JUNG HYUN PLANT CO., LTD.



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Seek for World Best ‘No.1
Total Plant Engineering Company

- Abundant Construction Experience for Pharmaceutical, Bio-industry and Factory Facilities
- Thorough Process Control
- Comply with URS, CODE, GMP in Construction and Management
- Thorough Safety Management & Quality Control
- Validation Service



☑ Contents

1. Company Profile
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3. Certificate

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   ASME BPE 2014&2016 / cGMP

5. Facilities

6. Clients

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JungHyun Plant **History**

1983

Established in Buchon

2005

Started up the fabrication in the 1st Factory

2006

Started up in the 2nd Factory

2007

Acquired ASME 'U' Stamp

2008

Started up in the 3rd Factory

2015

- **Combined 1st Factory with 2nd as current extending location**
- **ISO 9001 : 2008 Certificate TÜV Rheinland**

2017

- **Interphex Japan Exhibition (2012~2019)**
- **Renewed ASME 'U' Stamp**

2018

- **High Pressure Vessel Certificate**
- **CSEL Certificate (China Special Equipment License)**

2019

JungHyun Plant

JUNGHYUN PLANT

Manufacturing Area



1st Factory

Plottage : 39,600m²

Floor space : 12,540m²

- Head office
- Bio Industry, Plant Engineering,
- Stainless Steel Only



2nd Factory

Plottage : 7,590m²

Floor space : 3,630m²

- 2nd Office
- Glass Lining



3rd Factory

Plottage : 6,600m²

Floor space : 1,485m²

(Stainless Steel / Future)

JUNGHYUN PLANT

1. Company Profile

1.1) Principal Business

- JHP does our own Design and Fabrication for all process equipment related to Bio Industry, Pharmaceutical, and Fine Chemical, and etc.

- Hygienic Vessel
- Fermenter
- Vacuum Dryer
- Condenser
- Column
- Bio Reactor
- HTST
- Heat Exchanger
- PW System
- Chemical Storage Tank
- Process Vessel
- Filter Dryer
- Auto Filling
- PSG / Distiller
- Glass Lining
- Reactor
- Condenser
- Storage Tank

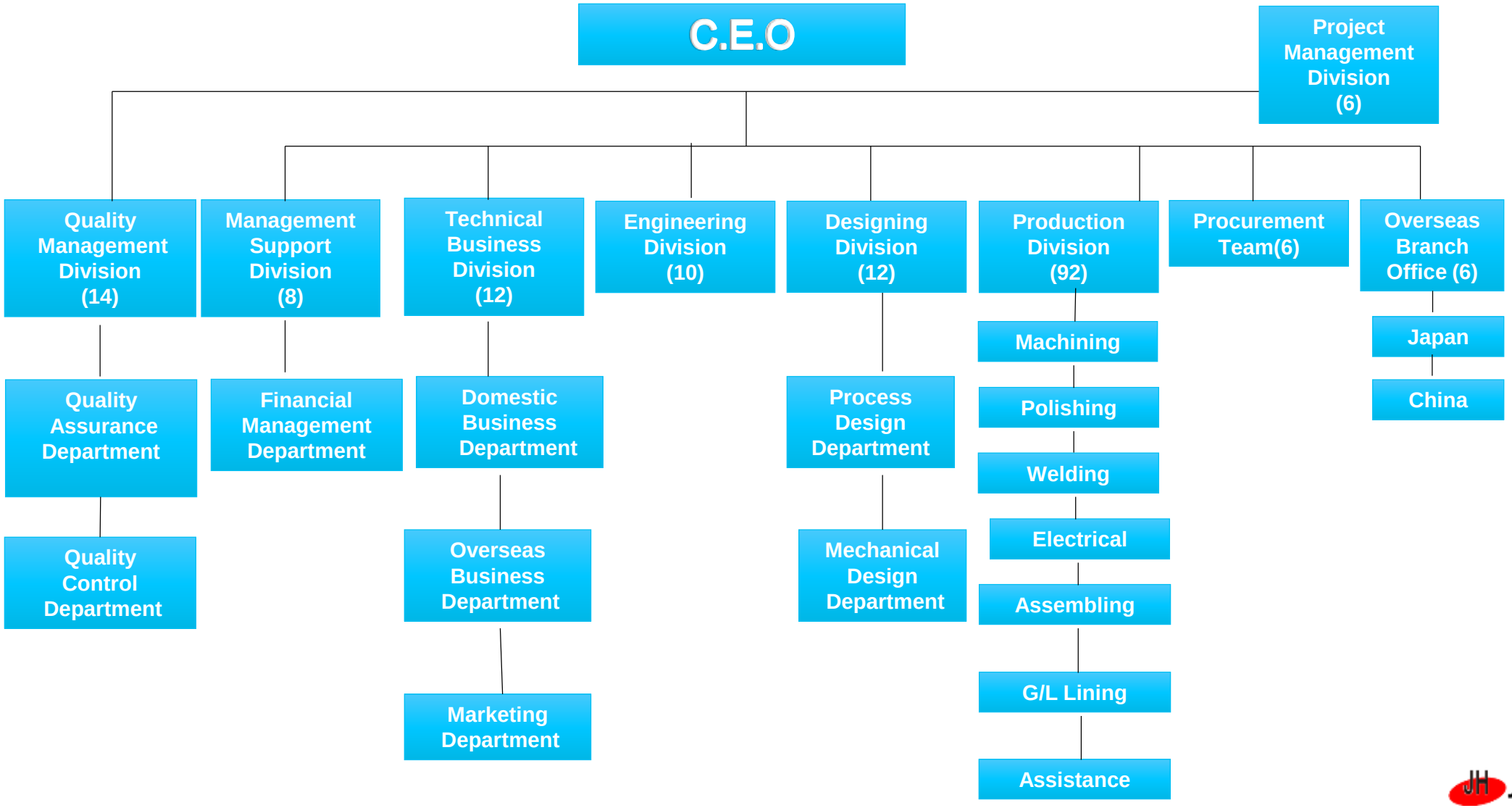


1.2) Material Experience & Fabrication Strength

- Hastelloy Alloys
- Stainless Steel (Duplex, AL-6XN, 836L, 904L, 254) with Clad
- DIN 1.4435 & DIN 1.4404(316L)
- Copper & Copper Alloy Steel
- Carbon Steel for High & Low Temp. Service

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1.3) Organization



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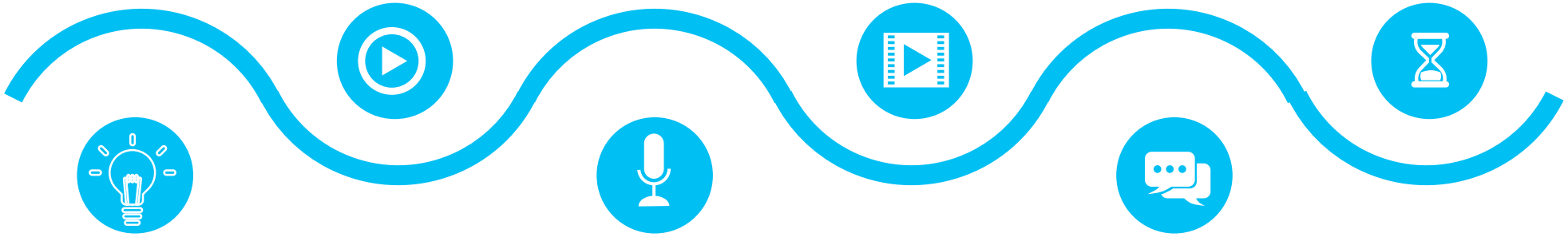
1.4) Validation

CODE: ASME BPE

Regulation : Gathering the Sufficient Latest Data for Global Standard

D.Q
Design Qualification

O.Q
Operational Qualification



U.R.S
User Required Specification

I.Q
Install Qualification

P.Q
Performance Qualification

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2. Project Reference List_2019 Year

No.	CLIENT	DESCRIPTION	YEAR
1	WUXI BIOLOGICS / CHINA	PROCESS VESSEL / 18 SET (MEDIA PREPARATION SYSTEM)	2018.10 ~2019.05
2	AUROBINDO / INDIA	ANFD PACKAGE SYSTEM SILICON LIFESCIENCES / VISAKHAPATNAM	2018.10 ~ 2019.05
3	MERCK / GERMANY	RETROFIT VESSEL	2019.03 ~2019.07
4	HITACHI / JAPAN	MP PROJECT NEW P PROJECT	2019.01 ~2019.09
5	YUHAN CHEMICAL	HC-22 FILTER DRYER	2019.03 ~ 2019.08
6	HANMI FINECHEMICAL	HC-22 FILTER DRYER HC-22 REACTOR	2019.04 ~ 2019.11
7	EN CHEM / POLAND	FORMULATION TANK SYSTEM	2019.06 ~ 2019.11

2. Project Reference List_2018 Year

No.	CLIENT	DESCRIPTION	YEAR
1	REDOX BIO	WFI SYSTEM	2018.02 ~2018.06
2	AUROBINDO / INDIA	ANFD PACKAGE SYSTEM_H BLOCK PROJECT	2017.01 ~ 2017.08
3	KEMTROS	G/L REACTOR SYSTEM	2018.04 ~2018.07
4	RIST	FILTER DRYER & REACTOR SYSTEM	2018.05 ~ 2018.08
5	YUHAN CHEMICAL	WFI TANK 6 SETS PROCESS VESSELS : Material 836L 14SETS PROCESS VESSELS : 44 SETS	2018.05 ~ 2018.08
6	LG CHEM	FILTER DRYER SYSTEM	2018.04 ~ 2018.06
7	HANMI PHARMA	PROCESS VESSEL : 37 EA	2018.05 ~2018.08

