

**PHARMACOPEIAL DISCUSSION GROUP
STAGE 5B SIGN-OFF DOCUMENT**

Residue on Ignition/Sulphated Ash (Revision 2)

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia's reference materials and general chapters.

Regional differences :

USP will replace the first sentence of the 2nd paragraph under **Procedure** by “Weigh accurately 1 to 2g of the substance, or the amount specified in the individual monograph, in the crucible.” Also, USP will insert “unless otherwise directed in the individual monograph,” after “After cooling,” in the 4th line of the 2nd paragraph. Another insertion “, unless another temperature is specified in the individual monograph,” will be made by USP after “600 ± 50 °C” in the 5th line of the 2nd paragraph. USP will also add texts on testing environment, use of a muffle furnace and its calibration at the end of the text.

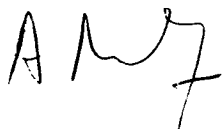
Full text to be published by USP is attached as Annex.

Note at sign-off:

Unless otherwise specified, an appropriate sample weight is chosen, typically 1-2 g, to result in a level of residue sufficient to be accurately measurable by weight (typically 1 mg). The sample size and the acceptance criteria should, in such cases, be specified in the application dossier. Calibration of the muffle furnace may be carried out using locally accepted temperature measuring procedures and GMP requirements.

European Pharmacopoeia

Signature



Name

Agnès ARTIGES

Date

28 July 2005

Japanese Pharmacopoeia

Signature



Name

AKIRA KAWAHARA

Date

14/Jul/05

United States Pharmacopoeia

Signature



Name

Eric B. Sheinin

Date

4-August-05