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Ministry of Health Malaysia

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GUIDANCE DOCUMENT: VERIFICATION FOR TRADITIONAL MEDICINES (TM) AND HEALTH SUPPLEMENTS (HS) MANUFACTURERS

1st Edition

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This guidance document is issued in accordance to Regulation 20, Control of Drugs and Cosmetics Regulations 1984.

NPRA reserves the right to amend any part of the guidance document whichever it deems fit.

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1.0 INTRODUCTION

1.1 BACKGROUND

Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines and Health Supplements (TMHS) of 1st Edition published in the year of 2008 serves as a guidance for TMHS manufacturers on GMP compliance to ensure that their products manufactured are safe and of quality.

Provision in para 5.18 from the guideline states that "Verification or validation work, that is needed to prove control of critical aspects of particular operations should be identified. Significant changes to the facilities, equipment and the processes which may affect the quality of the product should be verified or validated. A risk assessment approach should be used to determine the scope and extent of verification or validation."

It is expected that the manufacturer complies with the stated provision. However, the compliance on this provision till the publication of this guidance document is considered low due to insufficient knowledge on the implementation of verification among the manufacturers.

As part of preparation prior to implementation of the ASEAN Guidelines on GMP for TM and HS, it is recommended that the manufacturer understands and starts planning on documentation and execution of verification activities.

1.2 LIST OF ABBREVIATIONS

CCQC	: Centre for Compliance and Quality Control
CPP	: Critical Process Parameter
CQA	: Critical Quality Attributes
GMP	: Good Manufacturing Practice
HS	: Health Supplements
IV	: Installation Verification
NPRA	: National Pharmaceutical Regulatory Agency
OV	: Operational Verification
PeV	: Performance Verification
TM	: Traditional Medicines

2.0 OBJECTIVE

To provide guidance on verification activities implementation by the TMHS manufacturers in phases within 5 years' time (2023 - 2027).

3.0 SCOPE

Verification activities are applicable to all TM and HS manufacturers. Scope of the verification consists of:

- Verification program
- Verification of equipment and utilities
- Verification of process
- Change control
- Re-verification

For the introductory implementation, it is recommended that the manufacturer performs verification on critical production and packaging equipment and critical utilities such as ventilation or air handling unit and treated water systems. The details of the implementation are described in the timeline in **Table 1**.

4.0 DEFINITION

The glossary of the ASEAN Guidelines on GMP for TM and HS (Annex VIII) defines 'verification' as confirmation, through the provision of objective evidence, that the requirements for any procedure, process, equipment, material, activity or system have been fulfilled.

It also refers to as a documented act or conduct of confirmation that the control or procedure required in a particular critical aspect of manufacturing operation has been complied or implemented satisfactorily. The extent of verification may be determined by the manufacturer based on its own risk assessment.

In a simpler term, it is an act of checking if the procedures, processes, equipment, materials, activities, or systems are working consistently and delivering results in accordance with the requirements. When there are significant changes to the equipment, utilities and the processes which may affect quality of product, it should be verified. The manufacturer may have a risk assessment approach to determine the scope and extent of verification.

5.0 TIMELINE OF IMPLEMENTATION

Table 1: Implementation by Phases of Verification Activities in 5 Years

Scope of Verification	Tasks	Implementation by Year				
		2023	2024	2025	2026	2027
Verification program	i. Procedure drafting					
	ii. Procedure approval		✦			
	iii. Verification implementation and periodical review					
Verification of equipment	i. Identify existing and new equipment					
	ii. Identify verification approaches					
	iii. Prepare verification protocol		✦			
	iv. Execution of verification					
	v. Prepare verification report for approval				✦	
	vi. Periodical review					
Verification of utilities	i. Identify utilities (water system, air handling unit)					
	ii. Identify verification approaches					
	iii. Prepare verification protocol		✦			
	iv. Execution of verification					
	v. Prepare verification report for approval				✦	
	vi. Periodical review					
Verification of process	i. Identify active and non-active products					
	ii. Identify processes to verify					
	iii. Prepare verification protocol			✦		
	iv. Execution of verification					
	v. Prepare verification report for approval					✦
	vi. Periodical review					

✦Expected year which the related documents will be reviewed during GMP inspection.

