WM-5101
VIAL WASHING MACHINE
ROTARY, 4 STATIONS + ULTRASONIC BATH
300 VIALS/min 2R - 20R
WFI 0.9 m³/h CA 60 Nm³/h
VENDOR PACKAGE VP-5101

T-5101
RECIRCULATION TANK
60 L, 316L ATM / FV
DESIGN 95 °C
INSULATED

P-5101
RECIRCULATION PUMP
2.4 m³/h @ 3.5 bar
SANITARY CENTRIFUGAL
1.1 kW 400 V VFD

E-5101
RECIRCULATION HEATER
PLATE, CLEAN STEAM
22 kW 70 °C OUTLET
DOUBLE WALL PLATES

DT-5101
DEPYROGENATION TUNNEL
HOT AIR, 3 ZONES, BELT 600 mm
STERILISING 320 °C / 10 min
3 log ENDOTOXIN REDUCTION
HEATERS 3 x 18 kW

FN-5111 / 12 / 13
ZONE FANS (INFEED / HOT / COOL)
2 400 / 3 100 / 2 600 m³/h
VFD, EC MOTORS
HOT ZONE FAN RATED 350 °C

F-5111 / 12 / 13
ZONE HEPA FILTERS
H14 / H13 HT (350 °C) / H14
INITIAL dP 120 / 180 / 120 Pa
FACE VELOCITY 0.45 m/s

E-5113
COOLING COIL
CHW 6 / 12 °C 38 kW
316L FINS, DRAINABLE

FN-5114
HOT ZONE EXHAUST FAN
450 m³/h @ 600 Pa
RATED 250 °C 0.75 kW

CV-5140
TUNNEL BELT DRIVE
SPEED 30 - 250 mm/min
0.37 kW GEARED VFD

CHILLED WATER SUP. 6 °C — UTL-5001 / B2 — DN50-CHS-5104-C2A-IC
CHILLED WATER RET. 12 °C — UTL-5001 / B2 — DN50-CHR-5105-C2A-IC
COMPRESSED AIR 6 barg — UTL-5001 / B2 — DN25-CA-5103-A1C-N
WFI 80 °C LOOP — UTL-5001 / B2 — DN40-WFI-5102-S3A-IH
CLEAN STEAM 3.0 barg — UTL-5001 / B2 — DN50-CS-5101-S1C-IH

CONTINUED — PID-5102 / D8 (×6)
HOT EXHAUST — HVA-5401 / C7

DN150-EX-5117-DS-IP

HV-5113
DN15-WFI-5114-S3A-IH
XV-5104 FC
PCV-5105
PI 5105
PSL 5105
F-5102 STERILE AIR 0.2 µm
XV-5108 FC
FT 5104
0.9 m³/h
FQI 5104
DN15-CA-5116-A1C-N
DN15-WFI-5115-S3A-IH
DN25-CS-5113-S1C-IH

WM-5101 WASH CHAMBER
S1 RECIRC. WFI + ULTRASONIC
S2 AIR BLOW
S3 FRESH WFI FINAL RINSE
S4 AIR BLOW (FINAL)
S5 OUTFEED
XV-5106 FC
XV-5107 FC
VIALS FROM TL-5001
UT-5101 ULTRASONIC 2 kW

S3 CASCADE OVERFLOW
I 5101
LOW LEVEL T-5101 OR LOW AIR: STOP P-5101 AND WM-5101
XV-5111 FC
DN40-RW-5112-S3A-N
DN25-RW-5111-S3A-IH
TIC 5102 SP 70 °C
TT 5102
VENT
MAKE-UP, AIR GAP
DN25-RW-5110-S3A-IH
LAL 25 % LAH 90 %
LIC 5103
T-5101 60 L
N1 N2 N3 N4 N5 N6
TCV-5102 FC
E-5101 PLATE HEATER
F-5101 PRE-FILTER 5 µm
LT 5101
T ST-5101
PDT 5103
PDI 5103
H 80 kPa
CLEAN CONDENSATE UTL-5007 / A3
P-5101 RECIRC. PUMP
SP-5101 SAMPLE
HV-5101
TD-5101 AIR BREAK TO DRAIN

WM-5101 VIAL WASHING MACHINE - VENDOR PACKAGE LIMIT

ePM1 80%
SC 5111
M
FN-5111
PDIC 5116 +10 Pa vs WASH RM
PDT 5116
PDI 5117
PLENUM

ePM1 80%
SC 5112
M
FN-5112
PDIC 5126 -5 Pa vs Z1
PDT 5126
PDI 5127
PLENUM
EH-5112A
EH-5112B
EH-5112C

ePM1 80%
SC 5113
M
FN-5113
PDIC 5136 +15 Pa vs FILL RM
PDT 5136
PDI 5137
PLENUM
E-5113 CHW COIL

FN-5114
MD-5114 M
TCV-5132 FO

Z1 INFEED / PRE-HEAT GRADE A
F-5111
Z2 STERILISING (HOT) ZONE 320 °C
F-5112
Z3 COOLING ZONE GRADE A
F-5113

M CV-5140 BELT DRIVE

TT 5111 Z1 AIR
TI 5111
SIC 5140
I 5121 I-5121: BELT STOPS IF ANY Z2 TE < 300 °C OR ANY ZONE FAN FAULT; VIALS IN Z2 ARE REJECTED AT FL-5201 INFEED (SHEET 2)

