OPERATIONAL QUALIFICATION PROTOCOL/REPORT

COMPRESSED AIR SYSTEM

DOCUMENT NO. :

VERSION NO. :

DATE OF ISSUE :

XX PHARMACEUTICALS LIMITED
117 Adams Street, Brooklyn, NY 11201, USA

Approval of Document:

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CONTENTS

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1. DOCUMENT DESCRIPTION

Document No. :

Version No. :
Date :
Description :

2. PURPOSE

To verify and document that the oil free air compressor system operates as designed and intended. The operational parameters should be consistent with the requirements for the Manufacturing process. The OQ is aimed to verify that the installed equipment performs according to the manufacturer's specifications.

3. SCOPE

This Operational Qualification (OQ) is to be performed against agreed acceptance criteria on the air compressor systems, comprising of compressor, drying system, filtering system, piping, control system etc. installed in the General Block of XX Pharmaceuticals Ltd. The scope will include assessment of equipment design and installation, connection to utilities, presence & function of instruments.

The scope will include the operational testing of the normal sequence of operation and verification of the target limits of operation.

4. RESPONSIBILITIES

4.1 Preparation of protocol

Engineering Department.

4.2. Executing the protocol

Engineering department or other suitably qualified staff allocated from the site or contracted specialists as appropriate.

4.3. Providing documentation on the equipment

Related departments i.e. engineering Production, Validation or other appropriate departments and manufacturer.

4.4. Data documentation and preparation of the report

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Raw data documentation is the responsibility of those conducting the validation. Preparation of the report and incorporation of data will be the responsibility of the Engineering Department.

5. BACKGROUND

5.1 Project Description & Related issues

This air compressor system is installed to serve General and Cephalosporin Block. To meet the demand of quality of compressed air, this oil free air compressor has been installed.

5.2 Purchasing Information

Item	Brand	Model	Origin
Air Compressor	Atlas Copco	ZT 75	Belgium
Dryer	Atlas Copco	CD185+	Belgium
Air receiver	Atlas Copco	NA	Germany
Piping and distribution	Fabricated	N/A	Local

6. SYSTEM DESCRIPTION

The Atlas Copco Air Compressor and Air Dryer manufactured by Atlas Copco has a capacity of 10.4 m^3/min. Air drawn through an air filter is compressed in low-pressure compressor element and discharged to the intercooler. The cooled air is further compressed in high-pressure compressor element and discharged through silencer and after coolers. A check valve is provided downstream of the silencer. The compressed air leaves the compressor via the air outlet. The compressor delivers oil-free, pulsation-free air.

This is an air cooled type compressor which is facilitated with air filter, moisture trap, high pressure and low pressure safety valve, desiccant type dryer system etc.

After being compressed in compressor the oil free compressed air will be stored in a receiver tank. Air will be dried in the desiccant type dryer and then distributed through pipe line to the different production facility.

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7. VERIFICATION OF COMPLETION OF SOPs

The documents required to be finally approved are listed in the following tables:

Equipment	Details		Effective Date	Initial and Date
Air Compressor	SOP Name:	Operation and Maintenance of Atlas Copco Air Compressor and Air Dryer.		
	SOP No.			

Observations:

Documentation completed: Name.....Designation.....Signature……Date.....

8. VERIFICATION OF TRAINING

All the operators and engineers related to the compressed air system must be trained before execution of Operational Qualification. The training is to be recorded in the following table:

Trainer Name	Training Title	Trainee Name	Signature	Date

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Trainer Name	Training Title	Trainee Name	Signature	Date

Observations:

Training complete and verified by: Name.....Designation..... Signature.....……..Date....……

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9. OPERATIONAL TESTING

9.1 Functional Verification for Air Compressor

Sl. No.	Functional Test	Verification of Compliance with Acceptance Criterion			Remarks
		Compliant (YES/NO)	Initial	Date	
01	After Switching on the voltage, LED light will Illuminate. The panel will power up.				
02	After Pressing start button, The compressor will start running and automatic operation LED light will be illuminate.				
03	After Pressing the stop button. The compressor will stop and LED will go out.				
04	To stop the compressor immediately, press emergency stop button.				

Testing complete and verified by:

Name……Designation……..Signature……Date……..

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9.2 Functional Verification for Air Dryer

Sl. No.	Functional Test	Verification of Compliance with Acceptance Criterion			Remarks
		Compliant YES/NO	Initial	Date	
01	After Switch on Main Circuit Breaker, The control will power on.				
02	After Switch off Main Circuit Breaker, The control will power off.				
03	After Pressing the Start Button" I" ,the dryer will Start up				
04	After Pressing The Stop Button"0", the dryer will stop.				

Testing complete and verified by:

Name……Designation……..Signature……Date……..

9.3 Pressure Test

9.3.1 Test Method:

Measure the terminal pressure as desired user point by a calibrated pressure gauge.

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Record the results in the result sheet in Appendix 01.

9.3.2 Acceptance Criteria:

Pressure has to be within 6 to 8 bar.

