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 mn
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 050 °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
FT 5104
FQI 5104 0.9 m³/h
XV-5108 FC
DN15-WFI-5115-S3A-IH
DN25-CS-5113-S1C-IH
DN15-CA-5116-A1C-N

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
UT-5101 ULTRASONIC 2 kW

VIALS FROM TL-5001

XV-5111 FC
DN25-RW-5111-S3A-IH
S3 CASCADE OVERFLOW
I 5101
LOW LEVEL T-5101 OR LOW AIR: STOP P-5101 AND WM-5101
DN40-RW-5112-S3A-N
TIC 5102 SP 70 °C
TT 5102
VENT
MAKE-UP, AIR GAP
N1 N2 N3 N4 N5 N6
T-5101 60 L
LAL 25 % LAH 90 %
LIC 5101
LT 5101
DN25-RW-5110-S3A-IH
TCV-5102 FC
E-5101 PLATE HEATER
F-5101 PRE-FILTER 5 µm
T ST-5101
PDT 5103
PDI 5105 H 80 kPa
CLEAN CONDENSATE UTL-5002 / 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
ePM1 80% — SC 5112 — M — FN-5112 — PDIC 5126 -5 Pa vs Z1 — PDT 5126
ePM1 80% — SC 5113 — M — FN-5113 — PDIC 5136 +15 Pa vs FILL RM — PDT 5136
FN-5114 — MD-5114 — M

PLENUM — PDI 5117
PLENUM — PDI 5127 — EH-5112A — EH-5112B — EH-5112C
PLENUM — PDI 5137 — E-5113 CHW COIL

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

DEPYROGENATED VIALS — PID-5102 / A8

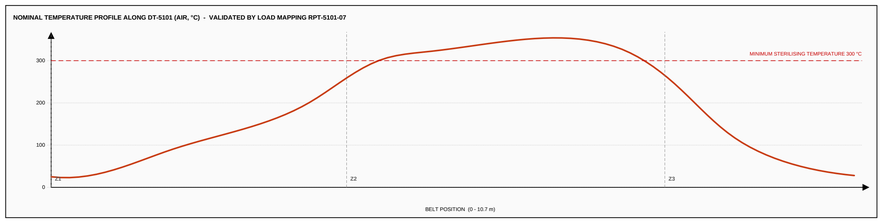
M CV-5140 BELT DRIVE

TT 5111 Z1 AIR — TI 5111
TE 5121A — TE 5121B — TE 5121C — TE 5121D — TE 5121E — TE 5121F — TT 5122 — TSHH 5122 350 °C
TY-5121 MULTIPOINT TEMPERATURE SCANNER (6 x TYPE K, CLASS 1)
SIC 5140
I 5121 =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)
SP 320 °C TAL 300 / TAH 340 — TIC 5121 — SCR POWER CONTROLLER — JY 5121
TR 5121 BATCH RECORD 21 CFR 11
I 5122 TRIPS EH-5112A/B/C MAIN CONTACTOR, FANS RUN ON (HARDWIRED, SIL 1)

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

DT-5101 DEPYROGENATION TUNNEL - VENDOR PACKAGE LIMIT

NOMINAL TEMPERATURE PROFILE ALONG DT-5101 (AIR, °C) - VALIDATED BY LOAD MAPPING RPT-S101-07



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	DESCRPTION	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 - 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 - 20 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 (×8)

XV-5207 FC
PCV-5204
PIC 5203 SP 0.3 barg
VENT
XV-5205 FO
PT 5203
F-5203 HEATED VENT FILTER
TO CIP-5201
RD-5201 3.5 barg
XV-5200 FC
XV-5221 FC
DN25-CIS-5108-C2A-IC
SB-5201
V-5201 150 L
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
M AG-5201
XV-5202 FC
DN15-PD-5202-S3A-N
XV-5208 FC
T ST-5201
TE 5221 SIP 121 °C
FILTER dP HIGH OR PUIT FAIL: HOLD FILLING
PDI 5211 H 1.5 bar
PDI 5213 H 1.5 bar
I 5211
PDT 5211
PDT 5213
PT 5212 SIP / PUIT
F-5201A
F-5201B
IT-5201A
IT-5201B
T ST-5202
T ST-5203
FLEX HOSE
FIT-5201 AUTOMATED FILTER INTEGRITY TESTER BUBBLE POINT / DIFFUSION
XV-5210 FC
DN15-PD-5203
S3A SU-01
AC-5201 STERILE CONNECTOR

