

PHARMACOPEIAL DISCUSSION GROUP

SIGN-OFF DOCUMENT

Stage 5B

NAME: SODIUM STARCH GLYCOLATE (Rev. 3)

	Harmonized attributes		
	EP	JP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
pH	+	+	+
Loss on drying	+	+	+
Limit of iron	+	+	+
Limit of sodium chloride	+	+	+
Limit of sodium glycolate	+	+	+
Assay	+	+	+
Microbial Contamination	+	+	+
Labeling	+	+	+

Legend

+ will adopt and implement; – will not stipulate

Non-harmonized attributes

Characters, Packaging and storage, Identification (IR), Heavy metals, Labeling

Local Requirements

Appearance of solution (EP), Identification (complies with pH test) (EP), Identification (formation of a suspension) (EP), Identification (sodium flame test), (USP)

Reagents and reference materials

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

Date:

Signatures:

June 27, 2013

European Pharmacopoeia

for Haruo Akagawa
Japanese Pharmacopoeia

United States Pharmacopoeia