	Performance Qualification	Protocol #: PQP- xxx Ver 01
Gismo Heat Sealer		Page 1 of 6



Performance Qualification Protocol


Prepared March 2008

Title	Heat Sealer Validation
Products	Sterile Gizmos – Codes 12345 through 12789
Equipment/Process to be Validated	Supplier Co., Model xyz, ABC Manufacturing Equipment Register: MER 98-1248 / Heat Sealing Process: SOP 20-12-14
Equipment Number	PPCN 98-364

Approval of the Validation Protocol

Sign here after reviewing and approving the document, standards and schedules

Title	Name	Signature	Date
Written By:			
Approved By:			
Validation Coordinator			
Laboratory Manager			
Technical/ Quality Assurance Manager			
Process Engineer			

	Performance Qualification	Protocol #: PQP-xxx Ver 01
Gismo Heat Sealer		Page 2 of 6

1 Section 1: Purpose

Supplier Co. has developed a new and improved heat sealer, which should improve process flow and reduce setup time. The heat sealer will be validated to assure it performs with existing barrier pouch materials and existing process procedure SOP 20-12-14. SOP 20-12-14 identifies a design requirement for a seal strength of 2 to 4 kg and a target of 3 kg. The most difficult pouches to seal are the smallest (PN 96-122) and the largest (PN 88-010). The target process capability is a Cpk of >1.33.


2 Section 2: Reference Documents

1. Heat Seal Process Procedure, SOP 20-12-14
2. Statistical Methodologies, SOP 3-8-51, SOP 3-9-12, SOP 3-13-81
3. Master Device Records, Codes 12xxx
4. Manufacturing Equipment Register, MER 98-1248
5. Supplier Co. Model xyz Heat Sealer Operating Manual
6. Process Validation Master Plan: PVP-98001
7. Lab Processes and Calibration: SOP 9-2-5
8. Production Processes and Calibration: SOP 20-1-2
9. Clean Room Procedures: SOP 1-12-77

3 Performance Qualification Pre-requisites

The sealer must pass IQ and OQ phases of qualification before commencing the performance qualification phase.

In addition interim or proposed manufacturing instructions should be drafted and approved, all measuring instruments should be calibrated, the sealer should pass a safety inspection and operators trained in the manufacturing instructions.

	Performance Qualification	Protocol #: PQP-xxx Ver 01
Gismo Heat Sealer	Page 3 of 6	

IQ Status

Installation Qualification has been successfully completed. Refer to report # IQR

Name	Signature	Date
------	-----------	------

OQ/PQ Status

Operational/Performance Qualification has been successfully completed. Refer to report # OQR

Name	Signature	Date
------	-----------	------

Equipment List

Measurement / Testing Equipment and Calibration:


1. Stopwatch, Process Development Lab, Calibrated per SOP 9-2-5
2. Remote IR Thermometer RST-12, Process Development Lab, Calibrated per SOP 9-2-5
3. Pressure gauge, 0 – 500kPa, Process Development Lab, Calibrated per SOP 9-2-5
4. VAR meter, ID 683, Process Development Lab, Calibrated per SOP 9-2-5
5. Heat Seal Pull Tester, PE 8167, Production, Calibrated per SOP 20-1-2

Performance Qualification Conditions

Performance Qualification will commence after satisfactory completion of installation and operational qualification.


The normal production process will be used. Production personnel will be trained on the use of the new heat sealer. Worst case combinations of time, temperature and pressure will be evaluated.

Optimal settings for the heat sealer will be used and the heat seal action levels for adjustment of time, temperature and pressure will be used.

	Performance Qualification	Protocol #: PQP-xxx Ver 01
Gismo Heat Sealer	Page 4 of 6	

