

**PHARMACOPOEIAL DISCUSSION GROUP
SIGN-OFF DOCUMENT
G-16
Thermal Analysis**

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.

Harmonised provisions:

<u>Provision</u>	<u>EP</u>	<u>JP</u>	<u>USP</u>
Introduction	+	+	+
Thermogravimetry	+	+	+
Differential Scanning Calorimetry	+	+	+

Non-harmonised provisions:

Local requirement

EP	JP	USP
	<p><i>Thermogravimetry can be used as an alternative method for "Loss on Drying <2.41>" or "Water Determination <2.48>". However, it must be confirmed beforehand that no volatile component except for water is included in the test specimen when Thermogravimetry is used as an alternative method for "Water Determination".</i></p>	

European Pharmacopoeia

Signature



Name

UESTEL

Date

26/6/14

Japanese Pharmacopoeia

Signature



Name

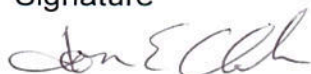
Haruhiro Okuda

Date

26/6/2014

United States Pharmacopoeia

Signature



Name

Jon E. Clark

Date

June 26, 2014