

**PHARMACOPOEIAL DISCUSSION GROUP**  
**SIGN-OFF DOCUMENT**  
**E-43 WHEAT STARCH**  
**REVISION 3**

**Harmonised attributes**

Attribute	JP	EP	USP
Definition	+	+	+
Identification			
A	+	+	+
B	+	+	+
C	+	+	+
pH	+	+	+
Iron	+	+	+
Total protein	+ <sup>1</sup>	+	+
Oxidising substances	+	+	+
Sulfur dioxide	+	+	+
Loss on drying	+	+	+
Sulfated ash	+	+	+
Microbial contamination	-	+	+

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

JP: <sup>1</sup> Total protein (factor of “0.035” instead of “0.03503”)

**Non-harmonised attributes**

Characters/Description, Containers and Storage

**Local requirements**

EP	JP	USP
Foreign matter, Absence of <i>Salmonella</i>	-	-

**Reagents and reference materials**

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

**European Pharmacopoeia**

Signature



Name

S. KETEI

Date

31/01/18

**Japanese Pharmacopoeia**

Signature



Name

H. OKUDA  
for Fumi Yamamoto

Date

2. Oct 2018

**United States Pharmacopeia**

Signature



Name

KEVIN MOORE

Date

3-OCT-2018