



COUNCIL OF EUROPE

EUROPEAN PHARMACOPOEIA COMMISSION

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES

REQUEST FOR REVISION OF A MONOGRAPH OR GENERAL CHAPTER

Presented by:	Group	
Concerning:	Monograph No:	Chapter No.
Title/Name:		

URGENT <input type="checkbox"/>	NOT URGENT <input type="checkbox"/>
REASON FOR REVISION:	
<input type="checkbox"/> Error in text	
<input type="checkbox"/> Quality defined by the monograph no longer available	
<input type="checkbox"/> New source on the market	
<input type="checkbox"/> Impurity not covered by the monograph: Name:	
<input type="checkbox"/> qualified	<input type="checkbox"/> others
<input type="checkbox"/> Analytical improvement	
<input type="checkbox"/> Reagents/equipment no longer available	
Name:	Test:
<input type="checkbox"/> Other (specify):	

For a MONOGRAPH, SECTION TO BE REVISED:			
<input type="checkbox"/> Title	<input type="checkbox"/> Definition	<input type="checkbox"/> Production	<input type="checkbox"/> Characters
<input type="checkbox"/> Identification	<input type="checkbox"/> Tests	<input type="checkbox"/> Assay	<input type="checkbox"/> Storage
<input type="checkbox"/> Labelling	<input type="checkbox"/> Impurities	<input type="checkbox"/> Functionality-related characteristics	<input type="checkbox"/> Other

DATA ATTACHED TO SUPPORT THE REQUEST FOR REVISION

Sufficient data must accompany the request to enable 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): *Generic validation against the in vivo method*

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*:

INFORMATION ON THE PRODUCT

multisource substance

single source

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

Route(s) of administration of the substance:

Use: human

veterinary

both

Extent of use/number of preparations marketed:

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