

Phenelzine Sulfate

Type of Posting: Notice of Intent to Revise

Posting Date: 29-Apr-2022

Targeted Official Date: 01-Mar-2023; Interim Revision Announcement

Expert Committee: Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the Small Molecules 4 Expert Committee intends to revise the Phenelzine Sulfate monograph.

Comments were received that indicate manufacturers cannot meet the resolution requirement when performing the test for *Limit of Hydrazine*. The current test for *Limit of Hydrazine* lists a *Resolution* requirement of NLT 1.25 between the phenelzine and salazine (hydrazine derivative) using the *Standard solution*. The current *Standard solution* only contains hydrazine and not phenelzine, therefore it is not possible to determine the resolution between these two compounds. Based on supporting data, the Expert Committee proposes to add a *System suitability solution* so that the requirement for the *Resolution* can be met. Other updates are also made in the monograph.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement in *Pharmacopeial Forum* 48(5) [Sep.–Oct. 2022] pursuant to the Rules and Procedures. The comment period for this revision ends on November, 30, 2022. In the absence of any adverse comments, the proposed IRA will become official on March 1, 2023.

Should you have any questions, please contact Mark Tiedje, Senior Scientist (mark.tiedje@usp.org).