

Diphenhydramine Hydrochloride Oral Powder

Type of Posting: Notice of Intent to Revise

Posting Date: 25–Sept–2020

Targeted Official Date: 01–Aug–2022, *USP–NF 2022, Issue 2*

Expert Committee: Small Molecules 5

In accordance with section 9.04 (c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Small Molecules 5 Expert Committee intends to revise the Diphenhydramine Hydrochloride Oral Powder monograph.

The Expert Committee proposes to widen the limit for the degradant, Benzophenone, from 0.2% to 0.4% in the Diphenhydramine Hydrochloride Oral Powder monograph because the API has a limit of 0.3% for this impurity. It is anticipated that the proposed revision will be published as an In-Process Revision in a future *Pharmacopeial Forum* pursuant to the Rules and Procedures.

Should you have any questions, please contact Clydewyn M. Anthony, Ph.D., Senior Scientific Liaison (301–816–8139 or cma@usp.org).

CN-21-019-00