

Does a monograph on a medicinal product containing a chemically defined active substance apply to all strengths and formulations?



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Answer:

Yes, medicinal product monographs apply to all strengths and formulations of the same dosage form containing the same active substance. An indication of the strength(s) of the medicinal product considered during the elaboration of the monograph is provided to users for information only (i.e. in a footnote of the draft monograph published in Pharmeuropa or in the EDQM Knowledge database once a monograph is published in the Ph. Eur.).

In line with section 1.1.2.3 of the Ph. Eur. *General Notices* (Demonstration of suitability of monographs), applicants must demonstrate the suitability of the monograph for the quality control of their substance or medicinal product to the satisfaction of the competent authority. For more information, please consult the Technical Guide for the elaboration of monographs on medicinal products containing chemically defined active substances, which is available on the [EDQM website](#).