

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	<input type="checkbox"/>	_____	_____
b) Validation Scheme	<input type="checkbox"/>	_____	_____
c) Validation Report			
o Pilot batch	<input type="checkbox"/>	_____	_____
o 3 full production batches	<input type="checkbox"/>	_____	_____

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)