) / [General Chapters and Monographs](#) / [IMPURITIES AND CHROMATOGRAPHY](#) / How are limits for impurities defined in monographs?

## Answer:

Limits are based on batch data that reflect the purity of the substance/the medicinal products currently available on the European market and are not higher than the limits approved during the marketing authorisation process.