2. Project Reference List_2018 Year

No.	CLIENT	DESCRIPTION	YEAR
8	CKD BIO	FERMENTOR	2018.03 ~2018.08
9	KB PHARMA	FILTER DRYER 2500L	2017.05 ~ 2018.09
10	LG CHEM	FILTER DRYER 5000L	2018.04 ~ 2018.08
11	SAMSUNG BIOLOGICS	MOBILE VESSEL 4SETS	2018.05 ~ 2018.09
12	RIST	REACTOR_LITHIUM BATTERY	2018.06 ~ 2018.08
13	YUHAN CHEMICAL	HC-22 REACTOR SET (100L, 200L, 300L) HC-22 FILTER DRYER (250L) HC-22 H_2 REACTOR	2018.08 ~2018.11
14	MERCK PERFORMANCE MATERIALS	MOBILE VESSEL_AMSE U STAMP	2018.08 ~ 2018.11

2. Project Reference List_2018 Year

No.	CLIENT	DESCRIPTION	YEAR
15	MERCK KOREA	MOBILE VESSEL	2018.07 ~2018.11
16	OSAKA SANITARY	REACTOR SYSTEM	2018.09 ~ 2018.11

2.1) Project Reference List (2016~2017 Year)

No.	CLIENT	DESCRIPTION	YEAR
1	SAMSUNG BIOLOGICS 3rd Factory	PROCESS VESSEL : 125 EA RO TANK 60t, CIP TANK etc. CIP SKID : 40 EA Clean Air Receiver & HTST system Transfer Panel : 40 EA	2016~ 2017.2
2	PIERRE GUERIN SAS (FRANCE)	BIO REACTOR : 18EA 15K BRX : 12 SETS 3K BRX : 6 SETS	2016~ 2017.2
3	HITACHI PLANT (JAPAN)	WFI TANK 6 SETS PROCESS VESSELS : Material 836L 14SETS PROCESS VESSELS : 44 SETS	2016~ 2017.4
4	HANMI PHARM.	REACTOR, PROCESS VESSELS STORAGE TANK : 33 EA	2017~ 2018
5	POLUS INC.	150,000 Liter WFI 2EA (DIN1.4435) PROCESS VESSELS : 14EA (AL-6XN) PROCESS VESSEL : 1EA(HC-22)	2017~ 2018
6	CJ HEALTH CARE	HC-276 FILTER DRYER	2017
7	CELLTRION	PROCESS VESSELS : 10EA	2017~ 2018

2.2) Project Reference List

No.	CLIENT	DESCRIPTION	YEAR
1	HANMI FINE CHEMICAL	UTILITY SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2015 ~ 2016
2	SAMYANG / E TEC	I-PROJECT G/L REACTOR SYSTEM, G/L TANK	2015 ~ 2016
3	KYONGBO PHARM	FILTER DRYER SYSTEM G/L REACTOR SYSTEM, G/L TANK	2015
4	PHARMA COSTECH (API Factory)	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2014
5	SAMSUNG BIOLOGICS 2nd Factory	BIO REACTOR – Total: 180EA RO TANK 100t, CIP TANK etc.	2014 ~ 2015
6	BIO-ENGINEERING AG (SWISS)	FILTER DRYER SYSTEM BIO PROCESS VESSEL	2014
7	YUHAN CHEMICAL	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2013 ~ 2014
8	HITACHI PLANT TECHNOLOGY (JAPAN)	POLYBUTYLENE PLANT 3100 x 7800 (110Kw)	2013 ~ 2014

2.2) Project Reference List

No.	CLIENT	DESCRIPTION	YEAR
9	KPX MPP-3 PROJECT (SC ENGINEERING)	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2014
10	AUROBINDO(APL) (INDIA)	AUTOFILLING MODIFICATION INSTALLED NEW SYSYEM WITH SCREW	2014
11	COVALENT PVT LTD (INDIA)	FILTER DRYER SYSTEM CO-MILL, BLANDING WITH SCREW	2013
12	DAEHE CHEM (SYNTHETIC NEW FACTORY)	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2013
13	HANSEA CHEM (INCREASE CONSTRUCTION)	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2012
14	IT CHEM	FILTER DRYER SYSTEM REACTOR SYSTEM, G/L REACTOR etc.	2012
15	SAMSUNG BIOLOGICS 1st Factory	BIO REACTOR – Total: 49EA RO TANK 100t, CIP TANK etc.	2012

Plant Engineering Reference #1

REDOX BIO : Hyangnam Factory

2018. 11 ~ 2019. 05

<PROJECT >

- PURPOSE : API / API / Antimalarial Drug Structure Factory
- SIZE: 4 FLOOR

<PARTICIPATED>

- Concept Design
- Process Design BE/DE
- Utility/Manufactory/Design process
- Process & Utility Piping Design
- Control System
- Test working



Plant Engineering Reference #2

Hanmi Fine Chemical : Manufactory "D", Utility & Piping System

2014. 10. ~ 2015. 09.

<PROJECT >

- PURPOSE : Equipment for new D Manufactory / Dangerous Articles Storage & Disposal Facilities
- SIZE: 9 FLOOR, 8,577 m2

<PARTICIPATED>

- Concept Design
- Process Design BE/DE
- Utility/Manufactory/Design process
- Process & Utility Piping Design
- Control System
- Test working



Plant Engineering Reference #3

Daewoong Bio(Hyangnam): 3rd Factory

2010. 03. ~ 2011. 02.

<PROJECT >

- PURPOSE : API / Antimalarial drug Structure Factory
- SIZE: 7 FLOOR, 46,500 m2

<PARTICIPATED>

- Concept Design
- Process Design BE/DE
- Utility/Manufactory/Design process
- Process & Utility Piping Design
- Control System
- Test working



Plant Engineering Reference #4

Shin Poong Pharm. : Anti-malarial Synthetic Raw Material Factory

Process Engineering Design & Construction

2007. 05. ~ 2008.05.

<PROJECT >

- PURPOSE : EMEA / API FACORTY
- SIZE : 7 FLOOR, 25,000 m2

<PARTICIPATED>

- Concept Design
- Process Design BE/DE
- Utility/Manufactory/Design process
- Process & Utility piping design
- Control System
- Test working



Plant Engineering Reference #5

Yuhan Chem. (Ansan Factory) Process Engineering Design & Construction

2013. 04. ~ 2014.02.

<PROJECT >

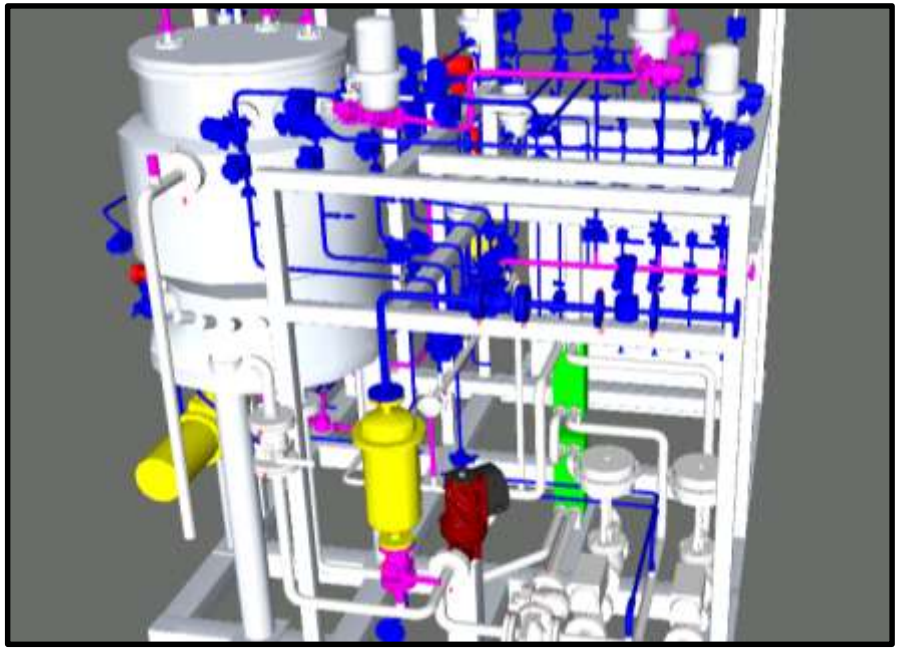
- PURPOSE : EMEA / API FACORTY
- SIZE : 7 FLOOR, 38,000 m2

<PARTICIPATED>

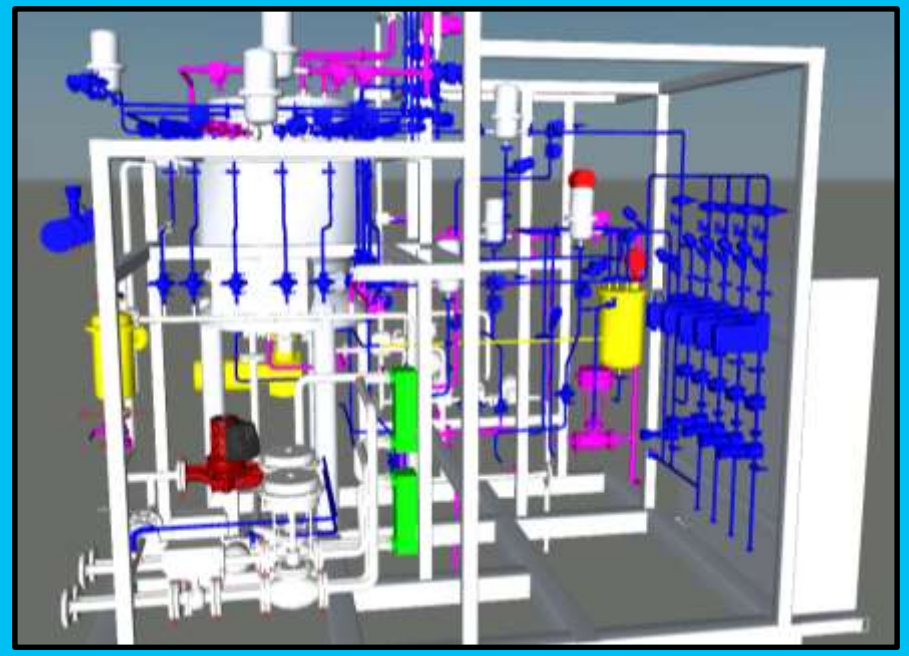
- Concept Design
- Process Design BE/DE
- Utility/Manufactory/Design process
- Process & Utility piping design
- Control System
- Test working



