

STABILITY SUMMARY AND CONCLUSIONS ON API

1. SUMMARY OF STABILITY STUDIES

Twenty four months of stability data are presented for three batches of Stelbatolol manufactured on a production-scale by the commercial synthetic process at AAA Molybdenum Products, Inc. The drug substance is packaged in containers representing those proposed for use in routine production. The results of long-term and accelerated stability studies demonstrate the chemical and physical stability of Stelbatolol when stored for up to 24 months at 30°C/65% RH and 6 months at 40°C/75% RH. No significant changes were observed, and all results complied with specification.

2. RETEST PERIOD AND STORAGE CONDITIONS

The data presented justify the defined retest period and storage conditions for Stelbatolol.

A retest period of 36 months will be applied to the drug substance when stored under the following conditions:

Store up to 30°C (86°F).