



# Process Validation Report Template

11 May 2023 / PharmaSafe Manufacturing, Inc. /  
Camilla Moralez

Complete

Actions	2
<b>Site conducted</b>	Unanswered
<b>Manufacturer</b>	
PharmaSafe Manufacturing, Inc.	
<b>Manufacturing Facility</b>	3784 Benedum Dr., VA 23219
<b>Equipment/System</b>	
Direct Compression	
<b>Protocol Author</b>	Camilla Moralez
<b>Conducted on</b>	11.05.2023 16:03 PST

**Actions**

2 actions

Process Validation Report Template / Qualification Protocol

**Environmental requirements**

Temperature

Humidity

To Do | Assignee Jona Tarlengco | Priority Medium | Due 22.05.2023 16:08 PST | Created by SafetyCulture Staff

Add waste management requirement

Process Validation Report Template / Qualification Protocol

**SOPs available**

Operation

Disaster Recovery

Cleaning

To Do | Assignee Juhlian Pimping | Priority Medium | Due 22.05.2023 16:09 PST | Created by SafetyCulture Staff

Formulate Preventive Maintenance SOP

## Equipment Criticality & Risk Assessment

### Mixing Tanks

Direct Impact



Photo 1



Photo 2



Photo 3



Photo 4

### Risk Priority

High

### Raw Material and Consumable Refrigerators and Freezers

Indirect Impact

### Risk Priority

Medium

### Toxic Gas Detectors

Safety Impact

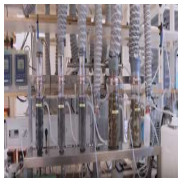


Photo 5

### Risk Priority

Medium

### Pipettes

No Impact

### Risk Priority

Low

### Product Transfer Pumps

Direct Impact

### Risk Priority

High

### Unfiltered HVAC System

Indirect Impact

### Risk Priority

Low

### Dust Extraction

Safety Impact

### Risk Priority





Medium

### Trolleys

No Impact

### Risk Priority

Low

<b>Laminar Flow and Safety Cabinets</b>	Direct Impact
<b>Risk Priority</b>	Medium
<b>Safety Barriers</b>	Safety Impact
<b>Risk Priority</b>	Low
<b>Scissors/Clamps</b>	No Impact
<b>Risk Priority</b>	Low
<b>Emergency Stops</b>	Safety Impact
<b>Risk Priority</b>	Low
<b>Retort Stands</b>	No Impact
<b>Risk Priority</b>	Low
<b>Product Storage Refrigerators and Freezers</b>	Direct Impact
<b>Risk Priority</b>	High
<b>Personal Protection Equipment</b>	Safety Impact
   <p>Photo 6      Photo 7      Photo 8</p>	
<b>Risk Priority</b>	Low
<b>Filling Equipment</b>	Direct Impact
 <p>Photo 9</p>	
<b>Risk Priority</b>	High
<b>Production Balances</b>	Indirect Impact
<b>Risk Priority</b>	High

**Autoclaves**

Direct Impact

**Risk Priority**

High

**Centrifuges**

Indirect Impact

**Risk Priority**

High

**Fire Suppression Systems**

Safety Impact

**Risk Priority**

Medium

**Process Water Generators**

Direct Impact



Photo 10



Photo 11

**Risk Priority**

High

**Automated Cleaning Equipment**

Indirect Impact

**Risk Priority**

Medium

**Filtered HVAC Systems**

Direct Impact

**Risk Priority**

Medium

**Manual Cleaning Equipment**

No Impact

**Risk Priority**

Low

## Qualification Protocol

2 actions

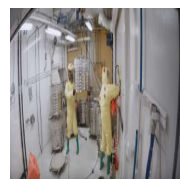
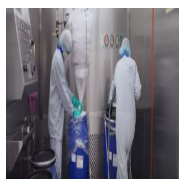
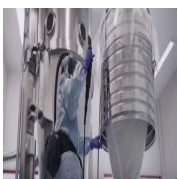
**Process(es) subject to process validation**