Piping_3D Model



3D



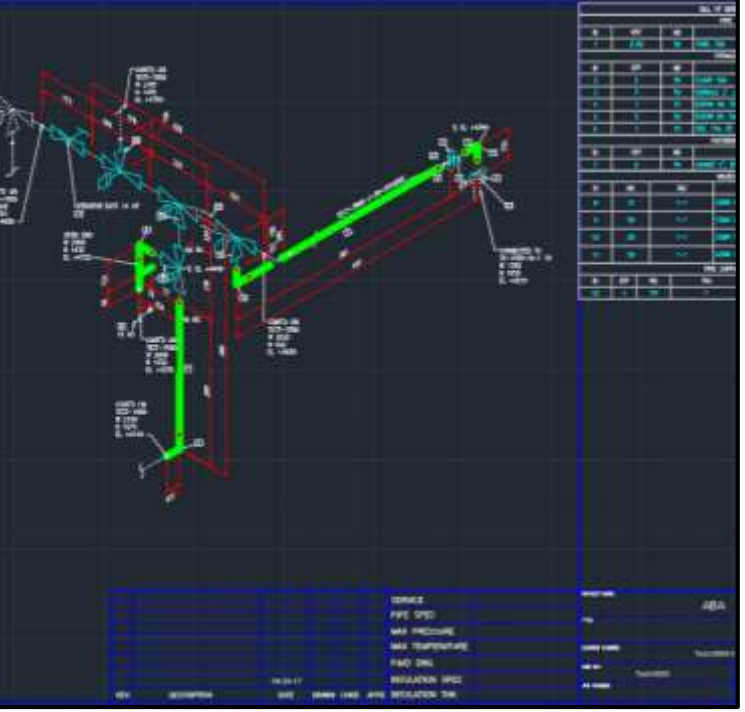
3D Modeling Execution Plan

- **Submission of 3D modeling file (Navisworks Format) after completion of the project**

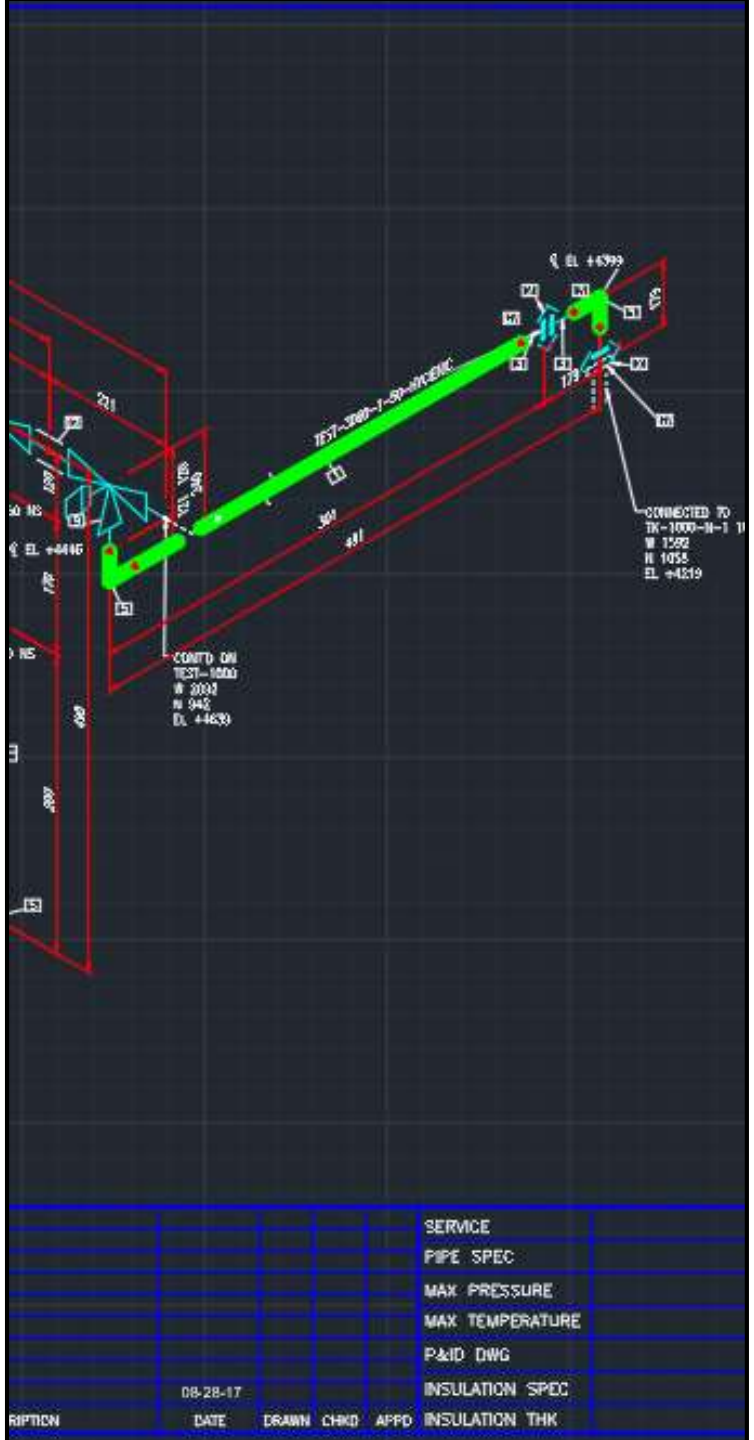
3D Modeling Execution Plan

- **Secure the Operatability and Maintainability of the facility with 3D modeling review at each design phase.**

  (i.e. 30%, 60%, 90%)



