	Title	Protocol Number
	<b>Installation/Operational Qualification for the New Blending Suite in Building 1</b>	<b>IQQ2020-020 Rev 0</b>

## **Attachment 20 – System Monitoring**

### **Objective:**

The objective of this section is to verify that the system was monitored.

### **Procedure:**

5. Verify that the “Environmental Monitoring” evaluation have been completed for the system.
6. Attach the results of the “Environmental Monitoring Evaluation” performed to the equipment.
7. Any deficiencies found in the evaluation report (if any) should be corrected.
8. Complete the information requested by the test case form.

### **Acceptance Criteria:**


The “Environmental Monitoring Evaluation” for the equipment must be performed, completed and attached. Deficiencies found on the evaluation must be corrected (if any) and complies with SOP LC 009 requirements.

### **Result:**

Have the acceptance criteria been met? (Y/N) \_\_\_\_\_ If Not, Deviation No: \_\_\_\_\_

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

	Title	Protocol Number
	Installation/Operational Qualification for the New Blending Suite in Building 1	IQQQ2020-020 Rev 0

Attachment 19 – System Monitoring (Cont.) ①

Step	Step Description	Expected Results	Actual Results	Meets Criteria? (Y/N)	Performed By / Date
1	Conduct the “Environmental Monitoring Evaluation” of the system.	The “Environmental Monitoring Evaluation” report has been issued.	The “Environmental Monitoring Evaluation” report has _____ issued.		
2	Attach copy of the “Environmental Monitoring Evaluation” report.	A copy of the “Environmental Monitoring Evaluation” report is attached.	A copy of the “Environmental Monitoring Evaluation” report _____ attached.		

Comments: ① Environmental monitoring of WC B26 was conducted on 10/08/2020 with satisfactory results. APP 10/08/2020

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Neftali Perez Rosario

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**From:** Julie Currie  
**Sent:** Thursday, October 8, 2020 1:21 PM  
**To:** Neftali Perez Rosario  
**Cc:** Rafeh Raza; Kevin Bobal  
**Subject:** RE: WC B26

COPY

*RC*  
10/08/2020

As per LC 009 Rev 16 DRAFT  
10/8/20

**Particle Counter:**

SITE	FREQUENCY	Greater than or equal to 0.5µm
B26 Area	Monthly	218

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**From:** Julie Currie  
**Sent:** Thursday, October 8, 2020 10:50 AM  
**To:** Neftali Perez Rosario <nperezrosario@aphenapharma.com>  
**Cc:** Rafeh Raza <rraza@aphenapharma.com>; Kevin Bobal <kbobal@aphenapharma.com>  
**Subject:** RE: WC B26

Hello Everyone,

I just performed the EM in B26 and although the micro for the air will be off on Monday October 19<sup>th</sup> the particle count is complete now. The result is **218** count, for it to pass ISO 8 it needed to be below 100,000 count. Hopefully some good news today, 😊

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