The timeline of implementation in **Table 1** acts as guidance for the industry to be ready and comply with the requirement. Manufacturer should be ready with adequate documentation such as protocol which will be reviewed during the inspection. Execution, reporting and periodical review will soon be inspected in the subsequent inspection as according to the expected timeline.

6.0 IMPLEMENTATION OF VERIFICATION

6.1 DOCUMENTATION REQUIRED FOR VERIFICATION

The manufacturer is required to prepare the following documents for the implementation of verification.

1. Verification program

2. Verification protocol (applicable for verification of equipment and utilities)
    a. Installation
    b. Operational
    c. Performance

3. Verification report (applicable for verification of equipment and utilities)
    a. Installation
    b. Operational
    c. Performance

4. Verification protocol (for verification of process)

5. Verification report (for verification of process)

The structure example for verification protocol and report of equipment/utilities is described in **APPENDIX 1** and for verification of process is described in **APPENDIX 2**.

6.2 VERIFICATION PROGRAM

A manufacturer is required to have a written verification program to describe the key elements of verification. The document should be brief, concise and clear.

The program should at least contain the following:

1. Objective of verification of the site.

2. Organisational structure including roles and responsibilities of personnel involved in verification activities. This is to at least describe personnel who is responsible for:
    a. Overall verification program
    b. Manage verification documentation preparation and control
    c. Approval or authorisation

3. Employee training including training support needed to perform/conduct relevant verification activities.

4. The management of documentation (e.g. format of protocol and report).

5. Summary of equipment, utilities and systems that include the following:
    a. Status of verification (Verified or not verified)
    b. Calibration status (calibrated and due date for next calibration)
    c. Maintenance status (next maintenance activity)

The summary can be attached as an addendum and be updated annually or when there are changes to the overall verification program.

6. Reference to the relevant list of manufacturing and laboratory procedures.

7. Detailed information and scope of verification carried out by the external consultant.

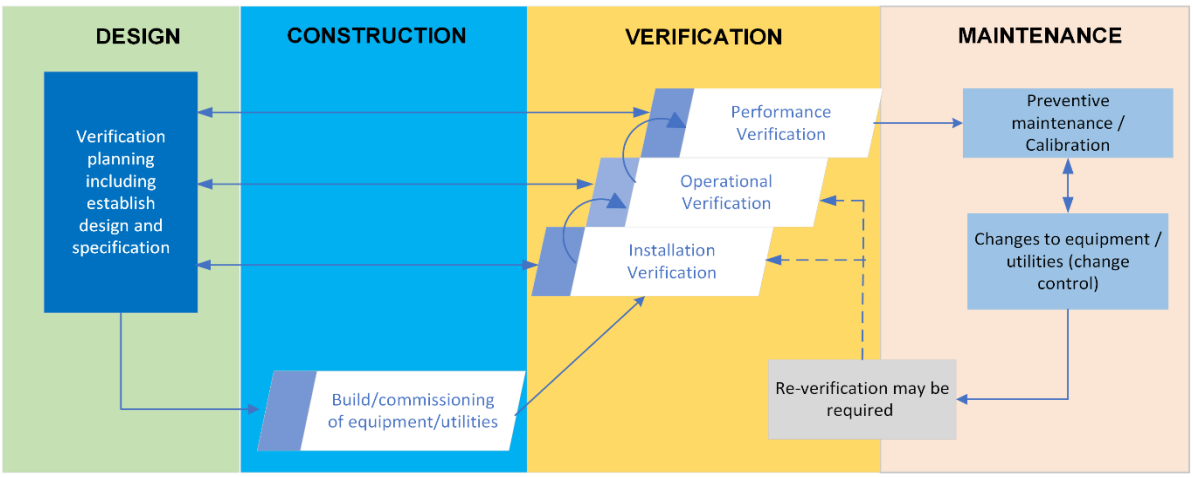
6.3 VERIFICATION OF EQUIPMENT/UTILITIES

Equipment and utilities used for processing and packaging should be suitably designed, operated and maintained to suit their intended purpose. Therefore, the manufacturer must perform verification as to ensure that the equipment and utilities are operating within the acceptance criteria and able to produce consistent quality batches of products.

There are 3 stages to perform verification on equipment/utilities. An overview of these stages is described further in **Figure 1**.

