

What is 'stated potency'?



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Answer:

As mentioned in general chapter 5.3. *Statistical analysis of results of biological assays and tests*, the 'stated potency' (or 'labelled potency') is the nominal (target) value estimated by the manufacturer for a bulk material or, in the case of formulated products, a value assigned from the knowledge of the potency of the bulk material. For compliance with the monograph, the estimated potency (i.e. potency calculated from the assay data, usually expressed in International Units per millilitre) must be within a specified range of the stated potency (e.g. 80-120 per cent). Similarly, the substance has to fulfil the potency criterion in International Units per milligram of protein (specific activity) stated in the 'Definition' section of the monograph.