

INDIAN PHARMACOPOEIA COMMISSION

IP Monograph Submission Checklist (Version.2)

S. No.	Requirements	Status
1.	Name of the Monograph	
2.	Name of the Molecule	
3.	Category (Therapeutic/ Prophylactic)	
4.	Monograph Source	
5.	Regulatory Approval (CDSCO)	
6.	Name & Profile of Innovator	
7.	Name of Manufacturers	
8.	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)	
9.	References (Scientific / Technical/ Others) <input type="checkbox"/> Merck <input type="checkbox"/> Martindale <input type="checkbox"/> Others.....(please specify)	
10.	Pharmacopoeial Comparison (Annexure)*	
11.	Justification for adopting any specific Pharmacopoeia	
12.	Justification for deviation for Innovator's specification, if available	
13.	Route of Synthesis (if applicable)	
14.	Availability of Samples & Standards with COA for method verification	
15.	Donation of Candidate material for Reference Standard development (Min. quantity 100 gm or more depending on nature of molecules)	
16.	Analytical Specifications & Methods	
17.	Analytical Method Validation Data	
18.	Stability Data including data of forced Degradation studies	

*For descriptive information annex separately

Brief Summary & Justification

	Name	Designation	Signature	Date
Prepared by				
Reviewed by				
Approved by				