- Installation verification (IV)
- Operational verification (OV)
- Performance verification (PeV)

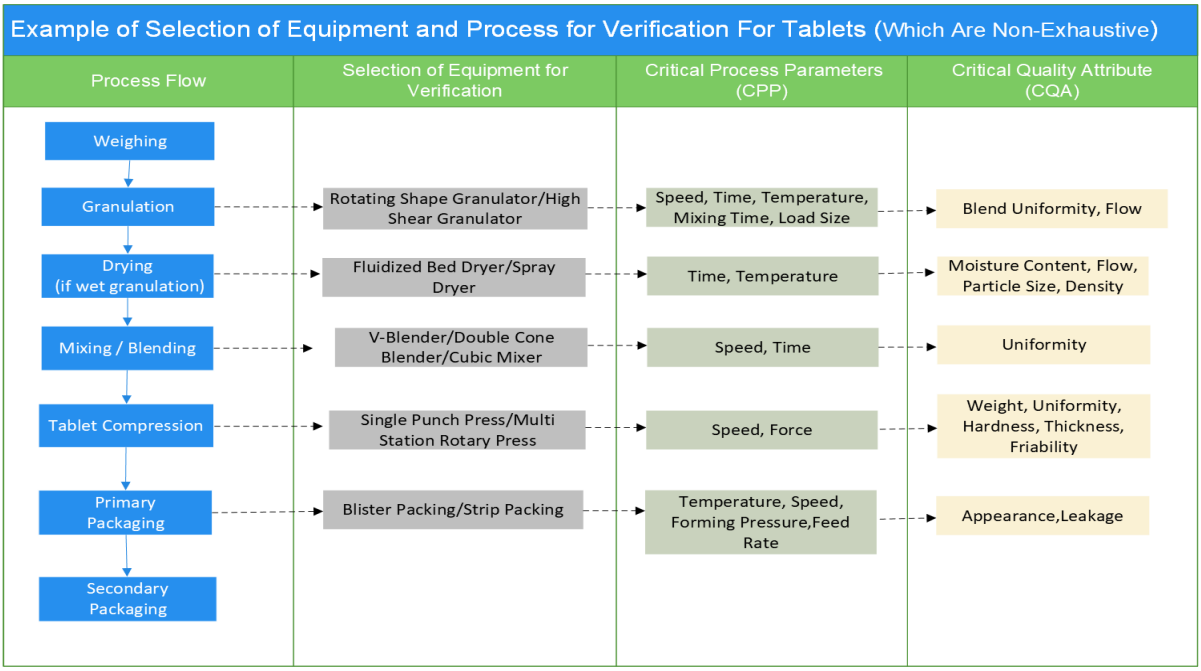
Figure 1: Stages of verification on an equipment/utilities



New equipment or utilities must pass through all stages of verification while for existing equipment or utilities, the extent of verification stages should be based on the criticality of its function.

Figure 2 shows an example of equipment selection for a typical tablet dosage form.

Figure 2: Example of Selection of Equipment and Process for Verification of Tablets



6.3.1 Installation Verification (IV)

Objective of this stage is to provide documented evidence that installation of equipment/utilities was complete and satisfactory. Relevant documentation such as specifications, drawings, operating manuals, vendor details and spare parts information should be kept and verified. When any control or measuring devices are included in the equipment/utilities, it should be calibrated at specified intervals by a qualified vendor. IV of an equipment/utilities should include but not limited to the following:

- Verification of the correct installation of components, instrumentation, equipment, pipe work and services according to drawings or specifications.
- Verification of the correct installation as per defined plans. This includes identification of all elements/parts/controls/gauges and other components.
- Requirements for calibration, maintenance and cleaning should be available or identified.
- Verification of the materials of construction.

6.3.2 Operational Verification (OV)

Objective of this stage is to confirm that the equipment/utilities operate correctly according to its protocol. The manufacturer should identify the critical operating parameter and consider conditions such as upper and lower operating limits. It is possible to combine IV and OV depending on the complexity of an equipment/utilities. During this stage, the manufacturer can finalize practices or document related to the equipment/utilities such as below:

- Standard operating procedure for the operation of equipment/utilities.
- Cleaning procedure and relevant record is identified.
- Training to operators on the equipment/utilities.
- Preventive maintenance requirements such as procedure and schedule.
- Calibration is completed.