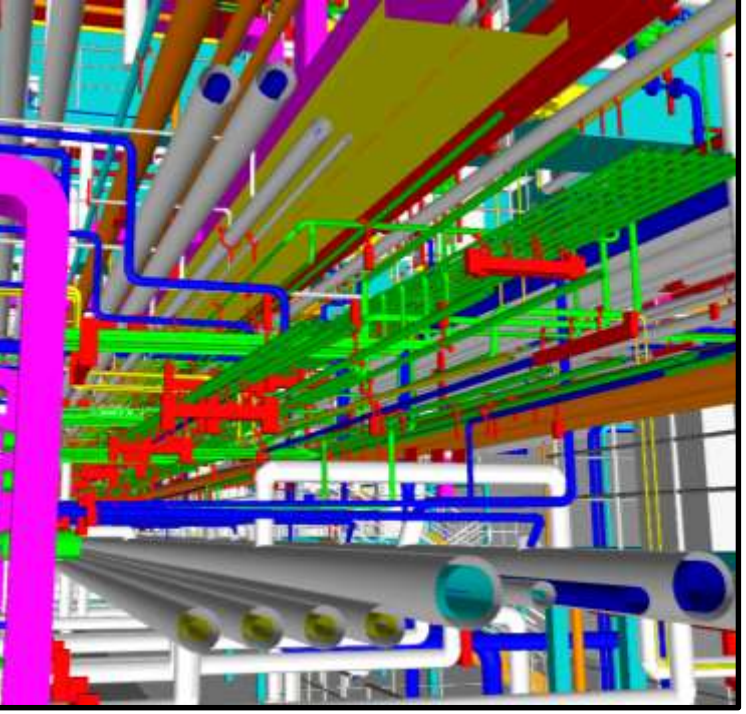


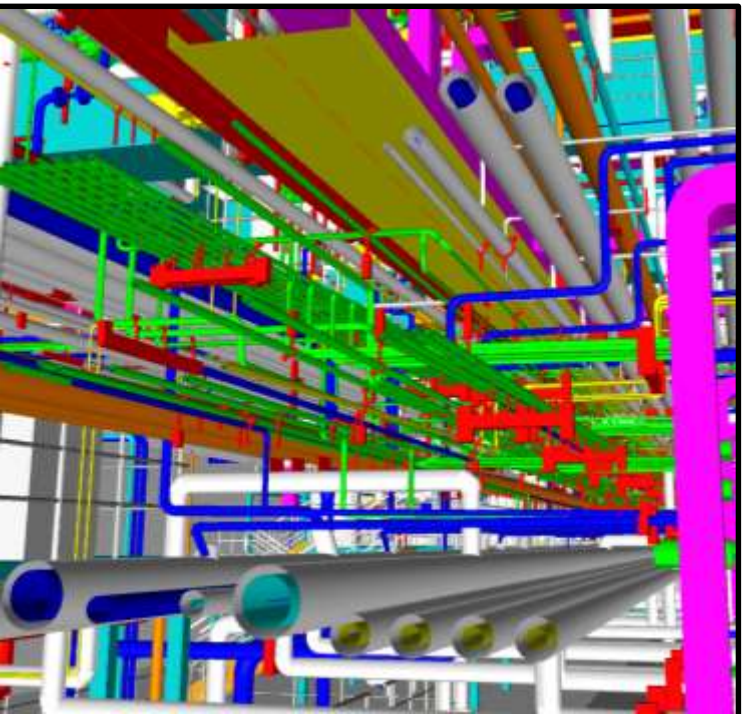


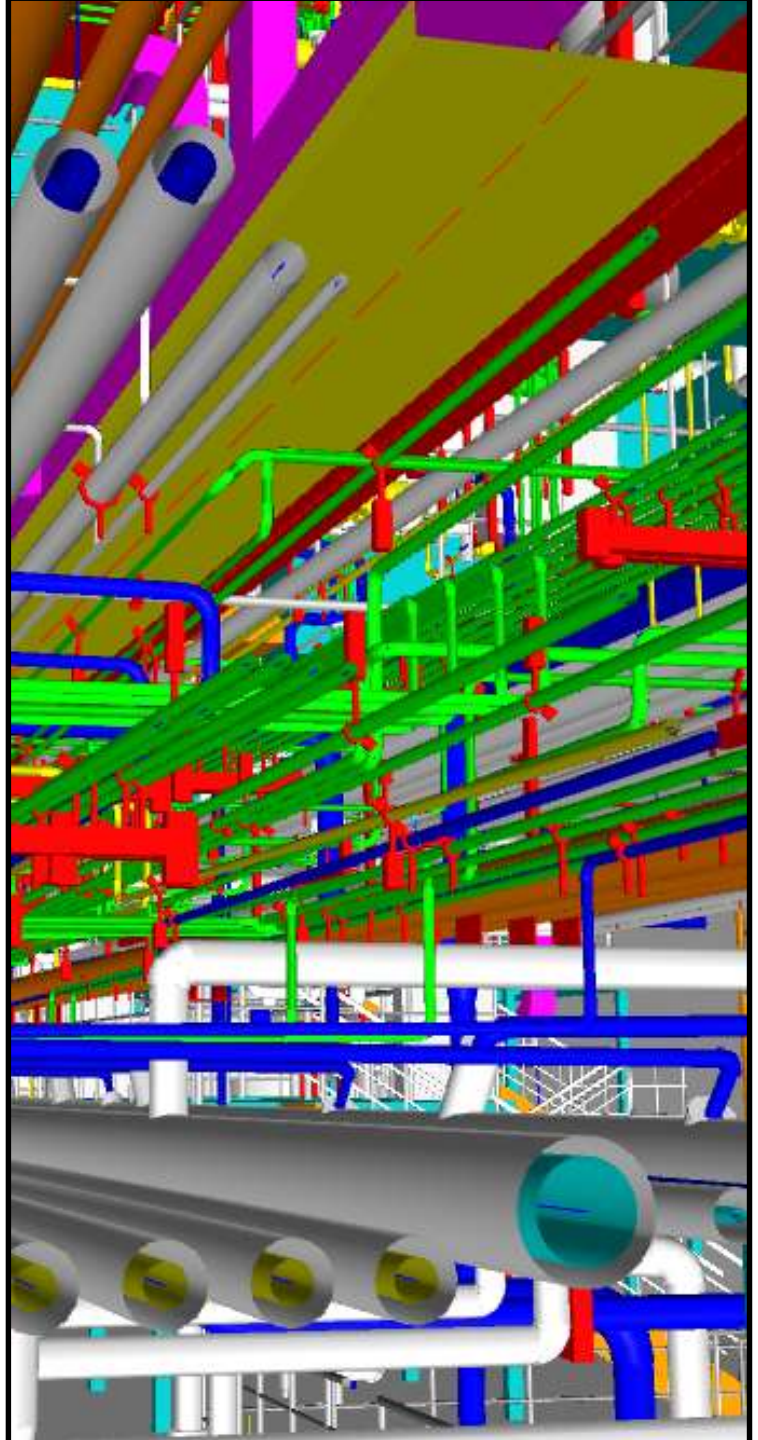
03. Piping_3D Drawing

- Accurate isometric drawing generated from 3D modeling for the construction.
  - ① Automatically generated from model.
  - ② Direction of multi-block valve and actuator can be

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04. Collision Check with Other Lines

- It is possible to check the collision between piping and other parts such as duct, structure, or platform prior to the construction.
- It has lots of positive points for efficient construction schedule

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Stainless Steel Bio & Pharmaceutical



Bio Reactor



Fermenter



Mobile Vessel



H.T.S.T System

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Water Treatment System





WFI System

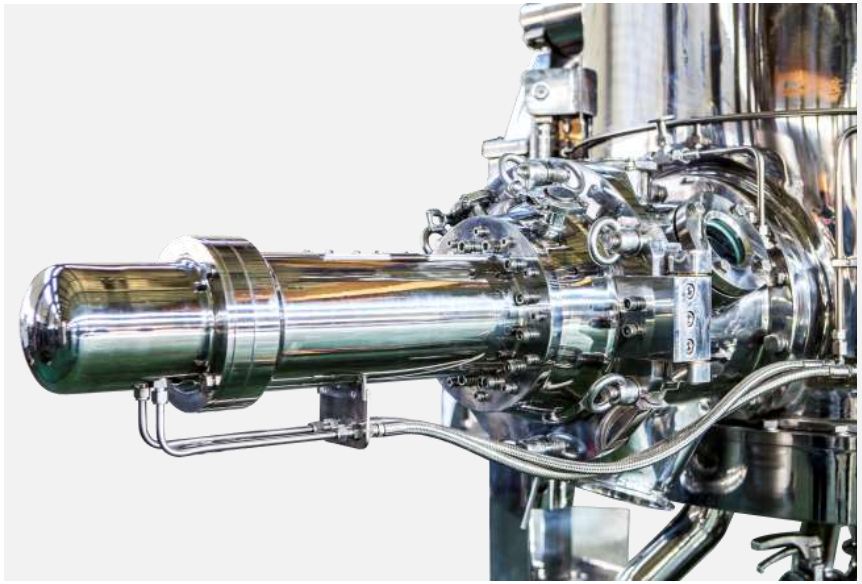


PW System

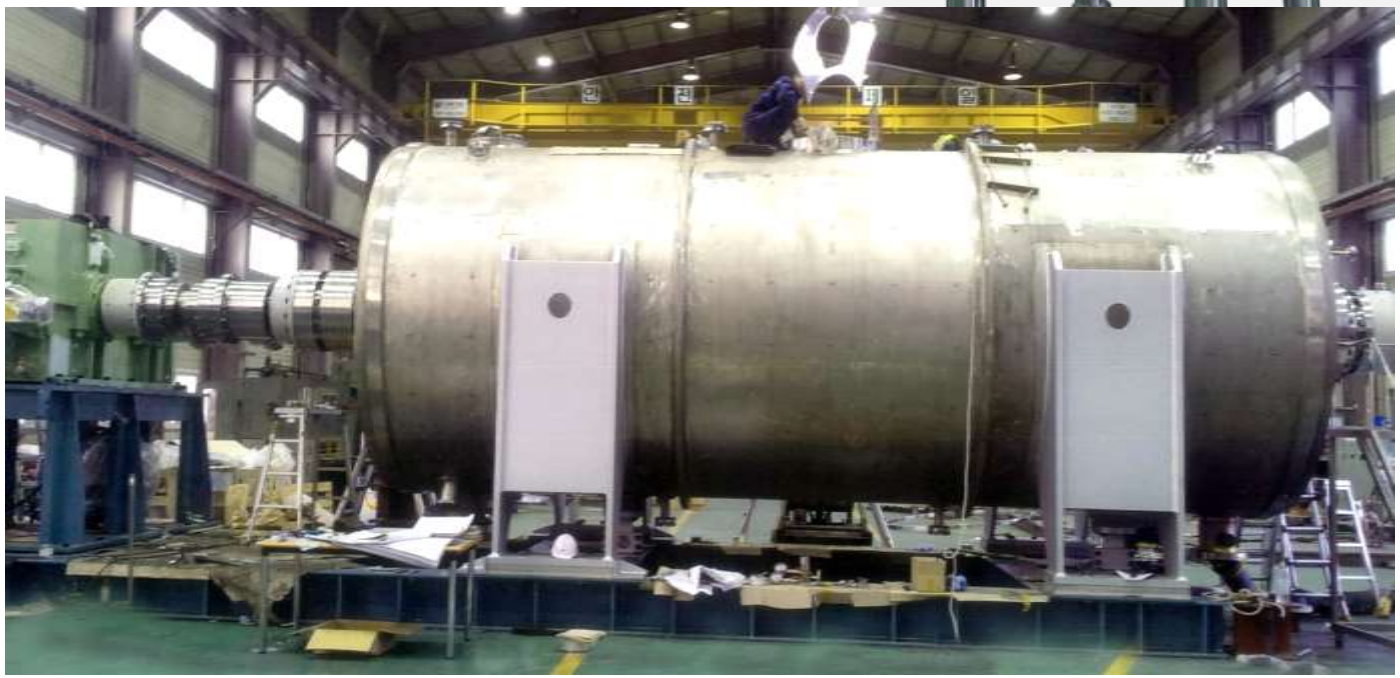


PSG System

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API & Chemical





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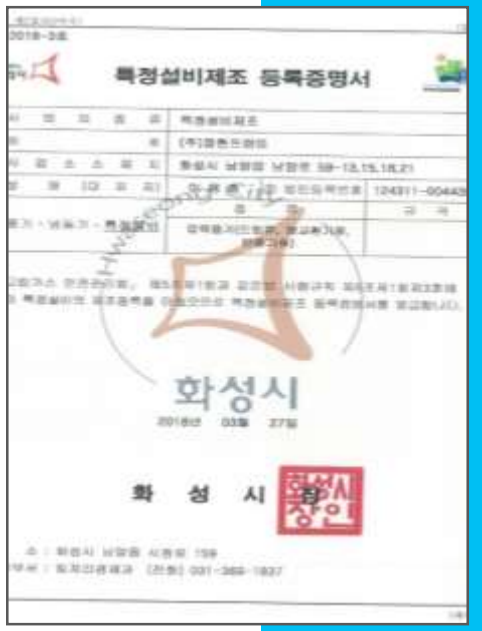
3. Certificate











- ISO 9001 : 2015 TÜV Rheinland
- ISO 14001 : 2015 Environmental Management System
- ASME U-Stamp
- CSEL
- High Pressure Vessel

4. ASME BPE (Bio Processing Equipment)

ASME BPE STANDARD COMMITTEE

ASME the latest (14 Oct. 2016) Standard provides the requirements applicable to **the design of equipment used in the bioprocessing, pharmaceutical and personal-care products industries, as well as other applications with relatively high levels of hygienic requirements.**

It covers materials, design, fabrication, inspections, testing and certification.