TE 5121A
TE 5121B
TE 5121C
TE 5121D
TE 5121E
TE 5121F
TY-5121 MULTIPOINT TEMPERATURE SCANNER (6 x TYPE K, CLASS 1)
SP 320 °C TAL 300 / TAH 340
TIC 5121
SCR POWER CONTROLLER
JY 5121
TR 5121 BATCH RECORD 21 CFR 11

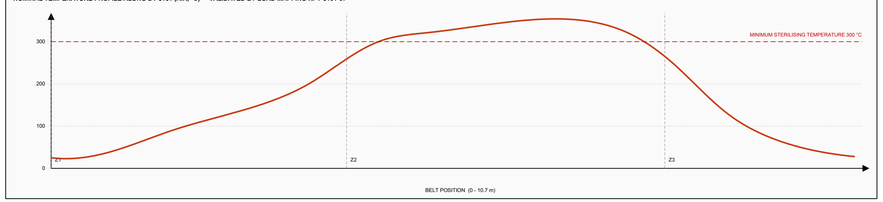
TE 5122
TSHH 5122 350 °C
I 5122
TRIPS EH-5112A/B/C MAIN CONTACTOR, FANS RUN ON (HARDWIRED, SIL 1)

TT 5131 Z3 AIR
TI 5131
TAH 35 °C
TT 5132 VIAL OUTLET
TIC 5132
0.5 / 5.0 µm (BOXNETX)
AT 5139
TO EMS-5401

DEPYROGENATED VIALS — PID-5102 / A8

DT-5101 DEPYROGENATION TUNNEL - VENDOR PACKAGE LIMIT

NOMINAL TEMPERATURE PROFILE ALONG DT-5101 (AIR, °C) - VALIDATED BY LOAD MAPPING RPT-5101-07



SHEET NOTES

1. VENDOR PACKAGE BOUNDARIES SHOW THE LIMIT OF SUPPLY; INTERNAL WIRING PER VENDOR DRAWINGS.
2. WASHER S3 FINAL RINSE USES FRESH WFI ONLY; S3 OVERFLOW CASCADES TO T-5101 FOR S1 REUSE.
3. DT-5101 Z2 TEMPERATURE BY SIX TYPE K ELEMENTS; LOWEST READING IS THE CONTROLLED VARIABLE.
4. I-5122 IS HARDWIRED AND INDEPENDENT OF THE LINE PLC (HAZOP ACTION H-12).
5. ZONE PRESSURES KEEP AIR FLOWING FROM THE COOLING ZONE TOWARDS THE WASHING ROOM.
6. ILLUSTRATIVE SPECIMEN: ALL TAGS, DUTIES AND FIGURES ARE FICTIONAL.

REV	DATE	DESCRIPTION	BY	CHK	APPR
1	2026-09-24	HAZOP ACTIONS H-07, H-12 AND H-19 INCORPORATED (CLOUDED)	RD	MB	SA
0	2026-07-14	ISSUED FOR DESIGN	RD	MB	TV
B	2026-05-22	ISSUED FOR HAZOP	RD	MB	TV
A	2026-03-06	ISSUED FOR INTERNAL REVIEW	RD	MB	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
ASEPTIC FILLING LINE 5 - VIAL WASHING AND DEPYROGENATION
UNIT 5100 - COMPONENT PREPARATION

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-PID-5101	1	1 OF 4	NONE	ANSI D

V-5201
PRODUCT BUFFER VESSEL
150 L 316L EP Ra < 0.4 µm
-1 / +3 barg @ 140 °C
JACKET -1 / +6 barg
LOAD CELLS 3 x 150 kg

