FN-5401
ISOLATOR SUPPLY FAN
1 950 m3/h @ 850 Pa
EC MOTOR 1.1 kW, VFD
316L HOUSING

F-5401A-D
SUPPLY HEPA FILTERS
H14 (EN 1822) 610 x 457 mm
DOP / PAO SCAN PORTS
INITIAL dP 110 Pa

F-5405 / F-5406
PRE-FILTER / EXHAUST HEPA
ePM1 80 % / H14 BAG-IN-BAG-OUT
EXHAUST 480 m3/h

FN-5402 / 5403
EXHAUST FANS (DUTY / STBY)
480 m3/h @ 1 200 Pa
AUTO CHANGEOVER ON FAULT

CC-5401
CATALYTIC CONVERTER
PALLADIUM ON ALUMINA
H2O2 OUTLET < 1 ppm

HG-5431
VHP GENERATOR
FLASH VAPORISER 2 - 12 g/min
CLOSED LOOP, DESICCANT DRYER
H2O2 35 % w/w, 1 L BOTTLE
VENDOR PACKAGE VP-5431

GLT-5451
GLOVE PORT LEAK TESTER
PRESSURE DECAY, 10 PORTS
TEST 1 000 Pa / 10 min

EMS-5401
ENVIRONMENTAL MONITORING
4 PARTICLE COUNTERS 28.3 L/min
2 ACTIVE AIR SAMPLERS
21 CFR PART 11 HISTORIAN

AT-5441 / 42 / 43
H2O2 MONITORS
0 - 2 000 ppm (GASSING)
0 - 10 ppm (AERATION)
0 - 10 ppm ROOM SAFETY

IS-5201
FILLING ISOLATOR
SEE DB-A7-PID-5102
+50 Pa vs GRADE C

INSTRUMENT AIR 6 barg
UTL-5001 / B2

DN15-IA-5401-A1C-N

CONTINUED
HVA-5402 / D8

SUPPLY AIR AHU-5410
HVA-5402 / D8

500 x 300 DS-5410

MAKE-UP AIR FROM GRADE C ROOM

F-5405 ePM1

BD-5401 FC

400 x 250 DS-5401

CAV-5411 650 m³/h

CAV-5412 910 m³/h

TH-5411 TERMINAL HEPA H14

TH-5412 TERMINAL HEPA H14

R-5402 GRADE C FILL ROOM (+30 Pa, 25 ACH)
BACKGROUND ENVIRONMENT OF IS-5201

EXTRACT TO AHU-5410
HVA-5402 / B8

MD-5413

ROOM PRESSURE BY BMS (PDT-5402)

M

SC 5401 VFD

FN-5401

Ø250 DS-5402

PDT 5422

TT 5425 ISOLATOR AIR

MT 5426 RH

TT 5415 ROOM

MT 5416 ROOM

BMS

UY 5400

BD-5402 FO

XV-5435 FC

DN25-VHP-5433-S3A-ET

Ø200 DS-5403

XV-5436 FC

F-5401A H14 F-5401B H14 F-5401C H14 F-5401D H14

IS-5201 FILLING ISOLATOR (PLAN SCHEMATIC)
GRADE A - UNIDIRECTIONAL AIRFLOW 0.45 m/s ± 20 %

PC-5451 PC-5452 PC-5453 PC-5454

SP-01 SP-02 SP-03 SP-04 SP-05 SP-06 SP-07 SP-08

AAS-5471 AAS-5472

AT 5442 0-10 ppm

AT 5441 0-2000 ppm

GP-01 GP-02 GP-03 GP-04 GP-05 GP-06 GP-07 GP-08 GP-09 GP-10

TEST CAPS ON FLEX HOSE MANIFOLD

VHP BIO-DECONTAMINATION CYCLE (TYPICAL, VALIDATED CYCLE VC-5431-03)

CONDITIONING | GASSING | DWELL | AERATION

H2O2 ppm (AT-5441 / AT-5442)

RH % x 10 (MT-5426)

H 250 Pa

0 250 500 750

0 30 60 90 120 150 180 TIME (min)

+1 bar RELEASE

AT 5461 AT 5462 AT 5463 AT 5464

PARTICLE COUNTERS 0.5 / 5.0 µm
ISOKINETIC TUBES, 1.5 m MAX

UY 5401 EMS-5401 HISTORIAN

AE 5471 AAS HEADS 2 x 100 L/min

PDI 5423 H 450 Pa

PDT 5423

PDT 5421 ISOLATOR vs ROOM

PDIC 5421 SP +50 Pa / PDAL +25 Pa

A 5421 LOW ISOLATOR dP OR GLOVE BREACH HOLD FILLING (I-5211, PID-5102)