ASME BPE Standard Committee

① General Requirements
② System Design
③ Metallic Materials
④ Polymeric and Other Nonmetallic Materials
⑤ Dimensions and Tolerance for Process Components
⑥ Process Instrumentation
⑦ Sealing Components
⑧ Materials Joining
⑨ Process Contact Surface Finishes
⑩ Certification Requirements

Spray ball (JHP)



Sprayball Coverage Test

Jung Hyun Plant

P3S-PV-4953 (Buffer Hold Vessel 4953)

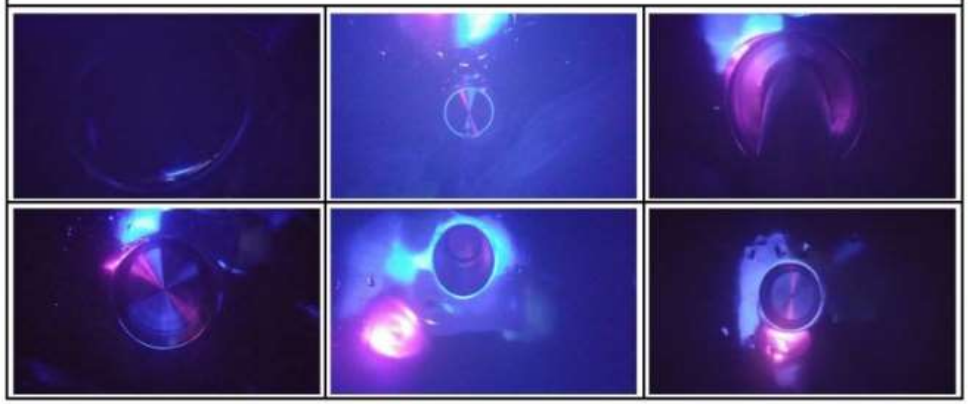
① Test Pressure : 1.5 bar
② Spray time: 2 minutes x 3 times
③ Cleaned out 확인
④ Flow Rate 확인
(Design max. flow rate) 21.2 m³/hr

(Test 결과)
: Cleaned out 조건에 부합됨.
: (Actual flow rate) 15.5 m³/hr

(before spraying) Soiled Vessel Top Head



(after spraying) Cleaned condition Top Head



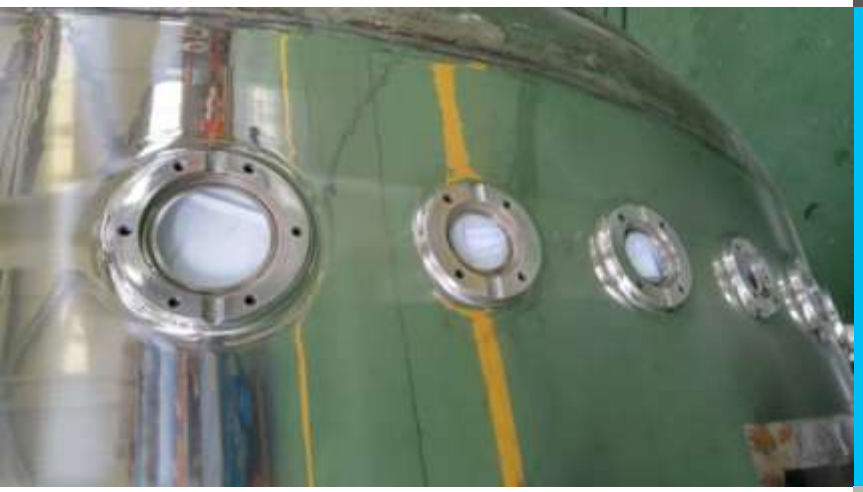
PLANT

- Inner Pipe (J-Tube & Baffle)

