

PHARMACOPOEIAL DISCUSSION GROUP

TEST FOR PARTICULATE CONTAMINATION : SUB-VISIBLE PARTICLES

SIGN-OFF (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.

European Pharmacopoeia

Signature

Name

Date

ART Agnes ARTIGES 10 June 04

Japanese Pharmacopoeia

Signature

Name

Date

Shimizu for S. Kishida June 10 '04

United States Pharmacopeia

Signature

Name

Date

Eric B. Sherman Eric B. Sherman 10-June-04