6.3.3 Performance Verification (PeV)

Objective of this stage is to confirm that the equipment/utilities perform in accordance with the intended specification. This stage usually occurs after successful IV and OV. However, it may be suitable in some circumstances to perform it in conjunction with Operational Verification (OV) or Process Verification. Verification at this stage should include:

- Tests using substitute or simulated product proven to have equivalent behaviour under normal operating conditions with worst case batch sizes.
- The frequency of sampling to confirm the process control should be justified.
- Tests cover the operating range of the intended process unless documented evidence from the development phases confirming the operational ranges is available.

6.4 VERIFICATION OF IN-USE OR EXISTING EQUIPMENT/UTILITIES (LEGACY)

There are equipment and utilities that have been in the manufacturing facility since the beginning of its operation. Therefore, it is possible that detailed information such as drawings, manuals, parts information or instrument information are not available, or the models have been outdated/discontinued. However, data must be made available to support that the equipment/utilities are still within operating limits. The manufacturer may conduct verification retrospectively from the installation stage or commencing with operational verification to confirm its operation, calibration, cleaning, maintenance requirements remain valid.

6.5 VERIFICATION OF PROCESS

Verification of process provides documented evidence that a product shall be produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and product specification.

Verification of process may involve demonstration, testing & analysis and in-process control, or other relevant to confirm that critical processes are kept under control. A process verification report shall be prepared to provide evidence that the process has been verified.

a) Demonstration

Demonstration is the operation of an item to provide evidence that it can meet its predetermined specifications and quality attributes. Demonstrations can be conducted in actual or simulated environments.

b) Testing & Analysis

Test is the application of scientific principles and procedures to determine the properties or functional capabilities of items. Test is similar to demonstration, but is more exacting, generally requiring specialized test equipment, configuration, data, and procedure in order to verify that the item satisfies the requirement. Analysis is the use of established technical or mathematical models or simulations, algorithms, or other scientific principles and procedures to provide evidence that the item meets its stated requirements.

