

## Atropine Sulfate Ophthalmic Solution

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

**Posting Date:** 31–Aug–2018; corrected 04–Sep–2018\*

**Targeted Official Date:** 01–Jul–2019, Interim Revision Announcement

**Expert Committee:** Chemical Medicines Monographs 4

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 4 Expert Committee intends to revise the Atropine Sulfate Ophthalmic Ointment monograph.

Comments with supporting data were received that indicate the need to revise the acceptance criteria within the test for *Organic Impurities* as shown below to be consistent with FDA approved acceptance criteria. Additionally, it is proposed to replace the procedures in the *Assay* and test for *Organic Impurities* to support the revised acceptance criteria.

Name	Acceptance Criteria, NMT (%)
Tropic acid	7.0
Atropic acid	1.0
Apoatropine	1.0
Any individual degradation product	1.0
Total impurities	7.0

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 45(1) [Jan.–Feb. 2019] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on March, 31, 2019. In the absence of any adverse comments the proposed IRA will become official on July 1, 2019.

Should you have any questions, please contact Heather Joyce, Ph.D., Senior Scientific Liaison (301–998–6792 or [hrj@usp.org](mailto:hrj@usp.org)).

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\* The Notice of Intent to Revise posted on August 31, 2018 incorrectly identified the monograph revision being proposed as Atropine Sulfate Ophthalmic Ointment. The monograph name was corrected on September 4, 2018.

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