Checklist for Protocol Analysis and Analytical Method Validation/Verification for Identification of Raw Materials used in Natural Products

These checklists are intended to provide guidance on the submission of documents/information for protocol of analysis and analytical method validation/verification. The checklists below are not exhaustive and the Centre for Compliance and Quality Control (PKKK), National Pharmaceutical Regulatory Agency (NPRA) reserves the right to request additional data as needed.

Table A shows the information required for protocol of analysis. Table B illustrate validation/verification parameters and documents required for validation of identification test.

These checklists will take effect on **15 September 2023.**

Table A: Checklist for Protocol Analysis

TEST	INFORMATION REQUIRED		AVAILABILITY
Identification test	1	Method reference and edition (e.g., USP 39/BP 2022/Malaysian Herbal monograph 2015/in-house, etc)	
	2	Copy of the method reference (e.g., the monograph)	
	3	List of equipment and apparatus	
	4	List of chemical and reagents	
	5	Preparation of solutions such as sample, standard and reagents. The amount of chemical/sample/ standard and volume of diluents used in the preparation must be stated.	
	6	Setting up of analytical instrumentation	
	7	Testing condition/ parameter such as HPLC/GC/TLC parameter, etc.	
	8	Testing procedure	
	9	System suitability tests and acceptance criteria of system suitability test	
	10	Interpretation of results	
	11	HPLC chromatogram / GC chromatogram / Image of TLC etc. for blank, sample, standard and system suitability solution	

Note: Statement “according to pharmacopoeias/monograph” shall not be accepted

Table B: Checklist for Analytical Method Validation/Verification

TEST	IDENTIFICATION TEST		
PARAMETER	**No.**	**DOCUMENTS REQUIRED**	**AVAILABILITY**
Specificity	1	Testing Method	
	2	Acceptance criteria	
	3	Chromatograms/Images etc. for following solutions (if applicable): a) Standard/ Markers b) Sample c) Blank d) Any supporting data to prove the method is specific	
System Suitability Testing (if applicable)	1	Parameter of system suitability	
	2	Acceptance criteria	
	3	Provide evidence such as HPLC chromatograms/UV spectrum, result and any other data which are able to prove the system suitability tests are fulfilled	

Note: For in-house test methods [test methods other than those specified in the Malaysian Herbal Monograph, the United States Pharmacopoeia, the British Pharmacopoeia and other national pharmacopeia (e.g. China, Taiwan, India, Japan, Indonesia and Thailand)], the applicant must produce the method validation data with plant or powdered plant material from at least three different sources (different location i.e. Northern Region, Central Region and Southern Region of Malaysia) to demonstrate the method reproducibility).