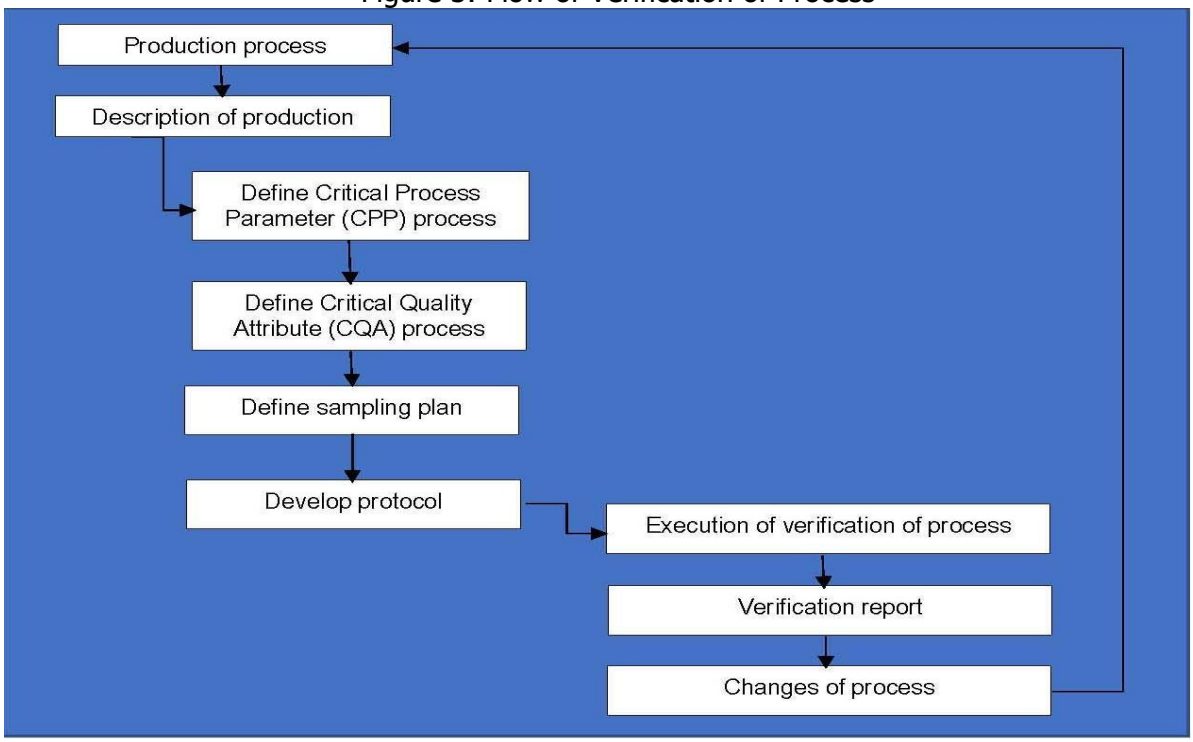
c) In-process control

Critical parameters shall be determined and monitored, checks performed during production in order to monitor and if necessary to adjust the process to ensure that the products confirm to its specification. The control of the environment or equipment may also be regarded as a part of in-process control.

Verification of process should normally begin once the verification of equipment and utilities are completed. This should at least cover the critical steps and parameters during processing, packaging and testing.

Generally, the flow of verification of process as described in **Figure 3**:

Figure 3: Flow of Verification of Process



6.5.1 Selection of Verification Approaches According to the Product Activity

There are 2 approaches in performing the verification of process which can be done prior to manufacture intended for sale or during the routine production run. These approaches are called prospective and concurrent verification.

The number of registered products usually owned/manufactured by a TMHS manufacturer is large in number. Therefore, the manufacturer must be able to select or prioritise which product to verify. The number of batches of a product to verify typically are 3 consecutive batches. However, this number of batches can be reduced depending on the extent of product and process knowledge. The type of approaches for process verification is detailed in **Table 2**.

Table 2: Approaches in Process Verification

Verification Approaches	**Newly Registered Products** (Products register beginning year 2024)	**Existing Registered Products** (Currently active)	**Existing Registered Products** (Inactive)
Prospective	√ Applicable to: ● New product under development and preparation for registration. 1 batch suffice to support the registration process, if required. While another 2 batches can follow suit.		
Concurrent	√ Applicable to: • Newly registered product after year 2024 and produce up to 3 batches and more.	√ Applicable to: ● Existing registered product that still actively being manufactured and able to produce 3 batches and more. ● Major changes occur to the existing registered product.	√ Applicable to: • Inactive products where manufacture of the product is less than 3 batches throughout its registration period (low volume production).
Verification not required			√ Applicable to: ● Products that have been discontinued or expired. registration status. ● Last manufactured was more than 2 years ago.

6.5.2 Process Verification Protocol

The protocol should have a clear standard format of documentation and usually it is developed as a single document. The protocol should include but not limited to the following:

- Brief description of product.
- Description of the process including detail of critical steps.
- Description of the verification approach.
- List of the equipment/facilities to be used (including measuring/monitoring/recording equipment) together with the verification and calibration status.
- Summary of the Critical Process Parameter (CPP) and Critical Quality Attribute (CQA) with its acceptance criteria. May refer to **Figure 2** for examples of CPP and CQA required.
- List of testing methods required to conduct on the product.
- Methods for recording and evaluating results.
- Personnel function and responsibilities.
- Reference of master Batch Manufacturing Record (BMR)/template BMR.

6.5.3 Process Verification Report

Results from the execution of verification of process should be documented in the verification report. Batches that run under the verification of process should be documented in each BMR separately. As a minimum requirement, the report should include:

- Description of the process including details of critical steps.
- Batches involved in this verification.
- Summary of results obtained from the defined CPP and CQA.
- Any changes or deviation occurred during the execution of verification.
- Acceptance/approval on the review of results.
- Conclusion.
- Recommendations on the acceptance criteria of CPP and CQA followed by monitoring during routine production.

Refer APPENDIX 2 for example of protocol and report documentation for process verification.

6.6 CHANGE CONTROL & RE-VERIFICATION

The manufacturer is required to control changes of equipment, premises, utilities and processes to ensure that the verified status remains valid throughout the production of the TMHS products. A change control procedure should be in place to describe actions to be taken if a change is proposed to a:

- Starting material,
- Product component,
- Process equipment,
- Process environment (or site),
- Method of production or testing, or
- Any other changes that may affect product quality/reproducibility of the process.

There should be a record of changes proposed and the impact of the change should be evaluated whether to accept or reject the proposed change. The decision to perform re-verification on machinery and equipment; and re-verification of process should be documented.