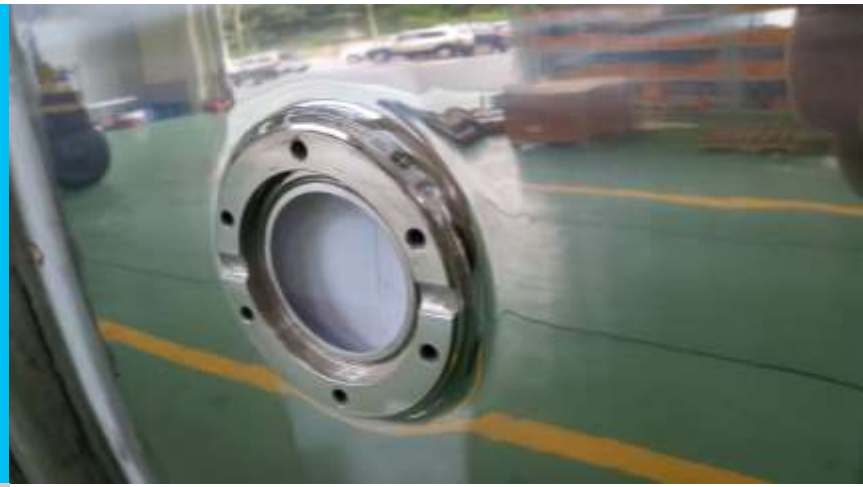








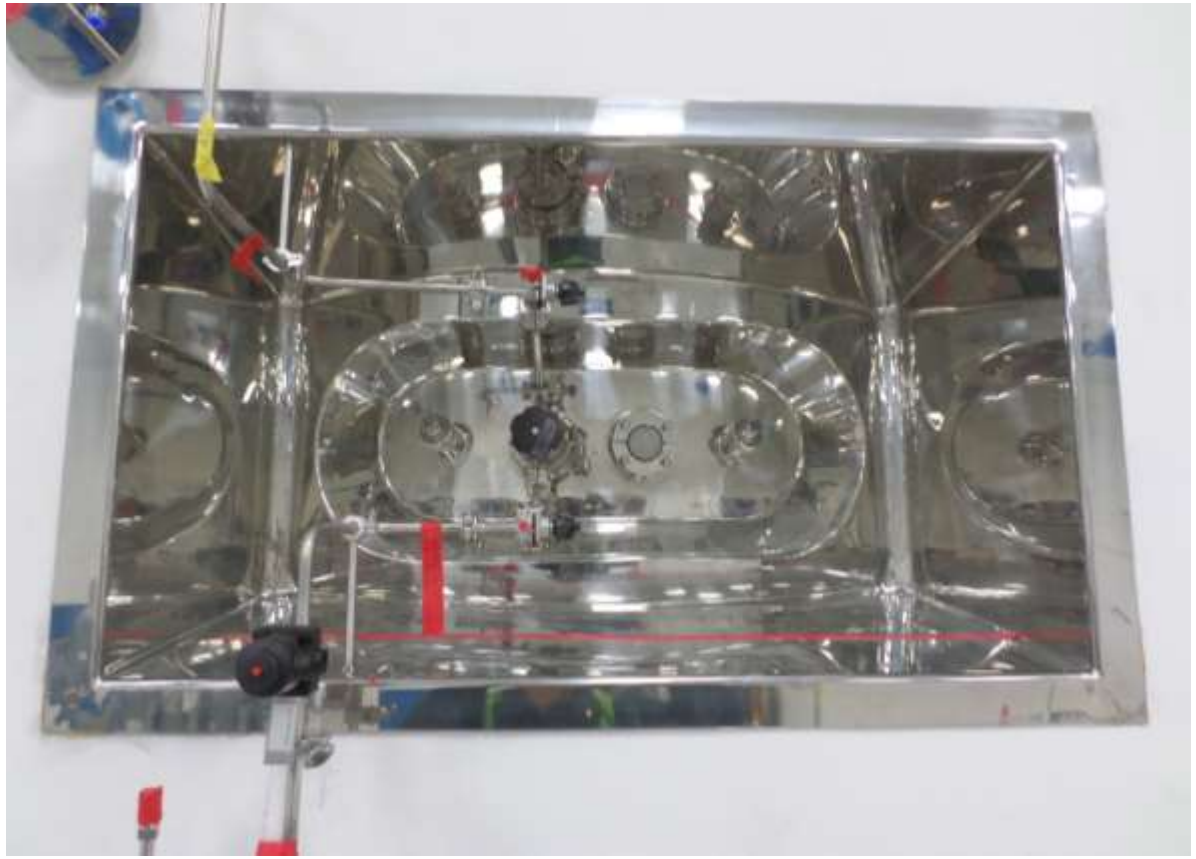
Nozzle



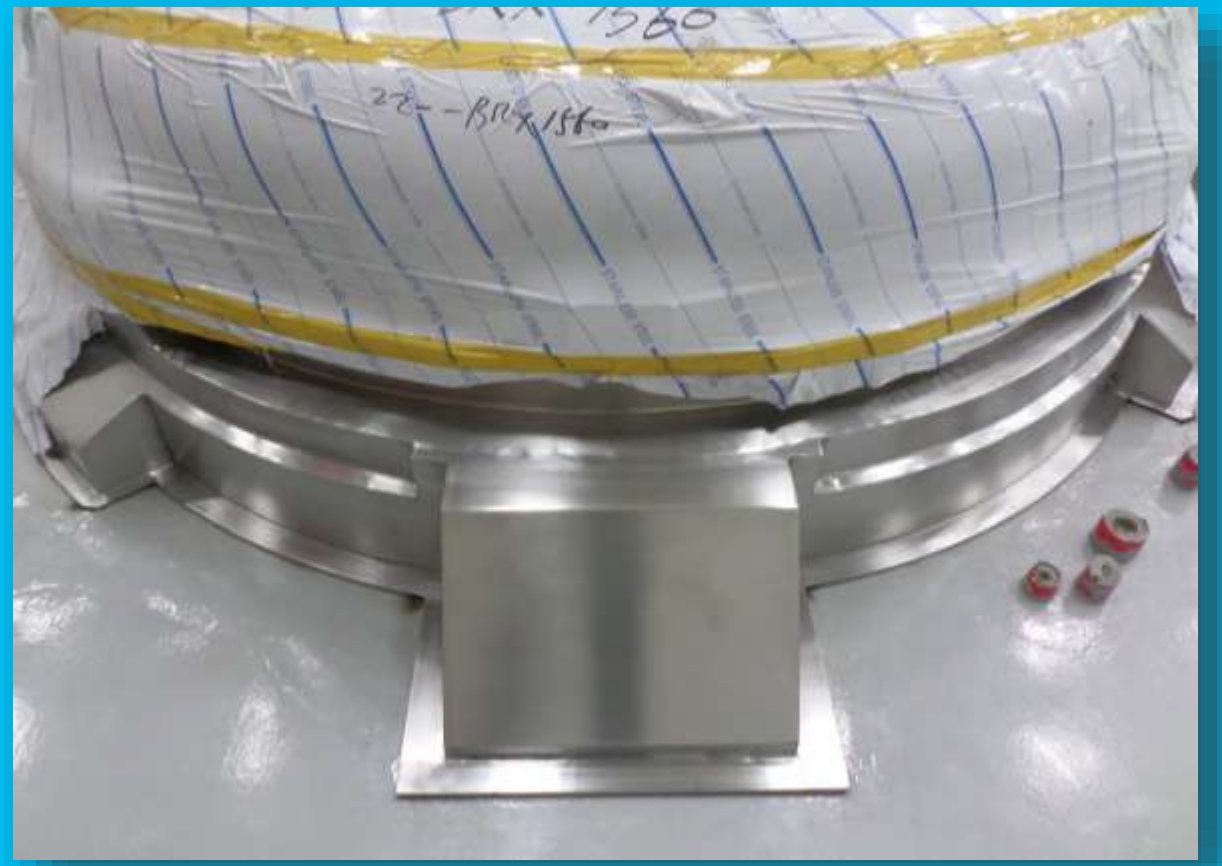


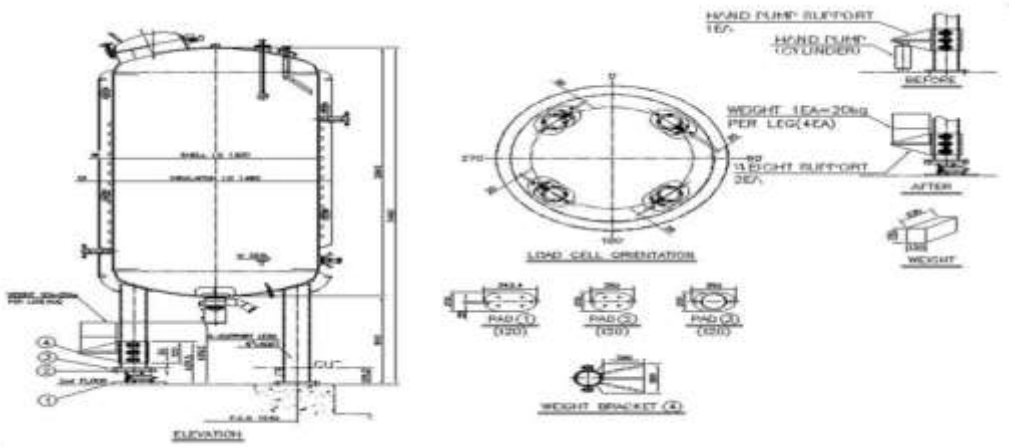
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Sampling Window



Skirt Ring



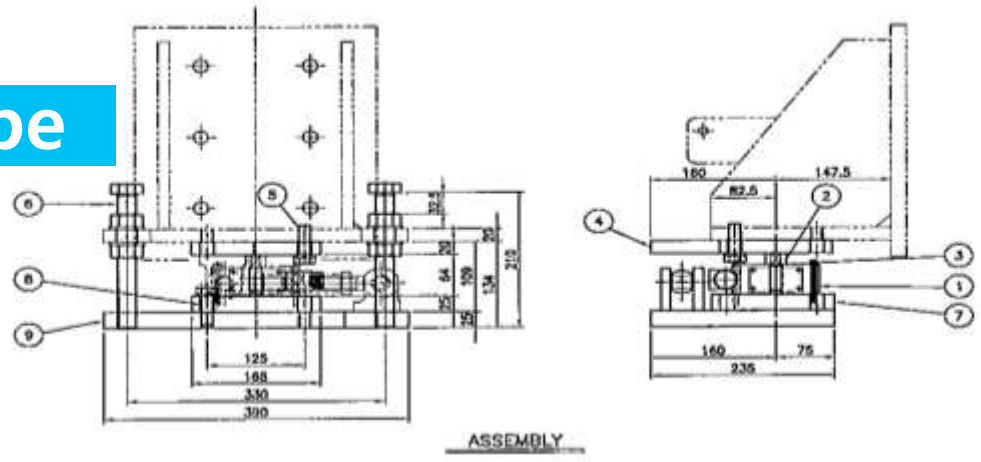


Leg Type





Lug Type



Insulation Material

	ENGINEERING SPECIFICATION INSULATION SPECIFICATION			
Project	Doc. No	Version	Date	F
	SF2437-P3-P-003	A	19AUG2015	5

for Nominal Sizes of Pipe and Tubing

ASTM C591 - Standard Specification for Unfaced Preformed Rigid Cellula Polyisocyanurate Thermal Insulation

ASTM C592 - Specification for Mineral Fiber Blanket Insulation and Blanke Pipe Insulation (Metal Mesh Covered) (Industrial Type)

ASTM C612 - Specification for Mineral Fiber Block and Board Thermal Ins

ASTM C680 - Standard Practice for Estimate of the Heat Gain or Loss and Surface Temperatures of Insulated Flat, Cylindrical, and Sph Systems by Use of Computer Programs.

ASTM C795 - Specification for Thermal Insulation for Use in Contact wit Stainless Steel

ASTM C1086 - Specification for Glass Fiber Felt Thermal Insulation

ASTM C1094 - Standard Guide for Flexible Removable Insulation Covers

ASTM C1126 - Specification for Faced or Unfaced Rigid Cellular Phenolic T Insulation

ASTM C1136 - Specification for Flexible, Low Permeance Vapor Retarders Thermal Insulation

ASTM E84 - Standard Test Method for Surface Burning Characteristics o Materials

ASTM E96 - Standard Test Methods for Water Vapor Transmission of Ma

KS M6962 - Standard Specification for Elastomeric Foam Thermal Insul Material

SF2437-P3-P-0004 - Painting Specification for Edison3 Project

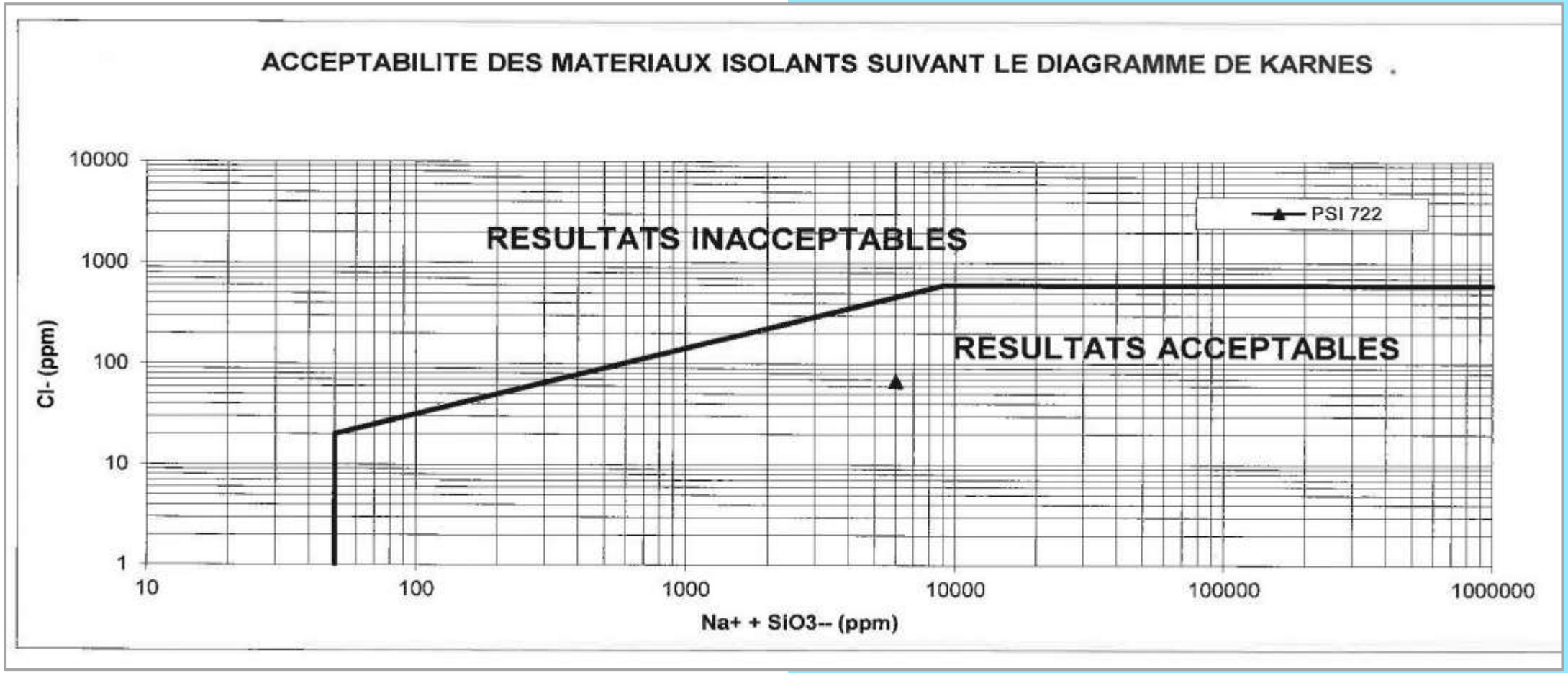
ASTM C795 (Chloride Free)

