

Process Validation Interim / Final Report

(Reference: SOP _____)

[Enter Product Title, Number & Strength]

PRODUCT CODE:

	WRITTEN BY:	REVIEWED BY:
Name:		
Signature:		
Position:		
Date:		

Qualification Status
<p>Qualification of [enter raw material item description, item code] as per protocol [enter protocol no] has been completed for the following:</p> <ul style="list-style-type: none"> [enter product name, code and lot no] <p>All deviations and additional protocol results for the batch are documented in this interim report. All acceptance criteria have been met according to protocol [enter protocol no] and all deviations resolved.</p> <p>The qualification for the use of [enter raw material item description, item code] in the manufacture of [enter product name, code and lot no] has been successfully completed.</p> <ul style="list-style-type: none"> The qualification status of the use of [enter raw material item description, item code] in the manufacture of [enter product name, code and lot no] remains on-going until all qualification data has been compiled for this study and will be documented in a subsequent report.

REPORT COMPLETION APPROVAL:			
Name:	[Type Name]	[Type Name]	[Type Name]
Signature:			
Position:	Validation Manager	Production Officer	QA Team-Leader
Date:			

1. OBJECTIVE

The objective of this interim report is to document the process results and process parameters obtained during the manufacture of [enter blend/granulate name and batch number] and [enter Cap/Tab product name and batch number] in the Manufacturing facility at [enter site name].

The [enter blend/granulate name and batch number] is the [first/second/third] validation blend in this study manufactured for the Local market. The [enter Cap/Tab product name and batch number] is the [first/second/third] run of three validation batches to be manufactured for the [Local /export] markets. Refer to table 1.0 below for details on all the validation runs covered in this report and from previous interim reports. A statistical review of these processes is

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6. VALIDATION STRATEGY

The manufacturing process of [enter blend name] (commercial lot size in kg) and [enter product caps/tab] (enter batch size or commercial batch size may depend on market demand) were validated under the control of the Technical Services Department. [Enter for both export and Local if applicable].

A [concurrent/prospective/retrospective] validation approach was used for this validation study. Justify concurrent e.g. because some of the [enter product name] dosages are not manufactured very frequently in the Manufacturing facility at [enter site name].

All validation batches were manufactured following the same manufacturing process as detailed in the manufacturing instructions [give Manufacturing Instruction number and current versus protocol version number/date].

All critical process variables in the manufacturing process [blending/granulation and tableting/encapsulation] were reviewed. [These/this] validation [batch/es] were analysed as set out in [enter section reference] of the protocol [enter protocol number] and the results are summarised in [enter Section reference] of this report.

This report will document the number of blend / granulate samples from the run e.g. minimum of 10 locations from the blender to show blend uniformity/homogeneity [dead spot characterisation in modified processes only, reference [enter no] and Blend sampling strategy report [enter no]. NIR blend analysis will be run on all blend samples to assess blend uniformity.

In-process testing - use what is applicable:

The NIR analysis performed throughout this run is [e.g. 6 capsules/ tablets each hour throughout the run] is documented in this report **OR** NIR analysis was run on 10 capsules at the following time points:

- the first 10 capsules/tablets from the start of the encapsulation / tableting process,
- from a composite* sample of 20 dosages from each bucket throughout the run
- Critical Time Points – first 10 capsules / tablets off the machine, after the event. Examples of Critical Time Points are as follows; major break down of tablet machine, after an extended break in [tableting/encapsulation] (i.e. outside normal operational stops & starts), blockages
- the last 10 capsules/tablets off the machine

The potency of the unit dosage with both the highest and lowest absorbance from the NIR scans over the entire run was analysed for potency by the QC Lab to equate the absorbance to the actual concentration. The results are documented in Section XXX of this report.

In-process weight results and statistical analysis performed to identify the state of process control are documented in this report in Section XXX.

