

**INDIAN PHARMACOPOEIA COMMISSION**  
**AR&D Division/ Monographs Development Division/ IP Technical**  
**Secretariat**

**Checklist for Monograph Development**

S. No.	Requirements	Status
1.	Monograph Source	
2.	Regulatory Approval (CDSCO)	
3.	Name & Profile of Innovator	
4.	Name of Manufacturers	
5.	Pharmacopoeial Status	
	<input type="checkbox"/> BP <input type="checkbox"/> EP <input type="checkbox"/> USP <input type="checkbox"/> JP <input type="checkbox"/> Int. Pharmacopoeia <input type="checkbox"/> Other Pharmacopoeias.....(please specify)	
6.	Scientific / Technical References	
	<input type="checkbox"/> Merck <input type="checkbox"/> Martindale <input type="checkbox"/> Others.....(please specify)	
7.	Pharmacopoeial Comparison	
8.	Justification for adopting any specific Pharmacopoeia other than BP	
9.	Justification for deviation of Innovator's specification	
10.	Route of Synthesis (if applicable)	
11.	Availability of Samples with COA	
12.	Analytical Specifications	
13.	Analytical Methods	
14.	Analytical Method Validation Data	
15.	Forced Degradation Data	
16.	Stability Data	

**Brief Summary & Justification**

	Name	Designation	Signature	Date
Prepared by				
Reviewed by				
Approved by				