2.2.1 Material specification for "Glass Wool"

Material Type:	Glass Wool
Note: Low chloride, in accordance with ASTM C795 "Acceptable Analysis" (See the figure 1 on the next page)	
Service Temperature Limit:	300°C
Specification:	KS L9102
K Factor:	0.035 W/m.K at 20°C
Nominal Density:	48 kg/cu.m.
Applicable Forms:	Pipe Sections, Board, and Flexible Blankets

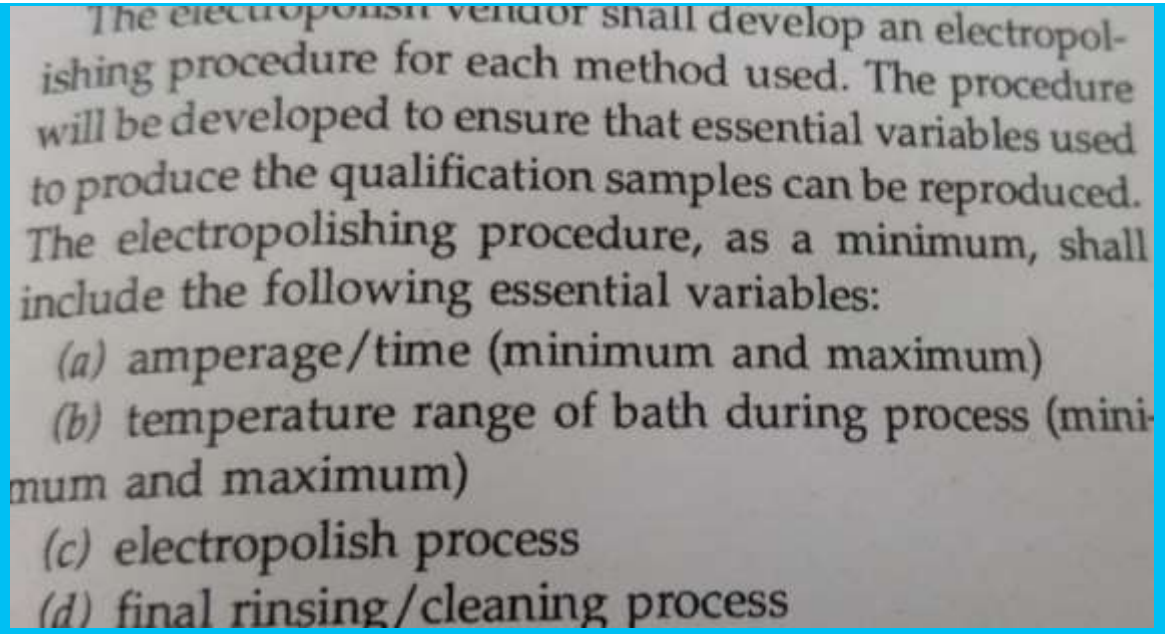
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Acceptance Criteria (ASTM C795)



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Main Test


The electropolish vendor shall develop an electropolishing procedure for each method used. The procedure will be developed to ensure that essential variables used to produce the qualification samples can be reproduced. The electropolishing procedure, as a minimum, shall include the following essential variables:

(a) amperage/time (minimum and maximum)

(b) temperature range of bath during process (minimum and maximum)

(c) electropolish process

(d) final rinsing/cleaning process

1) Electro Polishing

Material	Cr/Fe Ratio	Acceptance criteria	Surface Photo
UNS S31600 (316 SS)	1 to 1 or greater	15 Å minimum	150X [Note (2)]
UNS S31603 (316L SS)	1 to 1 or greater	15 Å minimum	150X [Note (2)]

CODE **(ASME BPE-2014 Table H-3.3-1) Minimum Surface Requirements for Process Qualification Samples.**

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• Witness after E.P Surface Finish



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5. Facility_Radiography Test Room



Radiographic Room(8700x4500X7900)
4,500 x 17,000L

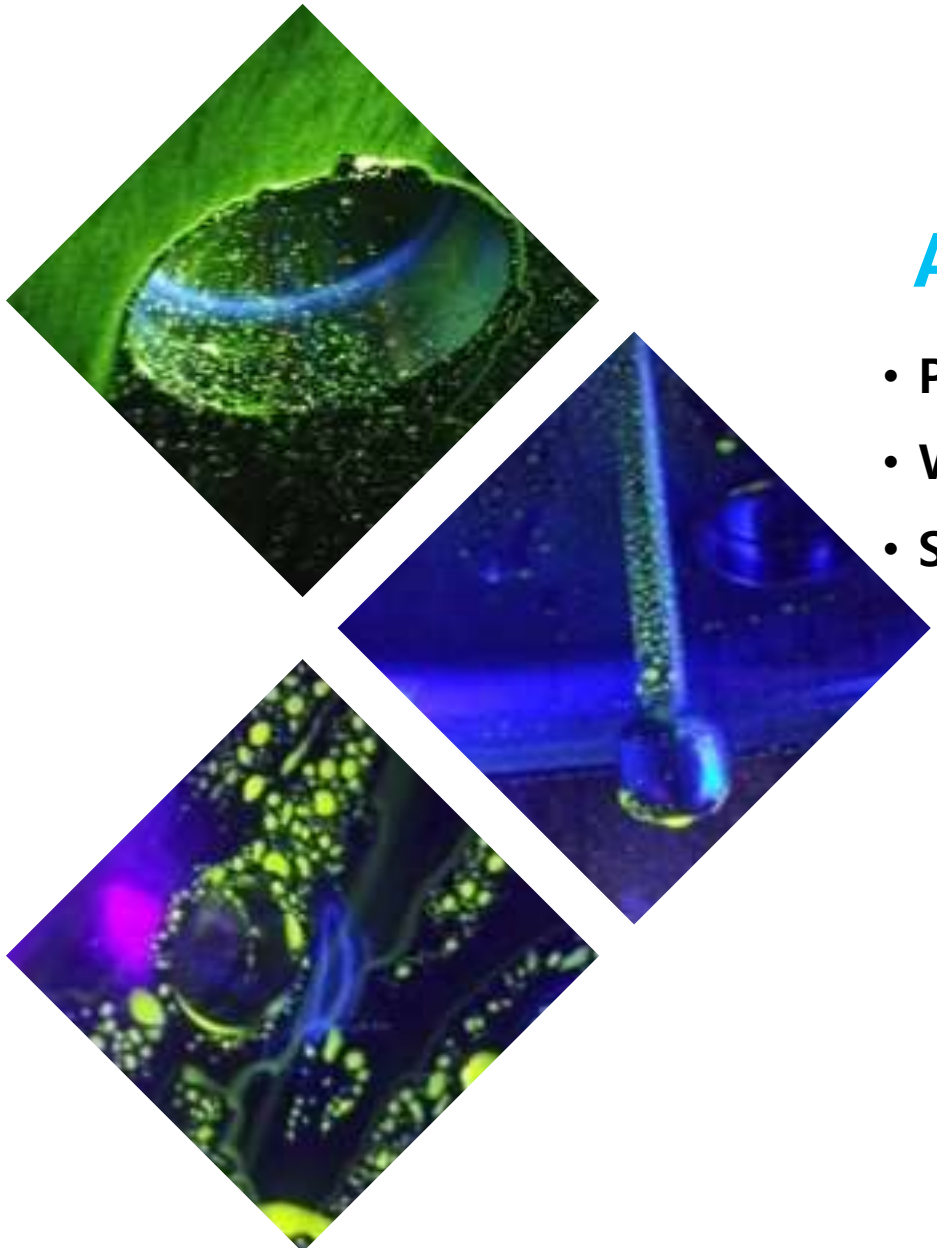


- Reinforce Local Regulation since 2014.07.01
- Mandatory to be furnished RT Room

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•CIP Test Room_Sprayball Coverage Test





Advantage

- Perfect CIP Test on Top Head
- Welding C.L to Shell
- SAT cost & time can be saved

