Galantamine Tablets (Reposted)

Type of Posting: Notice of Intent to Revise

Posting Date: 01-Aug-2008

Reposting Date: 12–Jun–2009

Official Date: Date To Be Determined

Expert Committee: Biopharmaceutics

In accordance with the Rules and Procedures of the Council of Experts, the Biopharmaceutics Expert Committee intends to revise the Galantamine Tablets monograph by adding another Dissolution test with a concomitant labeling requirement.

The revisions to the Monograph will be made official in the near future as a Proposed Interim Revision Announcement. In the absence of any adverse comments, the revision will be published as final in Pharmacopeial Forum.

The initial Notice of Intent to Revise for the Galantamine Tablets Monograph originally included revisions to impurities limits by the Monograph Development–Psychiatrics and Psychoactives Expert Committee. These changes were approved and published as an Interim Revision Announcement in PF 35(2) [Mar.–Apr. 2009]. See the original posting for Galantamine Tablets (posted 01–Aug–2008) in the <u>Retired Compendial</u> <u>Notices</u> section for more information.

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