**Installation/Operational Qualification Partial Report**

**For the**

**New Blending Suite in Building 1**

**at**

**Aphena Pharma Solutions, Easton, MD**

**Protocol Number: IQOQ2020-020R**

**Revision: 0**

**Date: 10/08/2020**

**Protocol Approvals**

This Installation/Operational Qualification protocol partial report (IQOQ2020-020R Rev 0) provide and evaluated the proper installation and capabilities of the New Blending Area, T3 Work Center B26 in Building 1 at Aphena Pharma Solutions, Easton. The IQOQ partial report has been reviewed, is understood, and is approved by:

|  |  |  |  |
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**Revision History**

|  |  |  |  |
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| **Revision** | **Date** | **Reason for Change** | **Person Completing Change** |
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1. Summary

The qualification activities performed to the T3, Work Center B26 demonstrated that the area operation meets the design specification before their use for the blending process.

All test required by the Installation Qualification and Operational Qualification Protocol, IQOQ2020-020 for the T3, Work Center B26 were successfully executed and completed.

1. Purpose

The purpose of this Partial Report is to provide documented evidence to demonstrate that T3 Work Center B26, one of the three blending areas that compose the New Blending Suite, was constructed and operates on a repeatable and consistent basis in accordance to the specified design criteria.

The following Blending areas are included in Protocol IQOQ2020-020:

* T1, B25 1000 gallons tank
* T2, B24 100 gallons tank
* T3, B26 1000 gallons tank

This Partial Report also provide documented evidence to a high degree of assurance, to support that the T3, Work Center B26 area, consistently operates to produce the desired execution in conformance with Aphena Pharma Solutions requirements, and current Good Manufacturing Practices (cGMP’s).

1. Scope

This Partial Report summarizes the T3, Work Center B26 area qualification activities as part of the Installation Qualification and Operational Qualification, IQOQ2020-020, of the New Blending Suite at the Aphena Pharma Solutions Manufacturing Facility in 7978 Industrial Park Road, Easton, Maryland.

1. System Description

The Aphena Pharma Solutions facilities is a building campus manufacturing facility, located in Easton, Maryland. The temperature/Humidity-controlled Blending Suite sits on the South/West side of the building 1. The area of the Blending Suite is 1535 square feet. There are three (3) blending areas and a Motor Control Center (MCC). The blending areas are identified as; T1 (B25, 1000-gallons), T2 (B24, 100-gallons), and T3 (B26, 1000-gallons), which are used to blend materials. The heating ventilation and air conditioning system (HVAC), AC-1, AC-2, AC-3 and their correspondently air handling units, AHU-A1, AHU-A2 and AHU-3A are supplied by TRANE.

1. Summary of Results



6. 1. **General Procedure**



11. 1. 1. **Signature Identification Log**

Each individual (documenting results and/or initializing any page or section) that participates in the IQ/OQ protocol execution (including Reviewed By individual(s)) shall enter their enter their printed name, signature, initials, and department on the Signature Identification Log in Attachment 1, Signature Identification Log.

**Status:** *Signatures related to execution of T3, B26, are completed,* ***Attachment still open.***

* + 1. **Training Log**

It is the responsibility of the persons performing operations associated with this protocol to have read and understood this document and understand their job specific functions prior to the protocol being executed. Use **Attachment 2**, Training Log, to document this information.

**Status**: *Training related to execution of T3, B26, is completed,* ***Attachment still open.***

* + 1. **Protocol Deviation Report Form**

During the execution of the IQ/OQ protocol log any deviation that occurs in **Attachment 3**, Protocol Deviation Report Form, to report the investigation and resolution of all deviations.

**Status**: *No deviation,* ***Attachment still open.***

* + 1. **Safety Inspection**

Use **Attachment 4** to document that a “Safety Inspection” was conducted and is approved. The objective of this review is to verify that that the Blending Suite B7 complies with Aphena safety guidelines.

**Status**: *Safety assessment for work center WC B26 issued and attached;* ***Attachment still open****.*

* + 1. **Test Instrument Log**

Use **Attachment 5** to document the calibration for all calibrated test instruments that are used for the execution of this IQ/OQ protocol.

**Status**: *Test Instruments related to execution of T3, B26, are documented;* ***Attachment still open.***

* + 1. **Supplemental Documentation Log**

Use **Attachment 6** to document all supplemental documentation identified during the IQ/OQ to support the execution.

**Status***:**Documents related to execution of T3, B26, are recorded;* ***Attachment still open.***

* 1. **Installation Qualification**

5. 2. 1. **Document Verification**

Use **Attachment 7** to document equipment manuals, submittals, and technical literature received from vendors for major components for the operation and maintenance of the New Blending Suite. The documents should include operation and maintenance instructions.

**Status**: ***Attachment still open.***

* + 1. **Major Components Verification**

Use **Attachment 8** to verify that the major components are installed per the manufacturer’s specifications. Verification can either be performed visually or using vendor documentation.

This verification shall be acceptable if major components are as identified and installed in accordance with manufacturer’s specifications, design criteria, safety features, and other Aphena Pharma Solutions requirements.

**Status**: *Major components related to New Blending Suite were verified and are in compliance;* ***Attachment was closed.***

* + 1. **Installation Verification**

Use **Attachment 9** to verify that the configuration and general installation conditions of the New Blending Suite meet all design requirements. Verification can either be performed visually or using vendor documentation.

This verification shall be acceptable if the New Blending Suite configuration and general installation conditions meet the specified requirements.