Mixing

Filling

Tableting

Release



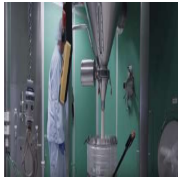


Photo 18

**Environmental requirements**

Temperature

Humidity

To Do | Assignee Jona Tarlengco | Priority Medium | Due 22.05.2023 16:08 PST | Created by SafetyCulture Staff

Add waste management requirement

**Utilities supply**

Electricity

Clean steam boiler

Compressed air

Nitrogen

**SOPs available**

Operation

Disaster Recovery

Cleaning

To Do | Assignee Juhlian Pimping | Priority Medium | Due 22.05.2023 16:09 PST | Created by SafetyCulture Staff

Formulate Preventive Maintenance SOP

**Calibration Equipment**

**Calibration Equipment 1**

**Apparatus/Instrument**

Materials testing machine

**Calibration Method**

Force in the tensile direction (0.02 N - 3,000 kN)

**Calibration Date**

11.05.2023 16:00 PST

**Calibration Equipment 2**

**Apparatus/Instrument**

Pendulum impact tester

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**Calibration Method**

Force in the compression direction (0.002 N - 5,000 kN)

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**Calibration Date**

11.05.2023 16:10 PST

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**Calibration Equipment 3****Apparatus/Instrument**

Brinell hardness tester

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**Calibration Method**

Ball indentation

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**Calibration Date**

11.05.2023 16:14 PST

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**Results****Results 1****Control Point/Alarm**

Lubrication blend time: 34 - 46 min

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**Output**

Uniform dosage units

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**Calibration**

Tensile direction 1,436 kN

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**Results 2****Control Point/Alarm**

Compression dwell time: 0.53 - 0.78 ms

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**Output**

Conforming tablet core disintegration and dissolution

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**Calibration**

Conforming tablet core disintegration and dissolution

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**Results 3**

**Control Point/Alarm**

Mill screen size 17 - 26 mm

**Output**

Conforming granule compactibility and particle size distribution

**Calibration**

N/A

**Acceptance Criteria Vs. Performance Test Results**

**Acceptance Criteria Vs. Performance Test Results 1**

**Criteria**

A specific, stability-indicating procedure should be included to determine the content of the new drug substance. In many cases it is possible to employ the same procedure (e.g., HPLC) for both assay of the new drug substance and quantitation of impurities.

**Result**

Acceptable assay and impurity levels

**Decision**

Pass

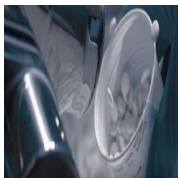


Photo 19

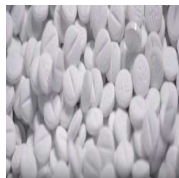


Photo 20



Photo 21

**Area(s) of Deviation**

Specification

**Deviations**

**Deviations 1**

**Requirement/Order**

Perform Factory Acceptance Test

**Actual**

Factory Acceptance Test not performed

**Justification for Acceptance**

PharmaSafe Quality Assurance Manager performed Site Acceptance Test with Supplier Representative



## Impact on Operation, Function, or Process

Negligible

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## Completion

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### Qualification Protocol Results

All acceptance criteria have been met according to qualification protocol and all deviations resolved.

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### Conclusions on the validity of the equipment/system

Qualification of direct compression as per qualification protocol has been completed for the routine commercial production for a new formula.

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### Production Officer Name & Signature



Julian Rodrigo  
11.05.2023 16:14 PST

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### Validation Manager Name & Signature



Camilla Moralez  
11.05.2023 16:14 PST

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### Head of Quality Assurance Name & Signature



Shine Obligacion  
11.05.2023 16:14 PST

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## Media summary



Photo 1



Photo 2



Photo 3



Photo 4



Photo 5



Photo 6



Photo 7



Photo 8



Photo 9



Photo 10



Photo 11



Photo 12



Photo 13



Photo 14



Photo 15



Photo 16



Photo 17



Photo 18



Photo 19



Photo 20



Photo 21