AG-5201
MAGNETIC MIXER
BOTTOM MOUNTED, 60 - 400 rpm
0.25 kW SANITARY

F-5201A / B
STERILISING FILTERS
0.2 µm PES 10 in REDUNDANT
IN SERIES ISO 13408-2
STEAM IN PLACE 121 °C

FIT-5201
FILTER INTEGRITY TESTER
BUBBLE POINT / DIFFUSION
AUTOMATED, 21 CFR 11

IS-5201
FILLING ISOLATOR
RIGID WALL, 10 GLOVE PORTS
GRADE A ISO 5 +50 Pa
VHP BIO-DECONTAMINATION
SEE OB-A7-HVA-5401

V-5202 / V-5241
SURGE AND RECOVERY BAGS
5 L / 10 L SINGLE USE
GAMMA IRRADIATED

P-5211 ... P-5218
PERISTALTIC DOSING PUMPS
8 HEADS, 0.5 - 25 mL
ACCURACY ±0.5 %
SERVO, CLOSED LOOP

SB-5221
STOPPER BOWL
VIBRATORY, 20 mm STOPPERS
400 / min, RTU BAGS

WT-5231
IPC CHECKWEIGHER
TARE / GROSS, 100 %
RESOLUTION 0.1 mg

RTP-5201 / 5202
RAPID TRANSFER PORTS
ALPHA 190 mm / 270 mm
INTERLOCKED DOORS

CHILLED WATER SUP. 6 °C — PID-5101 / D1 — DN50-CHS-5104-C2A-IC
CHILLED WATER RET. 12 °C — PID-5101 / D1 — DN50-CHR-5105-C2A-IC
COMPRESSED AIR 6 barg — UTL-5001 / B3 — DN25-CA-5103-A1C-N
WFI 80 °C LOOP — PID-5101 / D1 — DN40-WFI-5102-S3A-IH
CLEAN STEAM 3.0 barg — PID-5101 / D1 — DN50-CS-5101-S1C-IH
NITROGEN 4 barg — UTL-5001 / B3 — DN15-N2-5106-A1C-N
CIP SUPPLY — UTL-5002 / B2 — DN25-CIS-5207-S3A-N
BULK DRUG PRODUCT — PID-4205 / C1 — DN25-PD-5201-S3A-N
CIP RETURN — UTL-5002 / B3 — DN25-CIR-5209-S3A-N
CLEAN CONDENSATE — UTL-5001 / A3 — DN25-CC-5222-S1C-IH
DEPYROGENATED VIALS — PID-5101 / B1
CONTINUED — PID-5103 / D8
FILLED, STOPPERED VIALS — PID-5103 / C8

XV-5207 FC
PCV-5204
PIC 5203 SP 0.3 barg
VENT
XV-5205 FO
PT 5203
XV-5200 FC
F-5203 HEATED VENT FILTER
0.2 µm
TO CIP-5201
RD-5201 3.5 barg
V-5201 150 L
SB-5201
TIC 5206 SP 5 °C
TT 5206
TCV-5206 FO
HIGH WEIGHT: CLOSE XV-5200
I 5201
WIC 5201 WARN 140 kg
3 LOAD CELLS SUMMING BOX
WT 5201
AG-5201
XV-5202 FC
DN15-PD-5202-S3A-N
XV-5208 FC
T ST-5201
TE 5221 SIP 121 °C
XV-5221 FC
DN50-CHS-5208-C2A-IC
FILTER dP HIGH OR PURT FAIL: HOLD FILLING
PDI 5211 H 1.5 bar
PDT 5211
PDI 5213 H 1.5 bar
PDT 5213
PT 5212 SIP / PURT
0.2 µm
IT-5201A
IT-5201B
F-5201A
F-5201B
T ST-5202
T ST-5203
FLEX HOSE
FIT-5201 AUTOMATED FILTER INTEGRITY TESTER BUBBLE POINT / DIFFUSION
XV-5210 FC
DN15-PD-5203
53A SU-01
AC-5201 STERILE CONNECTOR
XV-5214
V-5202 SURGE BAG 5 L
WT 5202
LEVEL BY WEIGHT
WIC 5202
SU-5204 6.4 mm ID
F-5401A H14
F-5401B H14
F-5401C H14
F-5401D H14
RTP-5202 TOOLS / EM MEDIA
EM LOCATIONS PER RISK ASSESSMENT EM-RA-5201: PC = ISOKINETIC PARTICLE PROBE, SP = SETTLE PLATE, AAS = ACTIVE AIR SAMPLER HEAD. SEE OB-A7-HVA-5401 FOR SAMPLING LINES.
AAS-5461
AAS-5462
SP-01
SP-02
SP-03
SP-04
PC-5451
PC-5452
PC-5453
V-5241 RECOVERY 10 L
XV-5241
RTP-5201 STOPPER BAG
SB-5221 STOPPER BOWL
LS 5221 BOWL LOW
VIBRATORY DRIVE
CHUTE
P-5211
P-5212
P-5213
P-5214
P-5215
P-5216
P-5217
P-5218
DOSE CTRL 8 AXES
SCL
ST 5222
FILLING NEEDLES N-5211 ... N-5218 ON SERVO LIFT BEAM
VIAL PATH
TARE
WT 5230
NET FILL IPC ±2 %
WIC
WT 5231
RJ-5231 REJECT TRAY
XV-5232 GATE
IS-5201 FILLING ISOLATOR - GRADE A (ISO 5 IN OPERATION)
UNIDIRECTIONAL AIRFLOW 0.45 m/s - +50 Pa vs GRADE C ROOM - HVAC / VHP / EM. SEE OB-A7-HVA-5401
GP-01
GP-02
GP-03
GP-04
GP-05
GP-06
GP-07
GP-08
GP-09
GP-10

