

ANNEX B TABLE OF CONTENTS OF PROCESS VALIDATION DOCUMENTATION

I. Document Submission (tick if submitted):

	<u>Document</u>	<u>Check Box</u>	<u>Enclosure</u>	<u>Page</u>
a)	Development Pharmaceuticals Report	☐	_____	_____
b)	Validation Scheme	☐	_____	_____
c)	Validation Report			
	o Pilot batch	☐	_____	_____
	o 3 full production batches	☐	_____	_____

II. Details of Validation:

a) Manufacturing site at which the validation is carried out:

No.	Name of manufacturer	Country

b) Type of Validation:

- ☐ Retrospective
☐ Prospective
☐ Concurrent
☐ Others; please specify: _____

c) Number of batches validated: _____

d) Details of batches:

Batch Number	Date of Production	Batch Size	Batch Type (production/pilot)