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 26 oct 2016 C. Vielle 8.0. Japanese Pharmacopoeia Signature Name Date Hampino Okuda for Masanobu Tanada & Auda 00 76 m/b **United States Pharmacopeia** Signature Name Date

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CATHERINE

Loct 2016.