SHEET NOTES

1. REDUNDANT STERILISING FILTRATION F-5201A / B IN SERIES. PRE-USE POST-STERILISATION TEST ON F-5201A.
2. PRODUCT PATH DOWNSTREAM OF AC-5201 IS A GAMMA IRRADIATED SINGLE USE ASSEMBLY (SPEC SU-01).
3. DOSE CONTROL: WIC-5231 TRIMS SC-5211 PER PUMP HEAD FROM THE 100 % IPC CHECKWEIGHER RESULT.
4. I-5211 HOLDS FILLING ON FILTER dP HIGH OR PUIT FAILURE (HAZOP ACTION H-07, CLOUDED).
5. SIP OF V-5201 AND FILTER TRAIN AT 121 °C / 30 min, VERIFIED AT LOW-POINT TE-5221.
6. ILLUSTRATIVE SPECIMEN: ALL TAGS, DUTIES AND FIGURES ARE FICTIONAL.

REV	DATE	DESCRIPTION	BY	CHK	APPR
1	2026-09-24	HAZOP ACTIONS H-07, H-12 AND H-19 INCORPORATED (CLOUDED)	RD	MIB	SA
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
ASEPTIC FILLING LINE 5 - PRODUCT PATH AND ISOLATOR FILLER
UNIT 5200 - ASEPTIC FILLING

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-PID-5102	1	2 OF 4	NONE	ANSI D

CP-5301
CRIMP CAPPER
ROTARY, 6 CRIMP HEADS
400 VIALS/min 20 mm CAPS
CRIMP FORCE MONITORED
GRADE A AIR SUPPLY (LAF)

CB-5301
CAP SORTING BOWL
VIBRATORY, 20 000 CAPS
RTU CAPS, BAG FED

FN-5301 / F-5301
LAF UNIT
1 800 m3/h 0.45 m/s
H14 HEPA, 1.2 x 0.6 m

FN-5306 / F-5306
CAPPING EXTRACT
350 m3/h @ 450 Pa
H13 BEFORE FAN

VI-5311
AUTOMATED VISUAL INSPECTION
100 %, 400 VIALS/min
4 PARTICLE + 2 COSMETIC CAMERAS
NIR FILL LEVEL, HVLD LEAK TEST
VENDOR PACKAGE VP-5311

UY-5316
VISION COMPUTER
RECIPE MANAGED, 21 CFR 11
IMAGE ARCHIVE 90 DAYS

RT-5321
REJECT HANDLING
3 LOCKED BINS CAT. A / B / C
COUNTS TO MES RECONCILIATION

TL-5331
TRAY LOADER
PICK AND PLACE, 2 AXES
TRAYS 240 VIALS (12 x 20)
MAGAZINE 12 TRAYS

AT-5331
ACCUMULATION TABLE
ROTARY, 1 200 VIALS
BUFFER 3 min AT 400/min

CV-5341
OUTFEED CONVEYOR
TO SECONDARY PACKAGING
PKG-6001

CHILLED WATER SUP. 6 °C — PID-5102 / D1 — DN50-CHS-5104-C2A-IC
CHILLED WATER RET. 12 °C — PID-5102 / D1 — DN50-CHR-5105-C2A-IC
COMPRESSED AIR 6 barg — PID-5102 / D1 — DN25-CA-5103-A1C-N
WFI 80 °C LOOP — PID-5102 / D1 — DN40-WFI-5102-S3A-IH
CLEAN STEAM 3.0 barg — PID-5102 / D1 — DN50-CS-5101-S1C-IH
NITROGEN 4 barg — PID-5102 / D1 — DN15-N2-5106-A1C-N
PROCESS VACUUM — UTL-5003 / C2 — DN25-VAC-5301-A1C-N

RETURN / END — UTL-5001 / B8 (×5)
CAPPED END — -
CAPPING EXTRACT — HVA-5401 / D2

DN100-EX-5306-DS-N

CA TO XV-5321

FN-5301
FN-5306
PCV-5310
PDI 5308
F-5306
XV-5310 FC
CB-5301 CAP BOWL
CAP CHUTE

CP-5301
CRIMP CAPPER
CAP PLACE
CRIMP TURRET
XV-5306 GATE
RB-5305 REJECT
AT 5307 0.5 / 1.5 µm TO EMS-5401
CAP PRESENT YS 5303
WT 5302 CRIMP FORCE PER HEAD
SIC 5309 LINE SPEED
WIC 5302
I 5301
CAP MISSING OR FORCE OUT OF LIMIT: REJECT

CAPPING ZONE - GRADE A AIR SUPPLY IN GRADE C ROOM

FILLED, STOPPERED VIALS — PID-5102 / B1

HV-5317

UY 5316 VISION COMPUTER
UZ 5317 REJECT DECISION

VIAL HOLD-DOWN

VI-5311
INSPECTION MACHINE

YE-5312A YE-5312B YE-5312C YE-5312D YE-5313A YE-5313B
SPIN / BRAKE PARTICLE STATIONS (SERVO SPIN 3 000 rpm)
COSMETIC (SIDE + BOTTOM)
LT 5314 NIR
AT 5315 HVLD
FILL LEVEL / HVLD LEAK TEST 25 kV

YQI 5319 INFEED COUNT
SIC 5318 SPIN SERVO
HS 5310 LINE STOP OPERATOR
XA 5311 CAMERA FAULT

MES BATCH RECONCILIATION KQ 5325

-VI-5311 AUTOMATED VISUAL INSPECTION - VENDOR PACKAGE LIMIT-

S XV-5321 3-WAY REJECT GATE

RT-5321 REJECT TABLE SEGREGATION BY CATEGORY

RB-5322A CAT. A LOCKED
RB-5322B CAT. B LOCKED
RB-5322C CAT. C LOCKED
YQI 5323A
YQI 5323B
YQI 5323C

I 5321 ANY BIN FULL (LSH) STOP INFEED

AT-5331

TL-5331
TRAY LOADER
PICK AND PLACE GANTRY
TRAY MAGAZINE
GOOD VIALS YQI 5331
I 5331 TRAY LOADER STOP OR ACCUMULATION < 60 % SLOW LINE (SIC-5309)
SIC 5341 OUTFEED

A: PARTICLES B: COSMETIC C: FILL / LEAK

CAUSE AND EFFECT MATRIX C&E-5300 (EXTRACT) - X = ACTION, T = ACTION AFTER 30 s DELAY

CAUSE	INITIATOR	REJECT VIAL XV-5305	DIVERT XV-5321	STOP CAPPER CP-5301	STOP INFEED VI-5311	SLOW LINE SIC-5309	STOP LINE (ALL)	HMI ALARM	BATCH RECORD
01 CAP NOT PRESENT AFTER PLACEMENT	YS-5303	●						●	●
02 CRIMP FORCE OUT OF LIMITS	WIC-5302	●						●	●
03 LAF HEPA DIFFERENTIAL PRESSURE LOW	PDI-5308			●				●	●
04 CAPPING EXTRACT FAN FAULT	FN-5306			T				●	●
05 PARTICLE COUNT ALARM, GRADE A	AT-5307							●	●
06 VISION SYSTEM / CAMERA FAULT	XA-5311				●			●	●
07 VIAL REJECTED, ANY CATEGORY	UZ-5311		●						●
08 REJECT BIN FULL (A / B / C)	LSH-5322				●			●	●
09 ACCUMULATION TABLE ABOVE 90 %	AT-5331					●		●	
10 TRAY LOADER STOPPED	TL-5331					T		●	
11 OPERATOR LINE STOP	HS-5310						●	●	●

FULL MATRIX IN OB-A7-CE-5300. ALL ACTIONS VIA THE LINE PLC EXCEPT OPERATOR LINE STOP (HARDWIRED).

INSPECTION RECIPE VI-5311 - DEFECT CLASSES (EXTRACT)

DEFECT CLASS	DETECTED BY	LIMIT	CAT.
VISIBLE PARTICLE, MOBILE	YE-5312A-D	≥ 50 µm, POD 70 %	A
GLASS FLAKE / LAMELLA	YE-5312A-D	≥ 100 µm	A
CRACK, CHIP IN SHOULDER	YE-5313A	ANY	B
CRIMP DEFECT / CAP SKEW	YE-5313B	> 0.5 mm	B
STOPPER MISSING / RAISED	YE-5313B	> 1.0 mm	B
FILL VOLUME LOW / HIGH	LT-5314	± 3 % NOMINAL	C
CLOSURE LEAK	AT-5315	HVLD > 0.5 µA	C
COSMETIC SCRATCH, SPOT	YE-5313A	> 2 mm	B

SHEET NOTES

1. CAPPING UNDER GRADE A AIR SUPPLY; CAPS ARE READY-TO-USE, FED FROM SEALED BAGS INTO CB-5301.
2. EVERY VIAL IS INSPECTED; REJECTS ARE SEGREGATED BY CATEGORY INTO LOCKED BINS RB-5322A/B/C.
3. YQI COUNTS FEED THE MES RECONCILIATION KQ-5325; ACCEPTANCE LIMIT 99.5 % UNIT ACCOUNTABILITY.
4. I-5321 BIN-FULL STOP ADDED PER HAZOP ACTION H-19 (CLOUDED).
5. ILLUSTRATIVE SPECIMEN: ALL TAGS, DUTIES AND FIGURES ARE FICTIONAL.

