

Chapter <87> Biological Reactivity, In Vitro

Type of Posting: Notice of Intent to Revise

Posting Date: 30–Jan–2015; updated 27–Feb–2015*

Targeted Official Date: Interim Revision Announcement; 01–Nov–2015

Expert Committee: General Chapters—Packaging, Storage, and Distribution

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the General Chapters—Packaging, Storage, and Distribution Expert Committee intends to revise General Chapter <87> Biological Reactivity, In Vitro.

The USP Positive Bioreaction RS, which is used as a Positive Control in the current General Chapter, is being discontinued due to the inability to acquire the material needed for the replacement lot. In the effort find a replacement, a Polyurethane film containing zinc diethyldithiocarbamate (ZDEC) and zinc dibuthyldithiocarbamate (ZDBC) from Hatano Research Institute was identified and determined to be suitable as a Positive Control. The General Chapter is being revised to remove the reference to the USP Positive Bioreaction RS and will include a reference to an alternate Positive Control that is suitable.

It is anticipated that the proposed revision will be published as a Proposed Interim Revision Announcement in Pharmacopeial Forum 41(3) [May–Jun. 2015] pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Desmond Hunt, Ph.D., Senior Scientific Liaison (301-816-8341, dgh@usp.org).

*The notice was updated to indicate that the proposed IRA will be published in Pharmacopeial Forum (PF) 41(3) [May–Jun. 2015]. The previous posting had indicated it would be posted in PF 40(2) [Mar.–Apr. 2015].