**Status**: *Installation information related to work center WC B26 is completed;* ***Attachment still open.***

* + 1. **Drawing Verification**

Use **Attachment 10** to document that the New Blending Suite drawings are redlined and field verified to match the “As Built” condition. Include any additional drawings if applicable. Identify documents on the Supplemental Documentation Log **Attachment 6**.

This verification shall be acceptable if the equipment/system drawings are verified to meet the current field conditions.

**Status**: *Drawings identified, red-lined and attached;* ***Attachment was closed.***

* + 1. **Material of construction Verification**

Use **Attachment 11** to verify that the materials of construction of the New Blending Suite components meet Aphena requirements. If the information regarding a required parameter is not directly available via visual inspection, the data may be obtained from the component submittals or similar documentation. Identify documents on the Supplemental Documentation Log **Attachment 6**.

This section shall be acceptable if the materials of construction are documented in **Attachment 11** and meet the manufacturer’s specifications, design criteria, safety features, and other Aphena requirements.

**Status**: *Material of construction information related to New Blending Suite is documented,* ***Attachment was closed.***

* + 1. **Utility Verification**

Use **Attachment 12** to verify that the New Blending Suite has the required supporting utilities for operation. Ensure that utilities are properly connected and identified via labels. If the information regarding a required parameter is not directly available via visual inspection, the data may be obtained from the component submittals or similar documentation. Identify documents on the Supplemental Documentation Log **Attachment 6**.

**Status**: *Installation information related to New Blending Suite is completed,* ***Attachment was closed.***

* + 1. **Instrument Calibration Verification**

Use **Attachment 13** to verify that New Blending Suite critical instruments are assigned unique identifier, have the correct accuracy and range for their intended use, are calibrated, and are incorporated into the Aphena calibration program. Additionally, verify that all non-critical instruments that don’t require calibration are identified and labeled.

This verification shall be acceptable if all new instruments are documented in **Attachment 13** and calibration certificates for critical instruments are available. Non-critical instruments not requiring calibration are identified and labeled.

**Status**: ***Attachment still open.***

* + 1. **Standard Operation Procedures (SOP) Verification**

Use **Attachment 14** to verify that New Blending Suite operation and maintenance SOPs are generated. A complete draft of the SOP may be used to meet the requirements for this protocol as long as Aphena SOP number is assigned to it.

This verification shall be considered acceptable if the New Blending Suite Operation and Maintenance SOPs are documented in **Attachment 14**, are generated in at least draft form, and have Aphena SOP number assigned.

**Status**: *Environmental Monitoring SOP, LC 009, revision drafted;* ***Attachment still open.***

* + 1. **Spare Parts List Verification**

Use **Attachment 15** to verify that a spare parts list is available and that recommended spare parts are identified for the New Blending Suite components. Identify documents on the Supplemental Documentation Log **Attachment 6**.

This section shall be acceptable if the spare parts list for the New Blending Suite components is documented in **Attachment 15**, is available, and recommended spare parts are identified.

**Status**: ***Attachment still open.***

* 1. **Operational Qualification**

5. 3. 1. **Parameters Verification**

Use **Attachment 16** to document New Blending Suite HVAC units’ parameters. Utilize equipment printouts where available.

This section shall be acceptable if all equipment parameters are documented.

**Status**: *All parameters related to the New Blending Suite were documented;* ***Attachment was closed.***

* + 1. **Functional Verification**

Use **Attachment 17** to verify the operation of the control systems for all applicable equipment and to verify the equipment responds correctly to modified conditions.

This verification shall be acceptable if all specified equipment responds correctly to modified conditions as specified.

**Status**: *Functional verification related the New Blending Suite equipment was executed;* ***Attachment was closed.***

* + 1. **Disaster Recovery and Power Failure Verification**

Use **Attachment 18** to verify the recovery to normal operations of each piece of equipment and the entire system after a power failure.

This verification shall be acceptable if all equipment returns to normal operation after experiencing a loss in power.

**Status**: *Power Failure Verification related the New Blending Suite equipment was executed;* ***Attachment was closed.***

* + 1. **System Air Balance Verification**

Use Attachment 19 to verify that an Environmental Monitoring exercise has been conducted in the New Blending Suite.

This verification shall be acceptable if the system Air Balance findings complies with all design requirements and the report is approved.

**Status:** *Room T3, WC B26 is pressurized against “ANTE” room. Test show that air flow from WC B26 room to “ANTE” room as design,* ***Attachment still open.***

* + 1. **System Monitoring**

Use **Attachment 20** to verify that an Environmental Monitoring exercise has been conducted in the New Blending Suite.

This verification shall be acceptable if the system meets all **attachment 20** Aphena operating requirements as per SOP LC 009 without any critical deviation.

**Status**: *Environmental Monitoring of WC B26 performed and results attached,* ***Attachment still open.***

* + 1. **Execution Checklist**

Use **Attachment 21** to verify that all the requirements of this Installation and Operational Qualification Protocol have been completed and the appropriate data forms have been reviewed.

**Status**: ***Attachment still open.***

1. Conclusions and Recommendation

Based on the data obtained from the partial execution of the Installation Qualification Operational Qualification Protocol IQOQ2020-020 it was demonstrated that the Blending Area T3, Work Center B26 is capable to maintain a repeatable and consistent performance.

The partial qualification activities of Protocol IQOQ2020-020 were satisfactorily completed. Therefore, the evaluated Blending Area, T3 Work Center B26, is considered qualified.

After the qualification of the New Blending Suite areas; T1 Work Center B25 and T2 Work Center B24, a Final Qualification Report will be issued.