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1	2026-09-24	HAZOP ACTIONS H-07, H-12 AND H-19 INCORPORATED (CLOUDED)	RD	MB	SA
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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
ASEPTIC FILLING LINE 5 - CAPPING, INSPECTION AND TRAY LOADING
UNIT 5300 - CAPPING AND INSPECTION

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-PID-5103	1	3 OF 4	NONE	ANSI D

INSTRUMENT SYMBOLS (ANSI/ISA-5.1-2009)

TIC 5101	DISCRETE INSTRUMENT, FIELD MOUNTED
TIC 5101	DISCRETE INSTRUMENT, LOCAL PANEL
TIC 5101	DISCRETE INSTRUMENT, MAIN CONTROL ROOM, ACCESSIBLE
TIC 5101	DISCRETE INSTRUMENT, BEHIND PANEL / NOT ACCESSIBLE
TIC 5101	SHARED DISPLAY, SHARED CONTROL (DCS)
TIC 5101	PROGRAMMABLE LOGIC CONTROL (LINE PLC)
TIC 5101	COMPUTER FUNCTION (VISION, MES, BATCH RECORD)
I 5101	INTERLOCK / LOGIC FUNCTION (SEE CAUSE AND EFFECT C&E-5100)

IDENTIFICATION LETTERS USED ON THIS SET

LETTER	FIRST LETTER (MEASURED VARIABLE)	SUCCEEDING LETTER (FUNCTION)
A	ANALYSIS (PARTICLES, H2O2)	ALARM
F	FLOW RATE	-
H	HAND (MANUAL)	HIGH
J	POWER	-
K	TIME / SCHEDULE	CONTROL STATION
L	LEVEL	LOW / LIGHT
M	MOISTURE / HUMIDITY	-
P	PRESSURE	POINT (TEST) CONNECTION
PD	PRESSURE, DIFFERENTIAL	-
S	SPEED / FREQUENCY	SWITCH / SAFETY
T	TEMPERATURE	TRANSMIT
U	MULTIVARIABLE	MULTIFUNCTION
W	WEIGHT / FORCE	WELL
X	UNCLASSIFIED	UNCLASSIFIED
Y	EVENT / STATE / PRESENCE	RELAY / COMPUTE
Z	POSITION	SAFETY ELEMENT
-	SUCCEEDING: C CONTROL, E ELEMENT, I INDICATE,	Q TOTALIZE, R RECORD, V VALVE

LINE SYMBOLS AND SIGNAL TYPES

- MAJOR PROCESS LINE
- MINOR PROCESS / UTILITY LINE
- AIR DUCT (SCHEMATIC)
- CONTAINER (VIAL) PATH
- ELECTRIC SIGNAL (4-20 mA / DISCRETE)
- SOFTWARE / DATA LINK (FIELDBUS, ETHERNET)
- PNEUMATIC SIGNAL
- CAPILLARY TUBE
- FLEXIBLE HOSE (TEMPORARY)
- VENDOR PACKAGE / EQUIPMENT BOUNDARY
- LINES CROSSING, NOT CONNECTED (LINE JUMP)

LINE NUMBER IDENTIFICATION

DN25 - PD - 5201 - S3A - N

DN25	NOMINAL SIZE, DN (mm)
PD	SERVICE CODE (SEE TABLE BELOW)
5201	LINE SEQUENCE NUMBER (UNIT 52)
S3A	PIPING CLASS (SEE TABLE BELOW)
N	INSULATION / TRACING CODE

SERVICE	DESCRIPTION	CLASS
PD	PRODUCT (DRUG PRODUCT SOLUTION)	S3A / SU-01
RW	RECIRCULATED WASH WATER	S3A
WFI	WATER FOR INJECTION, 80 °C LOOP	S3A
CS	CLEAN STEAM	S1C
CC	CLEAN CONDENSATE	S1C
CIS / CIR	CIP SUPPLY / RETURN	S3A
CA	COMPRESSED AIR, OIL FREE, 6 barg	A1C
N2	NITROGEN, STERILE FILTERED	A1C
CHS / CHR	CHILLED WATER 6 / 12 °C	C2A
VAC	PROCESS VACUUM	A1C
EX	EXHAUST / EXTRACT AIR	DS

