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## 2 PHARMACOPOEIAL DISCUSSION GROUP

## 3 SIGN-OFF DOCUMENT

4 **G14: CHARACTERISATION OF CRYSTALLINE AND PARTIALLY CRYSTALLINE**  
5 **SOLIDS BY X-RAY POWDER DIFFRACTION (XRPD)**

6 (CP = EP)

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

## 11 - Harmonised Provisions

12  

Provision	EP	JP	USP
PRINCIPLE	+	+	+
INSTRUMENT	+	+	+
SPECIMEN PREPARATION	+	+	+
SPECIMEN MOUNTING	+	-	+
CONTROL OF INSTRUMENT PERFORMANCE	+	+	+
QUALITATIVE PHASE ANALYSIS	+	+	+
QUANTITATIVE PHASE ANALYSIS	+	+	+
ESTIMATE OF THE AMORPHOUS AND CRYSTALLINE FRACTIONS	+	+	+
SINGLE CRYSTAL STRUCTURE	+	+	+

13 Legend

14 +: will adopt and implement

15 -: will not stipulate

## 16 - Non-harmonised provisions

## 17 Reagents and reference materials

18 Each pharmacopoeia will adapt the text to take account of local reference materials and  
19 reagent specifications.

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25/10/07

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7

8 **European Pharmacopoeia**

9  
10 Signature

Name

Date

11 

12 LEITEL

13 30/10/2007

14 **Japanese Pharmacopoeia**

15  
16 Signature

Name

Date

17  for Toshiko Nakagaki

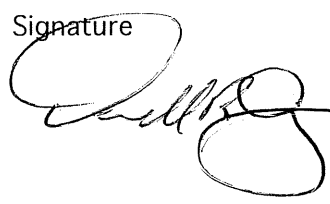
18 Oct. 30, 2007

19 **United States Pharmacopoeia**

20  
21 Signature

Name

Date

22  DARRELL R. ABERNETHY

29 Oct, 2007