Examples of changes that are likely to require re-verification may include:

- Change in manufacturing process, particularly that affects the processing parameters.
- Change of critical equipment or addition of system/parts, including relocation.
- Change in premises or utilities supporting systems that affect the process flow or current verification status of utilities.
- Transfer of process to another site.
- Change of testing procedure.
- Change of critical material supplier.

7.0 GLOSSARY

The following definitions are adopted and used for the purpose of this guideline and shall not be taken as legislative definitions:

Batch
A quantity of any product produced during a given cycle of manufacture and from a specific formulation order, that is uniform in character and quality [the essence of a manufacturing batch is its homogeneity].

Bulk Product
Any product that has completed all processing stages up to, but not including, final packaging.

Critical Steps/Process
A step/process which can manifest as a gain/loss of specific activity and/or an increase/decrease in an impurity level or whether the operating point is near the edge of failure and how well this can be controlled which can affect safety, purity or efficacy of a product.

Documentation
All written procedures, instructions and records involved in the manufacture of a product.

Finished Product
A product which has undergone all the stages of manufacture.

In-Process Control
Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

Intermediate Product
Any material or mixture of materials which have to undergo one or more stages of processing to become a bulk product.

Material
Any substance or component with certain physical properties that are used as components in production or manufacturing.

Packaging
All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product.

Packaging Materials
Any material, including printed material, employed in the packaging of a product, such as containers, closures, bags, packing, label materials [labels, inserts, etc.], seals, binding materials, adhesives and tapes.

Raw Materials
All materials whether active or inactive that are employed in the processing of product.

Verification
Confirmation, through the provision of objective evidence, that the requirements for any procedure, process, equipment, material, activity or system have been fulfilled.

8.0 REFERENCES

1. Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements; 1st Edition, 2008.
2. ASEAN Guidelines on GMP for Traditional Medicines/Health Supplements (TM/HS) Appendix 2 Verification; ASEAN TMHS Product Working Group; 30 November 2016.
3. ASEAN Guideline on Good Manufacturing Practice for Traditional Medicines/Health Supplements.
4. WHO Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines.
5. WHO Good Manufacturing Practices: Main Principles for Pharmaceutical Products.
6. ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Registration.

9.0 APPENDICES

Template for Verification Protocol and Report of Equipment/Utilities/System (This format is used for training or guidance purposes only)

VERIFICATION PROTOCOL OF EQUIPMENT/UTILITIES/SYSTEM (FORMAT) (Note: Please prepare according to the type of verification whether its IV/OV or PeV)
Standard introduction documentation format as below: Title of verification protocol …… Document/protocol number: ……. Protocol written by: ……... Date: …… Protocol approved by: …… Date: ……
Objective: State the relevant objective according to the type of verification to be performed. May include the equipment/utilities/system inventory or identification number *e.g.: To ensure that (name of equipment/utilities/system) installed conforms to the purchase specification and to document information that (name of equipment/utilities/system) meets its specifications.* *e.g.: To determine that the (name of equipment/utilities/system) operates according to specifications and to record information that the (name of equipment/utilities/system) function as expected.* *e.g.: To determine that the (name of equipment/utilities/system) perform consistently meets its specification.*
Scope: To describe verification activities to perform whether it is installation/operational/performance. Brief description of the equipment/utilities/systems can be included *e.g.: To perform installation verification as described in this IV Protocol at the time of installation, modification and relocation.* *e.g.: To perform operational verification after the installation verification has been completed* *e.g.: To perform performance verification after the installation and operational verification have been completed and approved*

Responsibilities:

Lists of personnel involved in this particular verification activity. The person/post that performs the verification, verify the results, approve protocol and report.

e.g. IV:

(Post/person) overseeing the installation will perform and record results
(Post/person) verify the results
(Post/person) will review and approve the protocol and report

Verification plan/procedure:

To describe the detailed verification activity. May include description of equipment/utilities, criticality of the equipment/utilities and pre-requisites required before performing verification.

e.g.
Verification plan for IV:
1) *prepare a checklist of all components and parts, including spare parts according to the purchase order and manufacturer's specifications.*
2) *Record the information for each actual part, component, item of auxiliary equipment, supporting facilities, and compare with the manufacturer's specifications.*
3) *Record any deviations to the equipment/utilities/system, and provide justification for deviation.*
4) *Prepare IV report and submit for review and approval.*

