

Alprazolam Tablets

Type of Posting Notice of Intent to Revise

Posting Date 22-Feb-2019

Targeted Official Date To Be Determined

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 Monographs – Chemical Medicines 4 Expert Committee intends to revise the Alprazolam Tablets monograph.

Comments with supporting data were received that indicate the relative response factors in the test for *Organic Impurities* are not suitable. In response, a Revision Bulletin was posted to postpone the test for *Organic Impurities* within the Alprazolam Tablets monograph. The Expert Committee proposes to revise the Alprazolam Tablets monograph to revise the relative response factors and/or to replace the use of one or more relative response factors with the use of external standards in the test for *Organic Impurities*.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in a future issue of *Pharmacopeial Forum*.

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

CN-19-034-00