

Request for revision of a monograph or a general chapter

Requester:

Date:

Text number:

Text name:

FOR A MONOGRAPH, SECTION(S) TO BE REVISED:

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

FOR A GENERAL CHAPTER, PARTS TO BE REVISED:

REASON FOR REVISION

Please explain in a few words the reason for this request (new source on the market, analytical improvement needed, reagent or equipment no longer available etc.)

Please submit a concrete proposal on how you would address this revision:
Please provide sufficient information to enable the EPC to decide whether revision is justified and necessary (validated analytical procedure, batch data, typical chromatogram etc.). If EDQM internal request, add links or official document reference.

Attached document(s): YES NO

Please indicate where the samples of the products/substances can be obtained from (manufacturer's data and contact details):

Do you have any additional comments(reagent, equipment etc.)?

Field for National Pharmacopoeia Authority

NEED FOR A RAPID REVISION?

see GUIDE FOR THE WORK OF THE EUROPEAN PHARMACOPOEIA § 7.3)

YES

NO

LEVEL OF CRITICALITY

Low

Medium

High

Please justify if the level of criticality is high: