STERILE BOUNDARY IS DEFINED BY F-3003A AND F-3003B.

REDUNDANT FILTRATION PER ISO 13408-2; BOTH FILTERS INTEGRITY TESTED BY FIT-3001 PRE-USE POST-STERILISATION AND POST-USE.

DOSING BY TIME-PRESSURE: DV-3001 HELD AT 0.8 barg N2 BY PCV-3051; FILL VOLUME SET BY NEEDLE OPEN TIME.

SHEET NOTES

1. REDUNDANT STERILISING FILTRATION F-3003A / F-3003B IN SERIES, BOTH INTEGRITY TESTED PER ISO 13408-2.
2. PRE-USE POST-STERILISATION INTEGRITY TEST ON F-3003A ONLY; BOTH FILTERS TESTED POST USE.
3. PRODUCT CONTACT PATH DOWNSTREAM OF THE SPEC BREAK IS A GAMMA IRRADIATED SINGLE USE ASSEMBLY.
4. TIME-PRESSURE DOSING CONTROLLED BY PIC-3051 ON DV-3001; FILL WEIGHT VERIFIED BY IN-PROCESS CHECK WEIGHING.
5. INTERLOCK IS-3001 STOPS FILLING ON LOSS OF FILTER DIFFERENTIAL PRESSURE OR ISOLATOR dP.
6. SEE OB-A7-PID-3002 FOR THE ISOLATOR, STOPPER BOWL AND ENVIRONMENTAL MONITORING POINTS.

REV	DATE	DESCRIPTION	BY	CHK	APPROVED
1	2026-09-18	HAZOP ACTIONS 12, 17 AND 24 INCORPORATED	RD	MIB	SA
0	2026-07-14	ISSUED FOR DESIGN FREEZE	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
BIOLOGICS MANUFACTURING

AURELIA SITE - BUILDING 7
DRUG SUBSTANCE / DRUG PRODUCT

DATE: **2026-09-18**

DRAWING TITLE

PIPING AND INSTRUMENTATION DIAGRAM
ASEPTIC FILLING LINE - PRODUCT PATH AND STERILE FILTRATION
UNIT 3000 - DRUG PRODUCT

DRAWN	CHECKED	PROCESS APPROVAL	QUALITY APPROVAL	ENGINEERING CONTRACTOR
R. DELACOUR 2026-09-18	M. ISHIKAWA-BRENT 2026-09-18	T. VANHOUTE 2026-09-18	S. ABERKANE 2026-09-18	**VELDRAN ENGINEERING PARTNERS** ILLUSTRATIVE DOCUMENT - NOT FOR CONSTRUCTION

DRAWING NUMBER	REV	SHEET	SCALE	SIZE
OB-A7-PID-3001	**0**	**1 OF 2**	**NONE**	**ANSI D**

PRESSURE CASCADE: ISOLATOR +45 Pa, GRADE B ROOM +30 Pa, GRADE C +15 Pa, CNC 0 Pa (REFERENCE).

BIO-DECONTAMINATION CYCLE: CONDITIONING 15 min, GASSING 35 min AT 8 g/min, DWELL 40 min, AERATION TO < 1 ppm H2O2.

EM DATA LINK SHOWN WITH ISA-5.1 SOFTWARE LINK SYMBOL; ALL EM POINTS ALARM TO EMS-3001 AND THE LINE PLC.

SHEET NOTES

1. ISOLATOR IS-3001 IS BIO-DECONTAMINATED WITH VAPOURISED HYDROGEN PEROXIDE FROM HG-3001.
2. AERATION CONTINUES UNTIL AT-3111 READS LESS THAN 1 ppm H2O2 AT THE WORST CASE LOCATION.
3. PDIC-3121 MAINTAINS +45 Pa RELATIVE TO THE SURROUNDING GRADE B ROOM AT ALL TIMES.
4. CONTINUOUS NON-VIABLE PARTICLE MONITORING AT PC-3001 TO PC-3003 DURING ALL FILLING OPERATIONS.
5. VIABLE AIR SAMPLING EM-3001 AND EM-3002 AT NOT LESS THAN 1 m3 PER OPERATING SHIFT.
6. GLOVE PORTS GP-3001 TO GP-3007 LEAK TESTED BEFORE AND AFTER EVERY BATCH.

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ORYVIA BIOLOGICS SA
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AURELIA SITE - BUILDING 7
DRUG SUBSTANCE / DRUG PRODUCT

DATE: **2026-09-18**

DRAWING TITLE

PIPING AND INSTRUMENTATION DIAGRAM
ASEPTIC FILLING LINE - ISOLATOR, STOPPER BOWL AND MONITORING
UNIT 3000 - DRUG PRODUCT

DRAWN	CHECKED	PROCESS APPROVAL	QUALITY APPROVAL	ENGINEERING CONTRACTOR
R. DELACOUR 2026-09-18	M. ISHIKAWA-BRENT 2026-09-18	T. VANHOUTE 2026-09-18	S. ABERKANE 2026-09-18	VELDRAN ENGINEERING PARTNERS

ILLUSTRATIVE DOCUMENT - NOT FOR CONSTRUCTION

DRAWING NUMBER	REV	SHEET	SCALE	SIZE
OB-A7-PID-3002	0	2 OF 2	NONE	ANSI D