

INDIAN PHARMACOPOEIA COMMISSION

PPI Monograph Submission Checklist (Version 1.0)

S. No.	Requirements	Status
1.	Name of the Monograph	
2.	Common Name	
3.	Category	
4.	Name of the Bio/analytical Marker	
5.	Existing in Indian Pharmacopoeia If Yes, Please specify IP volume, Page No.	
6.	Justification for Deviation from Existing Monograph in IP	
7.	Monograph in Exclusion List	
8.	Monograph Source	
9.	Name and Profile of Innovator	
10.	Name of Manufacturer/s	
11.	Pharmacopoeial Status: <input type="checkbox"/> BP <input type="checkbox"/> EP <input type="checkbox"/> JP <input type="checkbox"/> USP <input type="checkbox"/> Int. Pharmacopoeias <input type="checkbox"/> Other Pharmacopoeias..... (Please specify)	
12.	Pharmacopoeial Comparison*	
13.	Availability of samples and standards with COA for method verification	
14.	Donation of candidate material for Botanical Reference Standard development (Minimum 500 gm or more with voucher no.)	
15.	Donation of marker compound for Phytochemical Reference Standard Development (Minimum 100 gm or more with CAS no.)	
16.	Analytical specifications and methods	
17.	Analytical method validation data	

*Attach additional sheet, if required

Brief Summary and Justification

	Name	Designation	Signature	Date
Prepared by				
Reviewed by				
Approved by				