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PHARMACOPOEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

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

(CP = EP)

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

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	+	+	+

Legend
+: will adopt and implement
–: will not stipulate

- Non-harmonised provisions

Reagents and reference materials

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

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European Pharmacopoeia

Signature	Name	Date
	LEITEL	30/10/2007

Japanese Pharmacopoeia

Signature	Name	Date
for	Toshiro Nakagaki	Oct. 30, 2007

United States Pharmacopeia

Signature	Name	Date
	Patricia R. Abernethy	29 Oct, 2007