

## Amantadine Hydrochloride

**Type of Posting:** Notice of Intent to Revise

**Posting Date:** 27–May–2020

**Targeted Official Date:** To be determined, In Process Revision

**Expert Committee:** Chemical Medicines Monographs 1

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 1 Expert Committee intends to revise the Amantadine Hydrochloride monograph.

Comments were received indicating that the specifications for Related Compound A and Related Compound B in the test for Organic impurities may pose safety concerns. The Expert Committee proposes to revise the acceptance criteria for Related Compound A and Related Compound B from NMT 0.3% to NMT 0.15%.

It is anticipated that the proposed revision will be published in the future as an In-process Revision in *Pharmacopeial Forum* (PF) pursuant to Section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Shankari Shivaprasad, Senior Scientific Liaison to the Chemical Medicines Monographs 1 Expert Committee (301–230–7426 or [sns@usp.org](mailto:sns@usp.org)).

---

CN-20-064-00