

**CHECKLIST FOR PROTOCOL OF ANALYSIS (POA)
ADULTERATION SCREENING TEST**

NO.	INFORMATION/PARAMETER REQUIRED	AVAILABILITY
1	List of all apparatus & equipment used	
2	List of all chemicals & reagents used	
3	Preparation of solutions such as sample, standard, system suitability solution, mobile phase medium, buffer, IQC solution etc. (the amount of chemical/sample/ standard and volume of diluents used in the preparation must be stated)	
4	Setting up of analytical instrumentation	
5	Testing condition/ parameter such as HPLC parameter, etc	
6	Testing & IQC procedure	
7	System suitability tests and acceptance criteria of system suitability test	
8	Complete formula for calculation (if applicable) and interpretation of results	
9	Image of UV spectrum/chromatogram/mass spectrum Etc. for blank, sample, standard and system suitability solution etc.	
10	Sampling procedure	
11	Latest certificate of analysis. Minimum 2 certificate for every dosage form/matrix applied	
12	Test report for minimum 1 product to be provided for every dosage form/matrix applied	

**CHECKLIST FOR ANALYTICAL METHOD VALIDATION (AMV)
ADULTERATION SCREENING TEST**

PARAMETER	NO.	INFORMATION/DOCUMENTS REQUIRED	AVAILABILITY
General	1	List of samples / matrix to be validated	
	2	Validation must be done for all dosage forms/ each matrices	
Specificity	1	Testing method	
	2	Acceptance criteria	
	3	Image of UV spectrum/chromatogram/mass spectrum etc. for blank, sample, standard and system suitability solution etc. and any supporting data to prove the method is specific	
LOD	1	Testing method	
	2	Acceptance criteria	
	3	Based on signal to noise ratio - S/N > 3:1 - Minimum 10 replicates for each matrix	
	4	Based on linearity study - At least 5 levels of standard solutions with low concentration values	
	5	Perform precision on LOD obtained by spiking standard at LOD level in product (minimum 6 different products for each matrix). RSD NMT 2%	
	6	Image of UV spectrum/chromatogram/mass spectrum etc. and any supporting data	
System Suitability Testing	1	Parameter of system suitability	
	2	Acceptance criteria	
	3	Provide evidence such as UV spectrum/chromatogram/mass spectrum etc., result and any other data which are able to prove the system suitability tests are fulfilled	