Packaging Validation Report
(Reference: SOP _____)

2   SCOPE

The scope of this packaging validation is to evaluate the ruggedness of the packaging process on the [insert packaging line name] for the following product:

- [insert product name]

The packaging validation was performed as per the requirements of [insert reference].

3   RESPONSIBILITIES

Report Author

The signature of the report author indicates that the document has been created in compliance with all relevant policies and procedures, that the validation has been executed as per protocol requirements and that the results documented in the report have been accurately transferred from the protocol

Technical Department

The Technical Services signature indicates that the report is in accordance with site requirements and all applicable procedures. Technical Services are responsible for reviewing all packaging validation data and ensuring its accuracy and completeness. Any calculations, transcriptions from or references to workbooks must be verified as accurate.

Packaging

The packaging signature (as the end users of the system) indicates that the packaging validation study as described covers the functionality required for packaging operations and is suitable for routine operation.

Quality Assurance

The Quality Assurance signature indicates that the GMP aspects of the study are in accordance with relevant procedures and critical parameters and report conclusions are supported.

4   REFERENCES

[insert references as per protocol]

5   SYSTEM AND PROCESS DESCRIPTION

5.1   System Description

The [insert packaging line name] is comprised of the following equipment:

[insert equipment components on line above as per protocol]

5.2   Process Description

The Line X is a Blister Packaging Line employed to package tablets into sealed PVC/Aluminium foil blisters embossed with a batch number and expiry date. The blisters are then packed into cartons and the cartons are embossed with a batch number and expiry date and glue sealed at each end. The cartons are then stacked and shrink-wrapped, and placed in a shipper.

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Appendix 1

Validated Ranges for [state parameter] on [state equipment name]

State parameters and equipment name with asset number

Example of a table:

	Cartoner Speed (cartons/min)	Blister Packer Speed (Cycles/min)	Upper heating plate Temperature (°C) (MT2013)	Lower heating plate Temperature (°C) (MT2014)	Sealing Plate Temperature (°C) (MT2015)
Validated Settings	Include validated range here				