

APPLICATION NOTE

VALIDATION TEST FOR COMPRESSED AIR AND GAS
MICROBIOLOGICAL MONITORING

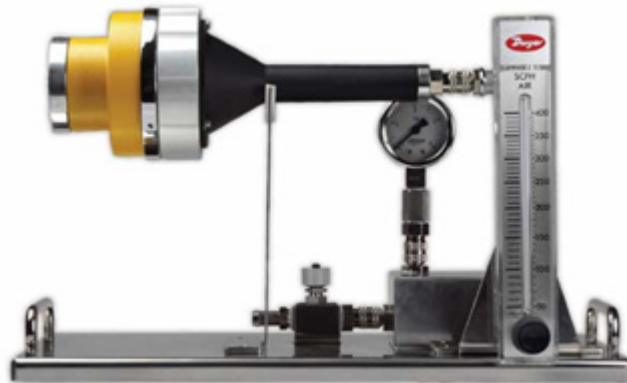
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APPLICATION NOTE

□ Introduction

The compressed air and the gases used in the pharmaceutical and biotechnology plants for drug production in Clean Rooms and in controlled environments should be periodically tested for sterility. The Standard Operating Procedure reported in this Application Note is a guideline how to perform such validation.



“Pinocchio Super” (Code: 39089)

□ STANDARD OPERATING PROCEDURE

- OBJECT

Validation test for “Pinocchio Super” equipment for compressed air and gases microbiological monitoring

- OBJECTIVE

Evaluation of the unit to test its suitability to collect micro-organisms from compressed air and gases used in Clean Rooms

- GLOSSARY

Bacterial population, certification, compressed air, CFU, Colony Forming Unit, contact plates, RODAC plates, sterility, sterilisation, validation

- REFERENCES

USA and European Pharmacopeia

- RESPONSIBILITY

Director of the project

- SAFETY

The operators should apply the basic safety precautions for laboratory biological risks

- MATERIAL

Equipment:

“Pinocchio Super” device (Cat.n. 39089 for contact plates, 35025 for Petri dishes) complete with connections, air flow meter, pressure gauge, tap, funnel head complete of Contact Plate Housing

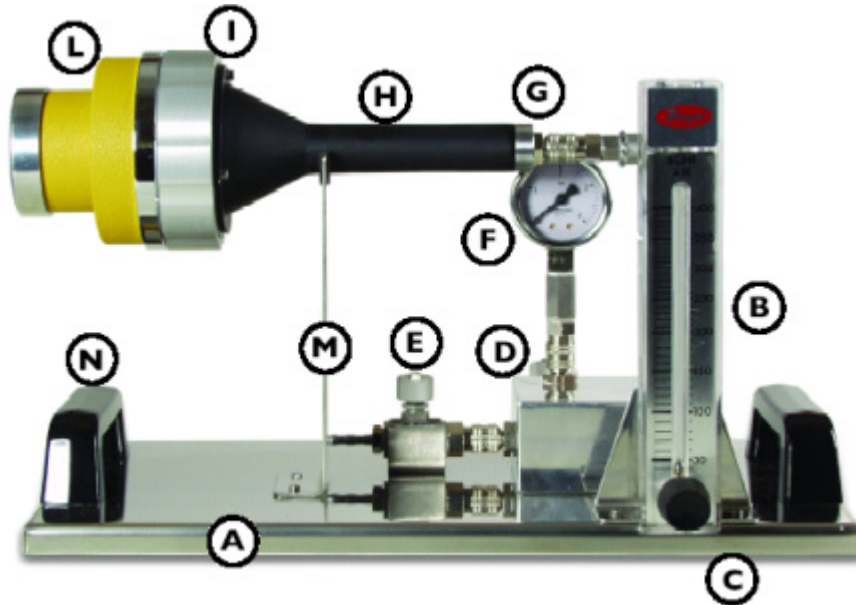
Material:

Contact plates with Plate Count Agar
Incubator for Contact plates

- PROTOCOL

1. Installation

- 1.1. Sterilisation by autoclaving (121°C for 20 minutes) of the “Pinocchio Super” metal base and funnel head (excluding the air flow meter and the pressure gauge). Use the aluminium foil to protect the base during the sterilisation
- 1.2. Application of the air flow meter, pressure gauge to the metal base of “Pinocchio Super”
- 1.3. Connection of the “Pinocchio Super” inlet to the compressed air or gas source
- 1.4. Connection of the air flow meter outlet to the funnel head
- 1.5. Screw the funnel head to the Contact Plate Housing



