EUROPEAN PHARMACOPOEIA COMMISSION

REQUEST FOR REVISION OF A MONOGRAPH OR GENERAL CHAPTER

Presented by: Date:

Concerning: Monograph No: Chapter No.

Title/Name:

URGENT ☐ NOT URGENT ☐

REASON FOR REVISION:

☐ Error in text

☐ Quality defined by the monograph no longer available

☐ New source on the market

☐ Impurity not covered by the monograph: Name:

☐ qualified ☐ others

☐ Analytical improvement

☐ Reagents/equipment no longer available

Name: Test:

☐ Other (specify):

FOR EDQM ONLY:

☐ Laboratory: PA/PH report:

☐ DBO: please specify (e.g. BSP, CAP, etc…):

Copy of supporting document (study or meeting report, OMCL testing report, etc…) must accompany the request.

☐ Other:

Please describe the issue/ suggestion:

For a MONOGRAPH, SECTION TO BE REVISED:

☐ Title	☐ Definition	☐ Production	☐ Characters
☐ Identification	☐ Tests	☐ Assay	☐ Storage
☐ Labelling	☐ Impurities	☐ Functionality-related characteristics	☐ Other

DATA ATTACHED TO SUPPORT THE REQUEST FOR REVISION

Sufficient data must accompany the request to enable the group of experts and/or the Commission to decide whether revision of the monograph is necessary. The data should be evaluated in this light by the requester. Wherever possible, a concrete proposal should be made for amendment of the monograph.

☐ validated method of analysis (comparison with the existing method should be provided wherever possible):

☐ batch data ☐ typical chromatogram (if applicable)

☐ other

Please indicate where *samples* of the product and any necessary *Reference Substance* for testing of the revision proposal can be obtained:

Where useful, please indicate suppliers for *reagents/equipment*:

Manufacturer(s) identified (name, address …):

If urgent revision is requested, please indicate why this is justified.