

1 **PHARMACOPOEIAL DISCUSSION GROUP**

2 **STAGE 5B, REV 2**

3 **NAME: E15 CITRIC ACID MONOHYDRATE**

Attribute	EP	JP	USP
Definition	+	+	+
Identification IR	+	+	+
Appearance of solution	+	+	+
Readily carbonisable substances	+	+	+
Oxalic acid	+	+	+
Sulphates	+	+	+
Aluminium	+	-	+
Water	+	+	+
Sulphated ash	+	+	+
Assay	+	+	+

4 **Legend**

5 + will adopt and implement ; - will not stipulate

6 **Non-harmonised attributes**

7 Heavy metals, Characters, Labelling, Bacterial endotoxins, Storage

8 **Specific local attributes**

9 Sterility (USP), identification (water) (EP)

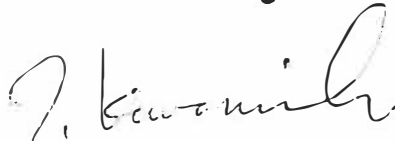
10 **Reagents and reference materials**

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

13 **Date:** 9/6/10

Signatures:

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for Masatoshi Narita

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15 European Pharmacopoeia

15 Japanese Pharmacopoeia

15 United States Pharmacopoeia

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