

PHARMACOPOEIAL DISCUSSION

GROUP B-01

Amino Acid Determination, Revision 1

It is understood that sign-off covers the technical content of the draft and each party will adapt it as necessary to conform to the usual presentation of the pharmacopoeia in question; such adaptation includes stipulation of the particular pharmacopoeia's reference materials and general chapters.

Items to be revised:

Language in the protein standard samples for hydrolysis methods 6 and 7 to be revised to provide additional clarity for the method.

The requirement of "1 to 8 mol of cysteine" changed to: "1 to 8 mol of cysteine per mol protein."

European Pharmacopoeia

Signature

Name

Date

P-01


C. Uelle

26 Oct 2016

Japanese Pharmacopoeia

Signature

Name

Date



Humbiro Okada
for Masamichi Yamada

Oct 26, 2016

United States Pharmacopoeia

Signature

Name

Date



CATHERINE SHEEHAN

Oct. 26, 2016