CLASS	MATERIAL / STANDARD	RATING
S3A	316L EP, ASME BPE SF4, ORBITAL WELD	PN10, 150 °C
S1C	316L, ASME BPE SF1, CLAMP / WELD	PN16, 150 °C
A1C	304L, PRESS FIT	PN16, 60 °C
C2A	CARBON STEEL GALV., GROOVED	PN16, 40 °C
DS	304 DUCT, WELDED SEAMS	±2 500 Pa
SU-01	PLATINUM-CURED SILICONE, GAMMA	2 bar, 40 °C

CODE	INSULATION / TRACING
IH	HEAT CONSERVATION, 25 mm MINERAL WOOL, SS CLAD
IC	COLD, 19 mm ELASTOMERIC FOAM
IP	PERSONNEL PROTECTION ONLY
N	NONE

VALVES, FITTINGS AND SPECIALITIES

- AUTOMATED DIAPHRAGM VALVE, PNEUMATIC (ON / OFF)
- CONTROL VALVE, DIAPHRAGM ACTUATOR (MODULATING)
- MANUAL SANITARY DIAPHRAGM VALVE
- PINCH / MOTOR OPERATED VALVE (SINGLE USE)
- PRESSURE REGULATOR, SELF ACTUATED
- BALL VALVE
- BUTTERFLY VALVE
- CHECK VALVE
- THREE WAY VALVE
- RUPTURE DISC IN HOLDER
- SPECIFICATION BREAK (CLASS CHANGE)
- STEAM TRAP, THERMODYNAMIC (CLEAN STEAM)
- TEST / SAMPLE POINT WITH BLIND CAP

EQUIPMENT SYMBOLS

- CENTRIFUGAL PUMP
- PERISTALTIC PUMP
- CARTRIDGE FILTER HOUSING
- HEPA FILTER
- CENTRIFUGAL FAN
- ELECTRIC HEATER BANK
- PLATE HEAT EXCHANGER
- CIP SPRAY DEVICE
- INSPECTION CAMERA
- STAR WHEEL / TURRET

ABBREVIATIONS

ABBR.	MEANING
CIP / SIP	CLEAN / STERILISE IN PLACE
EM / EMS	ENVIRONMENTAL MONITORING (SYSTEM)
FC / FO	FAIL CLOSED / FAIL OPEN
HVLD	HIGH VOLTAGE LEAK DETECTION
IPC	IN-PROCESS CONTROL
LAF	LAMINAR (UNIDIRECTIONAL) AIRFLOW
MES	MANUFACTURING EXECUTION SYSTEM
NIR	NEAR INFRARED
PUIT	PRE-USE POST-STERILISATION INTEGRITY TEST
RTP	RAPID TRANSFER PORT
RTU	READY TO USE (PRE-STERILISED)
SCR	SILICON CONTROLLED RECTIFIER
SU	SINGLE USE
VFD	VARIABLE FREQUENCY DRIVE
VHP	VAPOURISED HYDROGEN PEROXIDE
WFI	WATER FOR INJECTION

DRAWING INDEX - FILL / FINISH LINE 5

DRAWING	TITLE	REV
OB-A7-PID-5101	WASHING AND DEPYROGENATION	1
OB-A7-PID-5102	PRODUCT PATH AND ISOLATOR FILLER	1
OB-A7-PID-5103	CAPPING, INSPECTION, TRAY LOADING	1
OB-A7-PID-5104	LEGEND AND SYMBOL KEY (THIS SHEET)	1
OB-A7-HVA-5401	ISOLATOR HVAC AND VHP	0
OB-A7-ISO-5701	FILLING LINE 3-D VIEW	0
OB-A7-ISO-5801	WFI LOOP PIPING ISOMETRIC	0
OB-A7-GA-5901	ASEPTIC FACILITY GA, LEVEL 0	2
UTL-5001 / 5002	UTILITY AND CIP SCHEMATICS	1

LAYERS IN THIS FILE: PROCESS LINES, VALVES, INSTRUMENTS, SIGNALS, EQUIPMENT, BOUNDARIES, CONTAINER PATH. HIDE A LAYER TO DECLUTTER; ALL LAYERS PRINT.

GENERAL NOTES

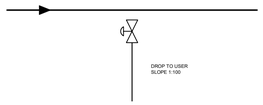
1. THIS SET IS AN ILLUSTRATIVE SPECIMEN. EVERY TAG, NAME, DUTY AND FIGURE IS FICTIONAL.
2. SYMBOLS FOLLOW ANSI/ISA-5.1-2009; SANITARY DETAILS FOLLOW ASME BPE-2022 CONVENTIONS.
3. ALL PRODUCT CONTACT SURFACES 316L, Ra < 0.4 µm ELECTROPOLISHED UNLESS NOTED SINGLE USE.
4. LINES ARE SLOPED 1:100 MINIMUM TOWARDS LOW POINT DRAINS; NO DEAD LEG EXCEEDS L/D = 2.
5. INSTRUMENT LOOP NUMBERS: FIRST TWO DIGITS = UNIT, LAST TWO = LOOP WITHIN THE UNIT.
6. INTERLOCKS ARE DEFINED IN THE CAUSE AND EFFECT MATRICES C&E-5100 TO C&E-5300.
7. HAZOP (2026-05) ACTIONS INCORPORATED AT REV 1 ARE CLOUDED AND MARKED WITH A TRIANGLE.

