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## Talc

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

**Posting Date:** 31-Jul-2020; updated 18-Dec-2020\*

**Targeted Official Date:** TBD, In-process Revision

**Expert Committee:** Simple Excipients Expert Committee

In accordance with section 9.04(c) of the 2020–2025 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Simple Excipients Expert Committee intends to revise the Talc monograph regarding the test for Asbestos.

In response to a request from FDA’s Monograph Modernization Task Group (MMTG) in 2010 to revise the USP Talc monograph ([Ref. 1](#)), USP established a series of Talc Expert Panels to address the MMTG’s request that: *“labeling should be revised to match the statements that are provided in the Talc FCC monograph, thereby assuring that Talc is not sourced from mines that are known to contain asbestos. Also, USP should consider revising the current tests for asbestos to ensure adequate specificity.”*

In the currently official Talc monograph, the infrared spectroscopy (IR) and x-ray diffraction (XRD) methods in the “Absence of Asbestos” test may produce false negative results, which could allow talc samples with asbestos contamination to appear to meet monograph specifications. Even after applying the currently official USP microscopy method, an analyst cannot rule out the presence of hazardous fibers in a sample of talc. In addition, the lack of identification procedures in the optical microscopy section of the method may lead to false positive results. This underscores the need to modernize the current monograph.

In order to address the above deficiencies, the Talc Methods Expert Panel #1 recommended the following revisions:

1. Modifying the Labeling section to state: “Label to indicate that talc containing (detectable) asbestos is not pharmaceutical grade.” (Ref. 2).
2. Test for Absence of Asbestos: (Ref. 2-3):
  - The IR spectroscopy test for Absence of Asbestos should be omitted in favor of an XRD technique.
  - A pass-fail result must include XRD in combination with one or more microscopic evaluations, i.e., polarized light microscopy (PLM),

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transmission electron microscopy (TEM), or scanning electron microscopy (SEM).

- Definitive microscopic identification and characterization of asbestos/mineral fibers is critical in the determination of the presence/absence of asbestos.

The Talc Expert Panel #2 recommends the following two-phase approach to support the above recommendations:

- Phase 1 encompasses XRD and PLM analyses based on round robin studies;
- Phase 2 would encompass the electron microscopy method (e.g., TEM, SEM, etc.).
- It is also recommended to rename the test from “Absence of Asbestos” to “Test for Asbestos” because it is more appropriately described as a test for presence.
- A new chapter specifically for determination of asbestos in Talc will be created to describe the detailed testing procedures.

USP held a virtual Talc roundtable meeting in March 2020. At the meeting, USP presented a proposed two-phase approach, round robin study results of XRD and PLM, and the timeline for the revision to the Test for Asbestos that will initially be presented in *Pharmacopeial Forum* (PF) as a *Stimuli* article for public comment and review. See [presentations](#) and [panel discussion Q&As](#) here. For additional questions, see FAQs [here](#).

The *Stimuli* article will be published in *PF* 46(5) [Sep.-Oct. 2020]. The comment period for this revision ends on November 30, 2020.

In addition, USP is planning to publish the Phase 1 revision of the Talc monograph including the XRD and PLM in *Pharmacopeial Forum* 47(4) [Jul.–Aug. 2021].

USP encourages stakeholders to provide comments on the *Stimuli* article and recommended monograph revision approaches.

Should you have any questions, please contact Jenny Liu, Senior Scientific Liaison (240-221-2072 or [JYL@usp.org](mailto:JYL@usp.org)).

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#### References:

1. US Pharmacopeial Convention (USP) website, Letter from FDA to USP on Apr. 13, 2007

<https://www.usp.org/sites/default/files/usp/document/get-involved/monograph-modernization/2010-11-16-letter-from-fda-task-group.pdf>

Accessed: 21Jul2020

2. USP *Stimuli* article: *Modernization of Asbestos Testing in USP Talc*, *PF* 40(4) [Jul-Aug 2014].

3. USP *Stimuli* article: *USPC Responses to Comments on Stimuli Article “Modernization of Asbestos Testing in USP Talc”*, *PF* 43(4) [Jul-Aug 2017].

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\*This Notice was updated on December 18, 2020 to updated the PF publication in which the proposal is expected to appear..