Components of “Pinocchio Super”:

- (a) Stainless steel base.
- (b) Air flow meter (the figures are in feet)
- (c) Adjustment knob of the air flow meter
- (d) Air inlet connection and valve
- (e) Air outlet connection and valve
- (f) Pressure gauge
- (g) Double O-rings connection between the “Pinocchio Super” and the “Pinocchio funnel”
- (h) “Pinocchio funnel”
- (i) “Pinocchio funnel head”
- (l) Contact Plate housing
- (m) “Pinocchio funnel” support
- (n) Handle

2. Air Washing

- 2.1. Open the compressed air (or gas) tap of the unit and adjust the valve of the air flow meter to 100 l/m to “wash” the system for 2-3 minutes with the air to be subsequently sampled

3. Testing

- 3.1. Close the valve of the air flow meter, unscrew the funnel head and insert a Contact plate with sterile medium inside its housing
- 3.2. Screw the funnel head to the Contact Plate Housing
- 3.3. Open the compressed air (or gas) of the unit and adjust the valve of the air flow meter to 100 l/m. Collect the sample for 10 minutes to obtain 1000 litres (1 cubic meter) of air
- 3.4. Unscrew the funnel head from the Contact Plate Housing, apply the lid to the contact plate and transfer it to the incubator
- 3.5. Incubate the contact plate for 48 hours at 32°C
- 3.6. Report the number of CFU counted on each contact plate on the form, at the end of the incubation time
- 3.7. Each test should be performed in triplicate

4. Microbiological Quality Control

- 4.1. The test should be completed by
 - (a) the growing test of the medium
 - (b) the sterility test of the medium
 - (c) the spiked test of the compressed air (gas)
 - (d) the environment test



“SAS Super 100”

CONVERSION TABLE FROM “SCFH” (standard cubic feet per hour) TO “LPM” (liters per minute)

SCFH	LPM	SCFH	LPM	SCFH	LPM	SCFH	LPM
40	18,876	140	66,066	240	113,256	340	160,446
45	21,236	145	68,426	245	115,616	345	162,806
50	23,595	150	70,785	250	117,975	350	165,165
55	25,955	155	73,145	255	120,335	355	167,525
60	28,314	160	75,504	260	122,694	360	169,884
65	30,674	165	77,864	265	125,054	365	172,244
70	33,033	170	80,223	270	127,413	370	174,603
75	35,393	175	82,583	275	129,773	375	176,963
80	37,752	180	84,942	280	132,132	380	179,322
85	40,112	185	87,302	285	134,492	385	181,682
90	42,471	190	89,661	290	136,851	390	184,041
95	44,831	195	92,021	295	139,211	395	186,401
100	47,190	200	94,380	300	141,570	400	188,760
105	49,550	205	96,740	305	143,930	405	191,120
110	51,909	210	99,099	310	146,289	410	193,479
115	54,269	215	101,459	315	148,649	415	195,839
120	56,628	220	103,818	320	151,008	420	198,198
125	58,988	225	106,178	325	153,368	425	200,558
130	61,347	230	108,537	330	155,727	430	202,917
135	63,707	235	110,897	335	158,087	435	205,277

- RESULTS OF THE TESTS

The present report should be used to perform the validation of the “Pinocchio Super” unit.

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8
	TEST 1/a	TEST 2/a	TEST 3/a	TEST 4/a	TEST 5/a	TEST 6/a	TEST 7/a	TEST 8/a
	CFU/CM	CFU/CM	CFU/CM	CFU/CM	CFU/CM	CFU/CM	CFU/CM	CFU/CM
Growth Test	+++++	+++++	+++	+++	++++	++++	++++	++++
Sterility Test								
Spiked Com-gas Test								
Environment Test								
Compressed gas / air Test								

Note 1. The “spiked test” is performed as for the protocol of this Application Note, but with contaminated “funnel head”

Note 2. All the manipulations should be performed applying the “Good Aseptic Practice”

- INTERPRETATION

The validation test is considered obtained when:

- (a) the growth test of the filled contact plates is positive
- (b) the sterility test of the filled contact plate confirms the absence of CFU
- (c) the environmental test is positive
- (d) the spiked test has a microbial population higher than the compressed air (or gas) test