This report documents the sampling and testing required and performed on the finished product. Full product testing on the routine end – of the – run sample of tablets / capsules was required apart from Dissolution, Assay and Content Uniformity which were required to be tested on the additional validation samples. The additional validation samples, taken from 7 different time points distributed throughout the validation run, include start, middle and end of run. Assay and Content Uniformity testing were required on 70 tablets / capsules (10 capsules from each time point) and [Comparative] Dissolution testing was required on 12 [or 6 if only dissolution profile] capsules from the end – of the – run sample. The Comparative Dissolution profile is required to be performed on 3 batches of the current process and compared to each validation batch [if applicable]. This report documents the first comparison dissolution profile.

Process Validation the following 2 paragraphs are applicable:

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Encapsulation	Encapsulation of the blend into tablets / capsules	Enter parameter	Critical/ Non critical
		Enter parameter	Critical/ Non critical
		Enter parameter	Critical/ Non critical
		Enter parameter	Critical/ Non critical

The machine settings and ranges listed in Table 7.3.2.2 below were identified as being the Normal Operating settings / ranges in protocol [enter protocol number]. The following operating ranges are allowed for these parameters and the actual settings used for the validation batch were recorded in [enter protocol Appendix number].

Table 7.3.2.2: The Actual **Tabletting / Encapsulation settings guides used**

Parameter	Dosage	Dosage
Enter parameter	Enter set point / range	Enter set point / range
Enter parameter	Enter set point / range	Enter set point / range
Enter parameter	Enter set point / range	Enter set point / range
Enter parameter	Enter set point / range	Enter set point / range
Enter parameter	Enter set point / range	Enter set point / range

7.4 Equipment Used – Validation Status

Table 7.4.1: Equipment used in the manufacture and testing of [enter product name]

Process Step	Equipment	Equipment #	Validation Status	Validation Reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference
Enter process step	Enter piece of equipment	Equip. number	Validated / Incomplete / legacy	Enter report reference

All equipment is in a validated state [with the following exceptions if there are any]. If any exceptions refer to Deviation # in Section # of this report and the deviation log in Appendix # of the protocol.

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The Control limits generated for the process above is based on the combined 30 sample data from each batch. To visualise the between batch variation the 30 data points from each batch should have separate control limits to show uniformity.

9.3 Final Blend Release test results

The Table 9.3.1 below details the release blend test results for [enter product name and lot number]. All release blend testing specifications have been met. Refer to [enter Appendix number] of this report for product results.

Table 9.3.1 – Release Blend Results for [enter batch number]

Test Name	Specification	Test Method	[enter batch number]
Enter test name	Enter specification number	Enter test method number	Enter result
Enter test name	Enter specification number	Enter test method number	Enter result
Enter test name	Enter specification number	Enter test method number	Enter result
Enter test name	Enter specification number	Enter test method number	Enter result
Entered by:			Date:
Transcription Verified by:			Date:

[Refer to where data is attached].

All validation assay test results and release blend test results meet their required specifications. The blend assay results for lot [enter lot number] are considered acceptable.

9.4 Final Blend Physical Test Results

9.4.1 Analysis of [enter lot number]

A composite sample of the final blend for [enter lot number] was tested for particle size distribution as per test methods [enter test method/s] respectively. This data was taken for information purposes and will be compared to the next scheduled validation batch. Refer to Technical services Request ID No. [enter number if applicable] in [enter Appendix number] of this report for Physical results. This batch is compared here to the previous validation batch [enter batch number].

Table 9.4.1.1 – Carr's Index and Hausner Ratio of final blend [enter lot number] versus previous validation [batch/es and enter lot number] (if available)

Batch Number	Bulk Density As is (ml/g)	Bulk Density Tapped (ml/g)	Carr's Index	Hausner Ratio
Enter batch number	Enter result	Enter result	Enter result	Enter result
Enter previous batch number	Enter result	Enter result	Enter result	Enter result
Entered by:			Date:	
Transcription Verified by:			Date:	

[enter reference to calculations in workbook]