

Process Validation Interim / Final Report

(Reference: SOP _____)

[Enter Product Title, Number & Strength]

PRODUCT CODE:

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Qualification Status

Qualification of [enter raw material item description, item code] as per protocol [enter protocol no] has been completed for the following:

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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.

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- 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.

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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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