EQUIPMENT LIST - FILL / FINISH LINE 5 (SUMMARY, SEE EL-5000 FOR FULL DATA)

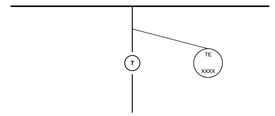
TAG	DESCRIPTION	KEY DATA	MATERIAL	SHEET
WM-5101	VIAL WASHING MACHINE	300 vials/min, 4 stations	316L / 304	5101
T-5101	RECIRCULATION TANK	60 L, ATM, 95 °C	316L	5101
P-5101	RECIRCULATION PUMP	2.4 m3/h @ 3.5 bar	316L	5101
E-5101	RECIRCULATION HEATER	22 kW, clean steam	316L	5101
F-5101 / F-5102	PRE-FILTER / STERILE AIR FILTER	5 µm / 0.2 µm	316L / PTFE	5101
DT-5101	DEPYROGENATION TUNNEL	3 zones, 320 °C, 600 mm belt	316L / 304	5101
FN-5111...5114	TUNNEL FANS	450 - 3 100 m3/h	304 / HT	5101
F-5111...5113	TUNNEL HEPA FILTERS	H14 / H13 HT / H14	SS FRAME	5101
EH-5112A/B/C	HOT ZONE HEATERS	3 x 18 kW	INCOLOY	5101
V-5201	PRODUCT BUFFER VESSEL	150 L, -1/+3 barg	316L EP	5102
AG-5201	MAGNETIC MIXER	60 - 400 rpm	316L	5102
F-5201A/B	STERILISING FILTERS	0.2 µm PES, redundant	316L / PES	5102
F-5203	VENT FILTER, HEATED	0.2 µm PTFE	316L / PTFE	5102
FIT-5201	FILTER INTEGRITY TESTER	bubble point / diffusion	-	5102
IS-5201	FILLING ISOLATOR	10 glove ports, grade A	316L / PC	5102
V-5202 / V-5241	SURGE / RECOVERY BAGS	5 L / 10 L	SU FILM	5102
P-5211...5218	PERISTALTIC DOSING PUMPS	0.5 - 20 mL, ±0.5 %	SU TUBING	5102
SB-5221	STOPPER BOWL	400 / min	316L	5102
WT-5231	IPC CHECKWEIGHER	0.1 mg	-	5102
CP-5301	CRIMP CAPPER	8 heads, 400 / min	316L	5103
CB-5301	CAP SORTING BOWL	vibratory	316L	5103
VI-5311	AUTOMATED VISUAL INSPECTION	6 cameras, NIR, HVLD	-	5103
RT-5321	REJECT TABLE + LOCKED BINS	3 categories	304	5103
TL-5331	TRAY LOADER	240 vials / tray	304	5103
AT-5331	ACCUMULATION TABLE	1 200 vials	304	5103

TYPICAL ARRANGEMENTS

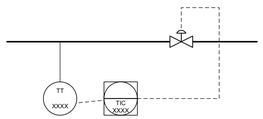
T1 ZERO DEAD LEG POINT OF USE
VALVE BODY WELDED TO THE LOOP TEE, L/D < 2



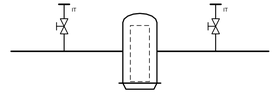
T2 SIP LOW POINT DRAIN
TRAP + VERIFICATION ELEMENT AT EVERY LOW POINT



T3 SINGLE LOOP CONTROL
TRANSMITTER - DCS CONTROLLER - CONTROL VALVE



T4 FILTER INTEGRITY TEST CONNECTIONS
UPSTREAM / DOWNSTREAM, BLINDED WHEN NOT IN USE



REV	DATE	DESCRIPTION	BY	CHK	APPR
1	2026-09-24	HAZOP ACTIONS H-07, H-12 AND H-19 INCORPORATED (CLOUDED)	RD	MB	SA
0	2026-07-14	ISSUED FOR DESIGN	RD	MB	TV
B	2026-05-22	ISSUED FOR HAZOP	RD	MB	TV
A	2026-03-06	ISSUED FOR INTERNAL REVIEW	RD	MB	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
ASEPTIC FILLING LINE 5 - LEGEND AND SYMBOL KEY
UNIT 5000 - GENERAL

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-PID-5104	**1**	**4 OF 4**	**NONE**	**ANSI D**