

**CHECKLIST FOR PROTOCOL OF ANALYSIS (POA)
DETERMINATION OF LOVASTATIN IN TRADITIONAL PRODUCTS**

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 and interpretation of results	
9	Injection sequence	
10	Image of UV spectrum/chromatogram/mass spectrum Etc. for blank, sample, standard and system suitability solution etc.	
11	Sampling procedure	
12	Summary Measurement of Uncertainty (MOU)	
13	Latest certificate of analysis. Minimum 2 certificate for every dosage form/matrix applied	
14	Test report for minimum 1 product to be provided for every dosage form/matrix applied	

**CHECKLIST FOR ANALYTICAL METHOD VALIDATION (AMV)
DETERMINATION OF LOVASTATIN IN TRADITIONAL PRODUCTS**

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	
Linearity & Range	1	Testing method	
	2	Acceptance criteria	
	3	Linearity graph starts at LOQ concentration and shall cover the regulatory limit 1%w/w. Minimum 5 levels of concentration.	
	4	Specification of r^2 of curve are stated. Minimum requirement r^2 NLT 0.999	
	5	Data such as: a) linear regression equation b) r^2 , y-intercept c) linearity graph	
	6	Image of UV spectrum/chromatogram/mass spectrum and any supporting data relevant to the parameter	
Accuracy	1	Testing method	
	2	Acceptance criteria	
	3	Spiking with a known concentration of standard in the sample matrices.	
	4	Minimum three (3) levels of concentration in triplicates covering the specified range	
	5	% recovery between 85% - 110%	
	6	Image of UV spectrum/chromatogram/mass spectrum and any supporting data relevant to the parameter	
Precision (Repeatability)	1	Testing method	
	2	Acceptance criteria	
	3	Minimum three (3) levels of concentration in triplicates covering the specified range, OR minimum six (6) replicates at 100% of working concentration	
	4	RSD NMT 2%	
	5	Image of UV spectrum/chromatogram/mass spectrum and any supporting data relevant to the parameter	
Precision (Intermediate precision)	1	Testing Method	
	2	Acceptance Criteria	
	3	Minimum three (3) levels of concentration in triplicates covering the specified range, OR minimum six (6) replicates at 100% of working concentration	

	4	Cover at least 2 parameters among variation of analyst, date and equipment	
	5	RSD NMT2%	
	6	Image of UV spectrum/chromatogram/mass spectrum and any supporting data relevant to the parameter	
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	
LOQ	1	Testing Method	
	2	Acceptance criteria	
	3	Based on signal to noise ratio - S/N > 10:1 - Minimum 10 replicates	
	4	Based on linearity study - At least 5 levels of standard solutions with low concentration values	
	5	Perform precision on LOQ obtained by spiking standard at LOQ 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 as per POA	
	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	