

## **STABILITY SUMMARY AND CONCLUSIONS ON STELBAT TABLETS, 20 MG**

### **1. SUMMARY OF STABILITY STUDIES AND CONCLUSIONS**

Eighteen months stability data are presented for three batches of Stelbat Tablets 20 mg manufactured on a production-scale at AAA Pharmaceutical, Inc., Lumberton. The batches of Stelbat Tablets 20 mg are identical to those proposed for marketing and were packed in the proposed market pack. The results of long-term stability studies demonstrate the chemical and physical stability of Stelbat Tablets 20 mg when stored for 18 months at 25°C/60% RH.

No significant changes were observed in Description, Identification, Assay by HPC, Dissolution, Uniformity of Dosage Units (by Weight), Microbiological Quality and Water Content, and all results comply with specification. Significant changes were observed for Impurity 1, Impurity 2, Impurity 3 and Total Degradation Impurities for Stelbat Tablets 20 mg after storage at 25°C/60% RH up to 18 months and 40°C/75%RH up to 6 months. An increase in these impurities was observed which is related to the increase water content observed as discussed in P5.4 Justification of Specification.

Statistical analyses performed on or Degradation Products by HPLC Impurity 1, Impurity 2 and Impurity 3 confirm the stability of Stelbat Tablets 20 mg and predict a shelf-life of > 24 months at 25°C/60% RH.

In addition, data have been generated following accelerated storage of batches of Stelbat Tablets 20 mg. The results demonstrate the chemical and physical stability of Stelbat Tablets 20 mg. No significant changes were observed in any test, and all results comply with specification.

### **2. SHELF-LIFE AND STORAGE CONDITIONS**

A shelf-life of 24 months will be applied to the product when stored under the following conditions:

Do not store above 30°C.

Keep the bottle tightly closed.

Store in the original container.