21 May 2019 / PharmaSafe Manufacturing, Inc. / Camilla Moralez

Process Validation Report Template Conducted on **21st May, 2019** By **SafetyCulture Staff**

Complete

Created actions

2

Site	Manila
Manufacturer	PharmaSafe Manufacturing, Inc.
Manufacturing Facility	3784 Benedum Dr., VA 23219
Equipment/System	Direct Compression
Protocol Author	Camilla Moralez
Conducted on	21st May, 2019 12:18 PM +08

Actions

2 Actions

SafetyCulture Staff created a High priority action

To Do 27th May, 2019 8:00 AM +08

Add waste management requirement

Detail how we have our own state-of-the-art water treatment plant that enables us us properly manage our waste and comply with statutory requirements

Process Validation Report Template / Qualification Protocol

Environmental requirements

SafetyCulture Staff created a High priority action

To Do 26th May, 2019 8:00 AM +08

Formulate Preventive Maintenance SOP

Coordinate with design engineers, manufacturing technicians and maintenance personnel to come up with preventive maintenance SOP

Process Validation Report Template / Qualification Protocol

SOPs available

Equipment Criticality & Risk Assessment

Mixing Tanks	Direct Impact

Photos


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

Photos


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

Photos

Photo 6

Risk Priority	Low
Laminar Flow and Safety Cabinets	Direct Impact
Risk Priority	Medium
Safety Barriers	Safety Impact
Risk Priority	Low
Scissors/Clamps	No Impact
Risk Priority	Low
Emergency Stops	Safety Impact
Risk Priority	Low
Retort Stands	No Impact
Risk Priority	Low
Product Storage Refrigerators and Freezers	Direct Impact
Risk Priority	High

Personal Protection Equipment	Safety Impact

Photos


Photo 7


Photo 8


Photo 9

Risk Priority	Low
Filling Equipment	Direct Impact

Photos


Photo 10

Risk Priority	High
Production Balances	Indirect Impact
Risk Priority	High
Autoclaves	Direct Impact
Risk Priority	High
Centirfuges	Indirect Impact
Risk Priority	High
Fire Suppression Systems	Safety Impact
Risk Priority	Medium

Process Water Generators	Direct Impact

Photos


Photo 11


Photo 12

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

Photos


Photo 13


Photo 14


Photo 15


Photo 16


Photo 17


Photo 18


Photo 19

Environmental requirements

Temperature Humidity

Actions

To Do **Detail how we have our own state-of-the-art water treatment plant that enables us us properly manage our waste and comply with statutory requirements**

Utilities supply

Electricity Clean steam boiler Compressed air Nitrogen

SOPs available

Operation Cleaning Disaster Recovery

Actions

To Do **Coordinate with design engineers, manufacturing technicians and maintenance personnel to come up with 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

10th Apr, 2019 12:27 PM +08

Calibration Equipment 2

Apparatus/Instrument

Pendulum impact tester

Calibration Method

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

Calibration Date

22nd Apr, 2019 12:31 PM +08

Calibration Equipment 3

Apparatus/Instrument

Brinell hardness tester

Calibration Method

Ball indentation

Calibration Date

9th May, 2019 12:32 PM +08

Results

Results 1

Control Point/Alarm Lubrication blend time: 34 - 46 min
Output Uniform dosage units
Calibration Tensile direction 1,436 kN

Results 2

Control Point/Alarm Compression dwell time: 0.53 - 0.78 ms
Output Conforming tablet core disintegration and dissolution
Calibration Compression direction 3,754 kN

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

Photos


Photo 20

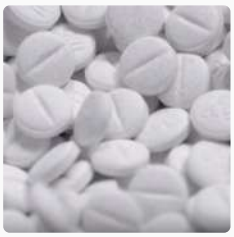
Photo 21


Photo 22

Area(s) of Deviation — Specification

Deviations

Deviations 1

Requirement/Order

Perform Factory Acceptance Test

Actual

Factory Acceptance Test not performed

Deviation

User Requirements Specification and Purchase Order

Justification for Acceptance

PharmaSafe Quality Assurance Manager performed Site Acceptance Test with Supplier Representative

Impact on Operation, Function, or Process

Negligible

Completion

Qualification Protocol Results

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

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.

Production Officer Name & Signature

Julian Rodrigo

21st May, 2019 2:29 PM +08

Validation Manager Name & Signature

Camilla Moralez

21st May, 2019 2:29 PM +08

Head of Quality Assurance Name & Signature

Shine Obligacion

21st May, 2019 2:30 PM +08

Photos

22 Photos

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

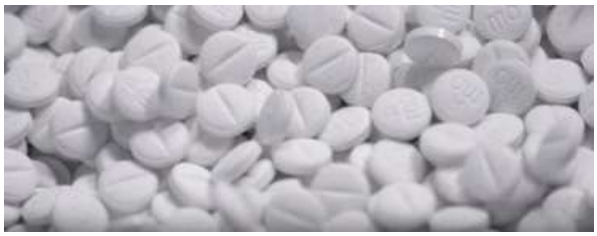

Photo 22