

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	+ ¹	+	+
Oxidising substances	+	+	+
Sulfur dioxide	+	+	+
Loss on drying	+	+	+
Sulfated ash	+	+	+
Microbial contamination	-	+	+

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

JP: ¹ 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. KETEL

Date

31/01/18

Japanese Pharmacopoeia

Signature



Name

H. OKUDA
for Fumi Yamamoto

Date

3. Oct 2018

United States Pharmacopeia

Signature



Name

KEVIN MOORE

Date

3-OCT-2018