F-5406 H14 BIBO

BD-5403 FC

MD-5404 FO

FN-5402 DUTY

FN-5403 STBY

SC 5405

SC 5406

CC-5401 CATALYST

UC 5430 GENERATOR PLC CYCLE SEQUENCER

DN6-H2-5431

T-5431 H2O2 35 %

WE-5431 SCALE

WT 5431 CONSUMPTION

SC 5434 INJECTION g/min

F-5431 FLASH VAPORISER

TIC 5435 PLATE 120 °C

F-5431 DOSING

CC-5432 CATALYST

D-5432 DESICCANT DRYER

MT 5437 DEW POINT

F-5433 H14

E-5432

BL-5432

CARRIER 20 m3/h

FIC 5435

FT 5436

TIC 5436 CARRIER 60 °C

HG-5431 VHP GENERATOR - VENDOR PACKAGE LIMIT

PT 5451

PDT 5452 DECAY < 30 Pa

GLT-5451
GLOVE PORT LEAK TESTER
PRESSURE DECAY, 10 CHANNELS

AT 5443 ROOM SAFETY ALARM 1 ppm

5441

ROOM H2O2 > 1 ppm: ABORT GASSING, CLOSE XV-5435, BEACON + EVACUATION ALARM

PRESSURE CASCADE AND ROOM MONITORING (NOMINAL, AT REST)

CNC CORRIDOR **0 Pa** ← PDT 5491 PDAL ← GRADE D CORRIDOR **+15 Pa** ← PDT 5492 PDAL ← GRADE C FILL ROOM **+30 Pa** ← PDT 5493 ← IS-5201 ISOLATOR **+50 Pa**

AIR FLOWS FROM HIGH TO LOW PRESSURE (ARROWS). ALARMS TO BMS AFTER 60 s DELAY; DOOR OPENINGS MASKED FOR 30 s.

SHEET NOTES

1. DUCTS ARE SHOWN AS DOUBLE LINES; DIMENSIONS ARE INTERNAL, mm. DS = WELDED STAINLESS DUCT.
2. BD = BUBBLE-TIGHT ISOLATION DAMPER (LEAK CLASS 4, EN 1751). MD = MODULATING DAMPER.
3. DURING VHP THE ISOLATOR IS SEALED BY BD-5401 / BD-5403; FN-5401 RECIRCULATES THE AGENT.
4. AERATION ENDS WHEN AT-5442 < 1 ppm FOR 10 min AT THE WORST CASE LOCATION.
5. ROOM SAFETY MONITOR AT-5443 AND I-5441 ARE INDEPENDENT OF THE GENERATOR PLC.
6. ILLUSTRATIVE SPECIMEN: ALL TAGS, DUTIES AND FIGURES ARE FICTIONAL.

DAMPER / VALVE POSITIONS BY OPERATING PHASE (I-5431 SEQUENCE)

PHASE	BD-5401	BD-5402	BD-5403	MD-5404	XV-5435	XV-5436	FN-5401	FN-5402	HG-5431
PRODUCTION	OPEN	OPEN	OPEN	MOD	SHUT	SHUT	RUN	RUN	OFF
GLOVE LEAK TEST	OPEN	OPEN	OPEN	MOD	SHUT	SHUT	RUN	RUN	OFF
CONDITIONING	SHUT	OPEN	SHUT	SHUT	OPEN	OPEN	RUN	OFF	DRY
GASSING	SHUT	OPEN	SHUT	SHUT	OPEN	OPEN	RUN	OFF	INJECT
DWELL	SHUT	OPEN	SHUT	SHUT	OPEN	OPEN	RUN	OFF	INJECT
AERATION	OPEN	SHUT	OPEN	MOD	OPEN	OPEN	RUN	RUN	CATALYSE

REV	DATE	DESCRIPTION	BY	CHK	APPR
0	2026-07-14	ISSUED FOR DESIGN	RD	MIB	TV
B	2026-05-22	ISSUED FOR HAZOP	RD	MIB	TV
A	2026-03-06	ISSUED FOR INTERNAL REVIEW	RD	MIB	TV

ORYVIA BIOLOGICS SA
STERILE DRUG PRODUCT MANUFACTURING

AURELIA SITE - BUILDING 7
FILL / FINISH LINE 5 - PROJECT 24-0317

DATE 2026-09-24

DRAWING TITLE

PIPING AND INSTRUMENTATION DIAGRAM

FILLING ISOLATOR IS-5201 - AIR HANDLING AND VHP BIO-DECONTAMINATION

UNIT 5400 - CLEANROOM HVAC

DRAWN	CHECKED	PROCESS APPROVAL	QA APPROVAL	ENGINEERING CONTRACTOR
R. DELACOUR 2026-09-24	M. ISHIKAWA-BRENT 2026-09-24	T. VANHOUTE 2026-09-24	S. ABERKANE 2026-09-24	VELDRAN ENGINEERING PARTNERS

ILLUSTRATIVE DOCUMENT - NOT FOR CONSTRUCTION

DRAWING NUMBER	REV	SHEET	SCALE	SIZE
OB-A7-HVA-5401	0	1 OF 1	NONE	ANSI D