Example of test parameters during the conduct of IV. Minimally, results can be presented as below:

No.	*Test Parameters*	*Specification*	*Results*
1.	*Model/Serial No.*		
2.	*Manual*		
3.	*Drawing*		
4.	*Parts list/Parts Number*		
5.	*…….*		

e.g.
Verification plan for OV:
1) *Test and record calibration instruments and its status.*
2) *Test and record operative condition of control points and alarms.*
3) *Test and record operative outputs.*
4) *Test and record outputs of specific challenges to the equipment/utilities/system based on worst case conditions.*

5) Record any deviations to the equipment/utilities/system, and provide justification for deviation.
6) Prepare OV report and submit for review and approval.

Examples of test parameters during the OV. Minimally, results can be presented as below:

No.	*Test Parameters/ Operating parameters*	*Specification*	*Results*
1.	*Model/Serial No.*		
2.	*List of calibration instruments: ……..*		
3.	*Start Up and Shutdown*		
4.	*Alarms/emergency stop*		
5.	*Lists Outputs of the equipment/utilities ……*		

e.g.:
Verification plan for PeV:
1) Run normal procedure three times for each use (using actual load or placebo) and record all required data.
2) Record any Deviations to the equipment/utilities/system, and provide justification for deviation.
3) Prepare PeV report where information such as date study initiated; date completed; observations made; problems encountered; completeness of information collected; summary of deviation report; results of any tests stated.
4) Submit PeV document for review and approval.

Example of PeV:

Test parameters/ Performance required	*Specification*	*Results Run No.*		
		#1	*#2*	*#3*
Uniformity of weight	*…….*			
Hardness	*…….*			
Thickness	*…….*			
……	*……..*			

VERIFICATION SUMMARY/VERIFICATION REPORT OF EQUIPMENT/UTILITIES/SYSTEM (FORMAT)

(Note: Please prepare according to the type of verification whether its IV/OV or PeV)

Each verification stage will have its own summary/report. This is where the manufacturer is required to report all results that was obtained from the execution in its verification plan. The manufacturer can prepare this part in a separate document bearing its own identification number that is traceable to its protocol. Standard introduction documentation format applies when the verification report is prepared separately.

This report should evaluate and summarise all the results obtained and cross references the verification result towards the protocol in detail. Any deviations shall be reported and state corrective action, if any.

Conclusion of the verification should be stated if it is valid or invalid. If the verification is invalid, the manufacturer is required to state recommendations and determine if re-verification is needed.

This section also requires the person/post who reviews and approves the verification report and the date of approval.

IMPORTANT NOTES:

Ideally, protocol and report of each verification stage to be prepared in a separate document. However, it is still acceptable to have protocol and report to be combine as 1 document provided that any deviations from the protocol are recorded/reported during the verification execution.

If the verification report is separate from the protocol, please ensure that the document is cross referenced with its protocol. General documentation system also applies to the verification report.

Do not combine several types of verification stages as 1 document. For example, protocol and report of installation verification combine with operational verification as 1 document.

Template for Verification of Process Documentation
(This format is used for training or guidance purposes only)

VERIFICATION OF PROCESS PROTOCOL (FORMAT)
Standard introduction documentation format as below: Title of verification protocol: …… Document/protocol number: ……. Product Name: …….. Batch size: ……. Storage condition: …….. Shelf life: ……. Protocol written by: …….. Date: …… Protocol approved by: …… Date: ……
Objective: State the objective of the verification protocol. *e.g.* *To conduct the process verification of the manufacturing process for the (name of product) manufactured at (name of facility). This study is to establish documentary evidence that the manufacturing process used for (name of product) is capable of producing consistent products with reproducible as per defined specification.*
Personnel function and responsibilities: List of personnel responsible to prepare documentation, review and approve protocol and report.
Description of the verification approach and its pre-requisites: State types of verification if it's prospective or concurrent. State number of batches and the batch size subjected for verification. State conditions/pre-requisites required before conducting verification of process.
Description of product and manufacturing process with a schematic or flowchart: State the manufacturing process from weighing to packing of specific product.
Description of raw materials and packaging materials: State the raw and packaging material to be used for the product. This include the master formula and list of packaging material to be used for the product

List of the equipment/facilities to be used (including measuring/monitoring/recording equipment) together with the verification and calibration status;

Format or list can appear in a table form.

e.g.

