

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

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**Residue on Ignition/Sulphated Ash (Revision 2)**

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*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 2<sup>nd</sup> 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 4<sup>th</sup> line of the 2<sup>nd</sup> paragraph. Another insertion ", unless another temperature is specified in the individual monograph," will be made by USP after "600 ± 50 °C" in the 5<sup>th</sup> line of the 2<sup>nd</sup> 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	Date
	Agnès ARTIGES	28 July 2005

**Japanese Pharmacopoeia**

Signature	Name	Date
	AKIRA KAWAHARA	14/Jul/15

**United States Pharmacopoeia**

Signature	Name	Date
	Eric B Sheinin	4 August 05