10. INSTRUMENT CALIBRATION

Instrument calibration to be recorded in the following tables:

a) Class 4

ID No.	Instrument Description (including function)	Satisfactory Calibration Completion Date	Calibration Record Sheet Reference Number	Initial & Date

b) Reference Instruments

ID No.	Instrument Description (including function)	Within Current Calibration Yes/No	Calibration Record Sheet Reference Number	Initial & Date

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11. DEVIATION AND FAILURE INVESTIGATION SUMMARY

In the column below, record any deviation or failure that occurred during the OQ exercise.

Deviation/ Failure No.	Description and Assessment of Impact on Validation	Initial	Date
1			
2			
3			

4			
5			
6			
7			

12. LIST OF APPENDIX

Appendix 01: Test result sheet of pressure test.

13. ATTACHMENTS

Attachment	Description of Attachment	Initial	Date

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Attached document verified by: Name_____Designation_____.Signature_____Date_____

14. REPORT SUMMARY

The report summary of Operational Qualification of Compressed Air system is as follows:

Sl. No.	Checking parameter	Acceptance Criteria Met		Deviation found	
		Yes	No	Yes	No
1	Verification of completion of SOPs.				
2	Verification of training.				

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3	Operational verification of Air Compressor.				
4	Operational verification of air dryer.				
5	Pressure Test.				

Comments

Performed by: Name_____ Designation _____Signature_____Date_____

Verified by: Name_____ Designation _____Signature_____Date_____

15. CONCLUSION

The Operational Qualification of Compressed Air System installed at General Block **Complies / Does Not Comply** with the acceptance criteria taken above and the results obtained are attached with the protocol.

The Compressed Air System **is / is not** qualifying the Operational Qualification test as per this Protocol. Hence, the system **can be / cannot be** used for Performance Qualification.

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Performed by: Name_____ Designation _____Signature_____Date_____

Verified by: Name _____Designation _____ Signature _____ Date _____

16. VERIFICATION OF COMPLETION

Overall OQ records are satisfactorily completed.

Department	Name	Designation	Signature	Date

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Comments:

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17. REPORT APPROVAL

Name	Designation	Signature & Date
Milton Alvarado	Manager, Engineering	
Laurie Ramirez	Manager, Plant	
Joanna Warner	General Manager, Quality Assurance	

Comments:

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APPENDIX 01
Pressure Test

Sl. No.	Date	Room No.	Room Name	Terminal Pressure (bar)	Acceptance Criteria (bar)	Verification of Compliance (Yes/No)	Initial & Date
1		SPR012	Wash Bay		6 – 9		
2		SPR016	Solution Preparation		6 – 9		
3		SPR023	Blending		6 – 9		
4		SPR046	Coating Solution Preparation		6 – 9		
5		SPR048	IPC room		6 – 9		
6		SPR049	Washing and Drying		6 – 9		
7		SPR050	Dry syrup filling and sealing		6 – 9		
8		GPK003	Packing hall		6 – 9		
9		SQC010	Chemical Laboratory		6 – 9		
10		SQC013	Physical Laboratory		6 – 9		
11		SQC009	A.A.S & GC		6 – 9		
12		SMB011	Media preparation		6 – 9		
13		SPD012	Coating		6 – 9		
14		SPD017	Tablet Compression		6 – 9		
15		SPD014	Granulation (RMG)		6 – 9		
16		SPD014	Granulation (FBD)		6 – 9		
17		SPD022	Wash Bay		6 – 9		
18		SPR018	Granulation		6 – 9		
19		SPR034	Blister Packaging		6 – 9		
20		SPR030	Coating – 1		6 – 9		
21		SPR031	Coating – 2		6 – 9		
22		SEN007	Lab PW plant		6 – 9		
23		SPR025	Tablet Compression		6 – 9		
24		SPR027	Encapsulation		6 – 9		
25		SRT017	Filter Washing		6 – 9		

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Sl. No.	Date	Room No.	Room Name	Terminal Pressure (bar)	Acceptance Criteria (bar)	Verification of Compliance (Yes/No)	Initial & Date
26		SRT009	Garments Washing and Drying		6 – 9		
27		SRT008	Bottle Washing		6 – 9		
28		SRT006	Material Pulverization		6 – 9		
29		PCR010	Wash Bay		6 – 9		
30		PCR016	Granulation		6 – 9		
31		PCR017	Blending		6 – 9		
32		PCR018	Wash bay		6 – 9		
33		PCR020	IPC room		6 – 9		
34		PCR030	PFS room		6 – 9		
35		PCR030	PFS room		6 – 9		
36		CPK003	Packing Hall		6 – 9		
37		PCR024	Tablet Compression		6 – 9		
38		PCR031	Blister Packaging		6 – 9		
39		PCR028	Coating		6 – 9		
40		PCR025	Encapsulation		6 – 9		
41		CQC007	Chemical Laboratory		6 – 9		
42		CQC005	Physical Laboratory		6 – 9		
43		MCB007	Limit Test		6 – 9		
44		MCB005	Media Preparation		6 – 9		
45		PCD012	Coating		6 – 9		
46		PCD011	Tablet compression		6 – 9		
47		PCD009	Granulation and Blending		6 – 9		
48		PCD008	Wash Bay		6 – 9		

Tested by:	Verified by:

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