

PHARMACOPOEIAL DISCUSSION GROUP

E46-TALC: STAGE 5B REVISION 1

Attribute	EP	JP	USP
Definition	+	+	+
Identification A	+	+	+
Acidity or alkalinity	+	+	+
Aluminium	+	+	+
Calcium	+	+	+
Iron	+	+	+
Lead	+	+	+
Magnesium	+	+	+
Loss on ignition	+	+	+

Legend: + will adopt and implement; - will not stipulate

Non-harmonised attributes

Characters, Water-soluble substances, Labelling, Microbial contamination, Packaging and Storage
The absence of asbestos will be stipulated by USP in the test section, by EP in a Production section. In Japan, this parameter is covered by the government notification, LSB/ISHD/CHCD No. 0828001, Aug. 28, 2006.

Specific local attributes

- JP : Acid-soluble substances, Arsenic
- USP, EP : additional Identifications B and C.

Reagents and reference materials

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

Date: 05/06/08

Signatures:

European Pharmacopoeia

WEITEL

Japanese Pharmacopoeia

for Toshio Nakagaki

United States Pharmacopoeia

3 June 2008