4 Performance Qualification – Experimental Plan


Aim	To provide documented evidence that the bag heat sealing step is capable and reliable and can consistently manufacture products that meet pre-approved specifications.			
Procedure Reference	List Process Instructions # and Version for the steps		List Products manufactured at this step	
# of Experimental Runs (default = 3	Run #1	Lot #:	Date:	Where:
	Run #2	Lot #:	Date:	Where:
	Run #3	Lot #:	Date:	Where:
Process Variables (Factors)	Machine (Line) speed, seal dwell time, warm up time of sealer, Pouch width, operator(s),			
Process Measures: List the process parameters to be measured during the run	Monitor and Record	Expected Operating Ranges		
	Seal Dwell Time	30.0 sec – 45.0 sec		
	Sealer Temperature	200oC – 250oC		
	Sealer Pressure	1.0 bar – 1.5 bar		
	Line Speed	40 / hour - 60/ hour		
	Operator(s)	Use at least 2 different operators		
Experimental Details Describe the experimental approach for each run:	Runs will be completed as follows: 1) with the optimal settings per the Device Master Record target conditions - repeat 2 times 2) with a short dwell time (30 sec), low temperature (200oC) and low pressure (1.0bar); repeat 2 times 3) long dwell time (45sec), high temperature (250oC) and high pressure (1.5bar) repeat 2 times. Action levels for adjustment of the heat sealer will be determined as a result of this phase. Conduct each run with at least 300 bags.			
Sample and Test Plan	Describe the sampling plans for each run (number, location, frequency etc) Sample size: 3 consecutive bags per time Sample frequency: every 15 minutes, also 10 at start and last 10 bags Test: Subject each sample to the seal integrity challenge test SOP xxx			
Acceptance Criteria**	Statistical methods in SOP 3-x-x will be used as appropriate to analyse the data. 1. Seal strength Cpk must be greater than 1.33 across each run. 2. All sampled bags must be within acceptance limits 2.0Kg to 4.0Kg ** If any run does not meet the accept criteria raise a validation deviation notice.			

	Performance Qualification	Protocol #: PQP-xxx Ver 01
Gismo Heat Sealer		Page 5 of 6

5 Signature Record

All personnel involved in this qualification must complete the table below to provide identification of all the signatures/initials used in this document.

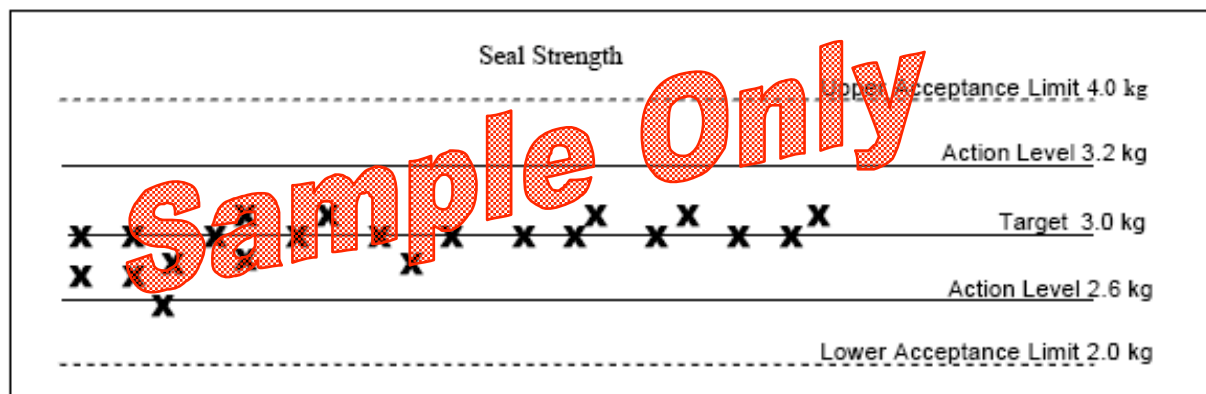
Company	Title	Name & Signature	Initials & Date

	Performance Qualification	Protocol #: PQP-xxx Ver 01
Gismo Heat Sealer		Page 6 of 6

6 Example PQ Report

Performance Qualification Results PVP 98-101

Normal production of codes 12345 and 12789 were run utilizing pouches PN 96-122 and PN 88-010. Optimal heat sealer settings were used. The heat sealer was allowed to warm-up with normal cycling for one half-hour prior to use. A week of production was completed for each code. Accelerated sampling plan 2-C from SOP 3-9-12 was used and the results control charted. Following is a typical control chart:



The resultant C_{pk} was 1.75 for the overall process during this performance qualification. The comparison of the C_p results for each day demonstrated that the process was both stable and capable. The following C_p values were calculated:

PN 96-122: 1.8, 1.9, 1.7, 1.6, 1.7;
PN 88-010: 1.6, 1.8, 1.7, 1.9, 2.0.

The centering of results about the target was very close: overall average seal strength was 2.93 kg with a target of 3.0 kg

The action levels were never reached, and therefore no adjustments were made and no root causes identified.

Lab Notebook Reference:

Quality Engineering Lab Notebook, JWS, 99-1, pages 1 – 48.

Issues / Commentary

The process has demonstrated stability and capability.

The Manufacturing Equipment Register, MER 98-1248, has been updated to include maintenance and calibration of the new heat sealer.

The Process Validation Master Plan, PVP-98001 has been updated to include the new heat sealer in the revalidation process.