PHARMACOPOEIAL DISCUSSION GROUP

TALC: SIGN-OFF

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

*In USP, this section will be included under "Absence of asbestos"

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

Non-harmonised attributes

Characters, Water-soluble substances, Labelling, Microbial contamination, Packaging and Storage

Specific local attributes

- JP : Acid-soluble substances, Arsenic
- USP : Identifications B and C (see below)

B. In a platinum crucible, melt a mixture of 0.2 g of *anhydrous sodium carbonate R* and 2.0 g of *potassium carbonate R*. To the melted mass add 0.1 g of the substance to be examined and heat until the mixture is completely melted. Allow to cool and transfer the melted mass into an evaporating dish with 50 ml of hot *water R*. Add *hydrochloric acid R* until effervescence ceases. Add 10 ml of *hydrochloric acid R* and evaporate to dryness on a water-bath. Allow to cool. Add 20 ml of *water R*, heat to boiling and filter. (The residue is used for identification test C). To 5 ml of the filtrate add 1 ml of *ammonia R* and 1 ml of *ammonium chloride solution R* and filter. To the filtrate add 1 ml of *disodium hydrogen phosphate solution R*. A white, crystalline precipitate is formed.

C. The residue obtained in identification test B gives the reaction of silicates (*2.3.1*).

Reagents and reference materials

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

Date: 10 november 2003

Signatures:

European Pharmacopoeia	Japanese Pharmacopoeia	United States Pharmacopeia
10 november 2003	10 november 2003	10-Nov-03
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