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.
WIC 5204 LEVEL BY WEIGHT
AAS-5461 · AAS-5462
XV-5214
V-5202 SURGE BAG 5 L
WT S202
SP-01 · SP-02 · SP-03 · SP-04
PC-5451 · PC-5452 · PC-5453
V-5241 RECOVERY 10 L
XV-5241
SU-5204 6.4 mm ID
RTP-5201 STOPPER BAG
SB-5221 STOPPER BOWL
VIBRATORY DRIVE
LS 5221 BOWL LOW
CHUTE
P-5211 · P-5212 · P-5213 · P-5214 · P-5215 · P-5216 · P-5217 · P-5218
DOSE CTRL 8 AXES SC 5214
FILLING NEEDLES N-5211 ... N-5218 ON SERVO LIFT BEAM
ST 5222
VIAL PATH
FILLED, STOPPERED VIALS — PID-5103 / C8
TARE
WT 5230
NET FILL IPC ±2 %
WIC 5234
WT 5231
XV-5232 GATE
RJ-5231 REJECT TRAY
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, 8 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 mn AT 400/mn

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
DN100-EX-5306-DS-N

RETURN / END — UTL-5001 / B8 (×6)
CAPPED END — -
CAPPING EXTRACT — HVA-5401 / D2

FILLED, STOPPERED VIALS — PID-5102 / B1

FN-5301
FN-5306
PCV-5310
PDI 5308
5306
XV-5310 FC
CB-5301 CAP BOWL
CAP CHUTE
CP-5301 CRIMP CAPPER
CAP PLACE
CRIMP TURRET
AT 5307 0.5 / 5 µm TO EMS-5401
CAP PRESENT YS 5303
WT 5302 CRIMP FORCE PER HEAD
RB-5305 REJECT
SIC 5309 LINE SPEED
WIC 5302
I 5301
XV-5305 GATE
CAP MISSING OR FORCE OUT OF LIMIT: REJECT
CAPPING ZONE - GRADE A AIR SUPPLY IN GRADE C ROOM

HV-5317
UY 5316 VISION COMP'UTER
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
AT 5315 HVLD
NIR
FILL LEVEL / HVLD LEAK TEST 25 kV
YQI 5319 INFEED COUNT
SIC 5318 SPIN SERVO
HS 5310 LINE STOP OPERATOR
XA 5311 CAMERA FAULT
VI-5311 AUTOMATED VISUAL INSPECTION - VENDOR PACKAGE LIMIT

CA TO XV-5321
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
MES BATCH RECONCILIATION KQ 5325
I 5321 ANY BIN FULL (LSH) STOP INFEED
A: PARTICLES B: COSMETIC C: FILL / LEAK

AT-5331
TL-5331 TRAY LOADER
PICK AND PLACE GANTRY
TRAY MAGAZINE
GOOD VIALS YQI 5331
SIC 5341 OUTFEED
I 5331 TRAY LOADER STOP OR ACCUMULATION < 60 % SLOW LINE (SIC-5309)
TO PACKAGING — PKG-6001 / A1

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.

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 - 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)
T	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

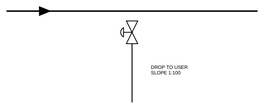
1. THIS SET IS AN ILLUSTRATIVE SPECIMEN. EVERY TAG, NAME, DUTY AND FIGURE IS FICTIONAL.
2. SYMBOLS FOLLOW ANSI/ISA-5.1-2009; SANITARY DETAILS FOLLOW ASME BPE-2022 CONVENTIONS.
3. ALL PRODUCT CONTACT SURFACES 316L, Ra < 0.4 µm ELECTROPOLISHED UNLESS NOTED SINGLE USE.
4. LINES ARE SLOPED 1:100 MINIMUM 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)

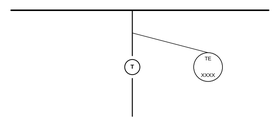
TAG	DESCRIPTION	KEY DATA	MATERIAL	SHEET
WM-5101	VIAL WASHING MACHINE	300 vials/min, 4 stations	316L / 304	5101
T-5101	RECIRCULATION TANK	60 L, ATM, 95 °C	316L	5101
P-5101	RECIRCULATION PUMP	2.4 m3/h @ 3.5 bar	316L	5101
E-5101	RECIRCULATION HEATER	22 kW, clean steam	316L	5101
F-5101 / F-5102	PRE-FILTER / 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

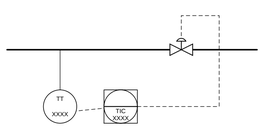
T1 ZERO DEAD LEG POINT OF USE
VALVE BODY WELDED TO THE LOOP TEE, L/D < 2



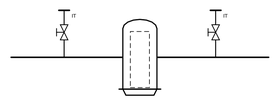
T2 SIP LOW POINT DRAIN
TRAP + VERIFICATION ELEMENT AT EVERY LOW POINT



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	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 - 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**