Equipment/ Facilities	Equipment ID	Capacity of Operation	Verification Status	
			Date of verification	Status
Granulator	GRN123	50kg	14/01/2021	Verified
Cubic Mixer	CM123	100kg	16/08/2021	Verified
Air conditioner	AHU1	-	01/07/2021	Verified
……	……	……	……	……
……...	……	……	……	……

Summary of the Critical Process Parameter (CPP) and Critical Quality Attribute (CQA) with its acceptance criteria:

Format can appear in a table form. May refer Figure 2 for reference; however, the list below is not exhaustive.

e.g.

Process step/Stage	Critical Process Parameter	Acceptance Criteria	Batches for Verification		
			B/N #	B/N ##	B/N ###
Granulation	Speed	Low/High	Data of 3 batches to be reported in verification process report		
	Mixing time	## minutes			
Mixing	Mixing time	## minutes			
	Mixing speed	## RPM			
Tabletting	Force	## Torque			
	Filling speed	## tablet per minute			
……	……	…….			

Process step/Stage	Critical Quality Attribute	Acceptance Criteria	Batches for Verification		
			B/N #	B/N ##	B/N ###
Granulation	Blend uniformity	% content	Data of 3 batches to be reported in verification process report		
	Flow	flowable			
Mixing	Uniformity	% content			
Tabletting	Weight	## mg			
	Uniformity	% content			
	Disintegration time	Less than 30 minutes			
……	……	…….			

List of testing methods required to conduct on the product:

State the testing required for In-Process Quality Control (IPQC) and Finished Product Quality Control (FPQC) with its acceptance criteria.

Methods for recording and evaluating results:

Describe collection of data and ensure it meets the acceptance criteria and specification. If any deviation or changes occur during the verification, it should be reported.

Reference of master Batch Manufacturing Record (BMR)/template BMR:

State the BMR document number.
State specification IPQC or FPQC number

VERIFICATION OF PROCESS REPORT (FORMAT)

Standard introduction documentation format as below:

Title of verification report ……. Document/report number: …….
Product Name: …… Batch size: ……..
Storage condition: …….. Shelf life: ……..

Report written by: …….. Date: ……
Report approved by: …… Date: ……

Objective:

State the purpose of the verification report.
e.g.

The objective of this report is to provide documented evidence derived from executing the verification of process for (name of product).

Manufacturing Details:

Description of batch number, batch size, pack size and manufacturing details.

e.g.

Batch No.	B/N #1	B/N #2	B/N #3
Batch Size			
Pack Size			
Date of Manufacturing			

Summary of results obtained from the defined CPP and CQA:

Report results as stated in protocol

e.g.

Reporting of results related to CPP by process stage:

Process step/Stage	Critical Process Parameter (CPP)	Acceptance Criteria	Batches for Verification		
			B/N #	B/N ##	B/N ###
Granulation	Speed	Low/High			
	Mixing time	## minutes			
Mixing	Mixing time	## minutes			
	Mixing speed	## RPM			
Tabletting	Force	## Torque			
	Filling speed	## tablet per minute			
……	……	…….			

e.g.

Reporting of results related to CQA by process stage:

Process step/Stage	Critical Quality Attribute (CQA)	Acceptance Criteria	Batches for Verification		
			B/N #	B/N ##	B/N ###
Granulation	Blend uniformity	% content			
	Flow	flowable			
Mixing	Uniformity	% content			
Tabletting	Weight	## mg			
	Uniformity	% content			
	Disintegration time	Less than 30 minutes			
……	……	…….			

Summary of FPQC:

This is to report overall FPQC results for the verified batches.

e.g.

Test Parameter	Specification	Results		
		B/N#	B/N ##	B/N ###
Appearance				
Uniformity of weight				
Disintegration				
Microbial Limit Test:				
Heavy Metal Limit Test:				

.....				

Discussion/review of results:

To report whether the overall results are meeting specification, any deviation reported and subsequent action taken or changes made during the verification.

Conclusion, recommendation and approval of report:

To state the conclusion that the verification of the process has demonstrated that the process was under control and within specification and acceptance criteria. This section also states any recommendation that should be made to the product and subjected for further monitoring.