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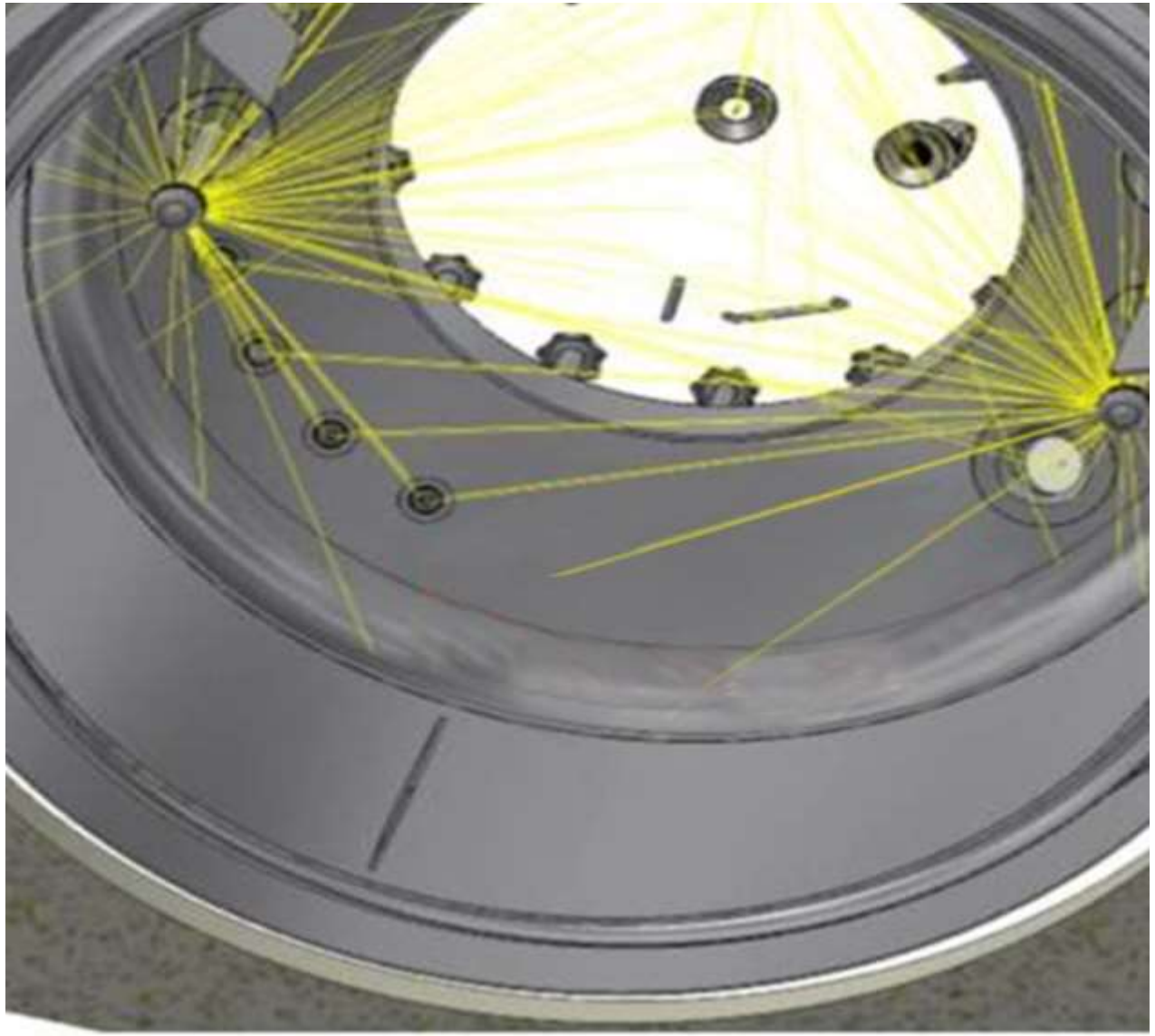
Top Head Sprayball Coverage Test



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Sprayball Coverage Test

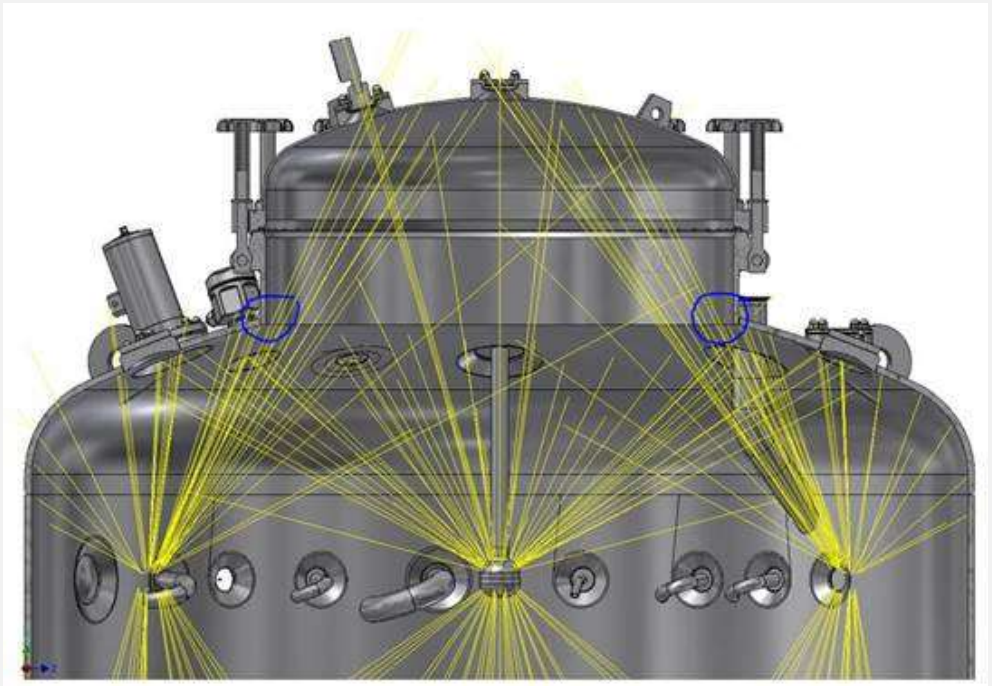
1. Riboflavin Testing



Purpose to test Clean in Place (CIP) spray patterns in stainless steel process vessels for completeness of spray coverage.

The tanks may contain an agitator, vortex breaker, nozzles, man-way, fittings, projections, etc., which could create spray "shadows."

These shadowed areas must be all cleaned.



Sprayball Coverage Test









JUNGHYUN PLANT

Sprayball Coverage Test

Test Report

Factory Acceptance Test Protocol

Title: Buffer Hold Vessel 4953	
Document No.: P3-FAT-P-2016-XXX	Tag No. : P3S-PV-4953
Version No: 1.0	Page: 41 / 48

TP 8 – Sprayball Coverage Verification

Results

Criteria	*Result*	*Initial/Date*
Test Part	☑ Top head ☐ Full	KNU 23 Aug 2016
UV Lamp Wave Length and Intensity	☑ 365 nm ☑ 4,000 μW/cm² (38cm)	KNU 23 Aug 2016
Check the internal surface using a UV lamp to verify complete coverage with the Riboflavin.	☑ Yes ☐ No, Exp. No.___	KNU 23 Aug 2016
Spray Time	☑ 2 minute X 3 times Start (hh:mm): 16 : 17 End (hh:mm): 16 : 23	KNU 23 Aug 2016
The Riboflavin is cleaned out successfully (Visual inspection using UV lamp) with equal or less than maximum design total flow rate. If no, leave a comment where riboflavin is remained on comment section and attach photo.	Total Flow Rate (m^3/hr) / Pressure (bar) Design Criteria (Max): 21.2 Execution Condition: 15.5 Execution Condition: 1.5 ☑ Yes ☐ No, Exp. No.___	KNU 23 Aug. 2016
Attach photographs of the soiled and cleaned internal surface of vessel.	☑ Yes Att. No.___ ☐ No, Exp. No.___	KNU 23 Aug 2016

Exceptions (List all associated Exceptions e.g. Exception 01, Exception 02)

Comments

Reviewed By:	Date:

Sprayball Coverage Test

Jung Hyun Plant

P3S-PV-4953 (Buffer Hold Vessel 4953)

① Test Pressure : 1.5 bar
② Spray time: 2 minutes x 3 times
③ Cleaned out 확인
④ Flow Rate 확인
(Design max. flow rate) 21.2 m³/hr

(Test 결과)
: Cleaned out 조건에 부합됨.
: (Actual flow rate) 15.5 m³/hr

(before spraying) Soiled Vessel Top Head



(after spraying) Cleaned condition Top Head





Water Jet (2 sets)

- 3D Modeling Program
- Tolerance : 0.01mm
- No thermal deformation while Nozzle Opening
- Capable of Deep Procession
- 360° Rotating Open
- Size: 4.5m x 4.5m



Borecope Inspction





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Stock Room (Instrument & Parts)







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Measurement Tools













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6. Customer_International

PIERRE GUERIN TECHNOLOGIES

BIOENGINEERING
Design and production of microbiological plants

MERCK

FOOSUNG (주)후성

AUROBINDO
Committed to Healthier Life

OSAKA SANITARY

HITACHI

Menicon Nect

AURONEXT
PHARMA PVT. LTD.

WuXi Biologics
Global Solution Provider

COVALENT
Laboratories Private Limited

Daana
Pharma Co.

NecLife
Nurturing Enriching Caring

6. Customer_Domestic

Domestic

SAMSUNG BIOLOGICS

New Paradigm In Pharma CELLTRION

종근당 Chong Kun Dang Pharm. Seoul, Korea

Hanmi

yuhan CHEMICAL INC.

대웅바이오

PHARMACOS

Hanmi 한미정밀화학 Hanmi Fine Chemical

KYONGBO PHARM 도전하는 기업, 사랑받는 기업 경보제약

신풍제약주식회사 SHIN POONG PHARM. CO., LTD.

HanaPharm 하나제약(주)

POLUS Solutions for Medical Equality

LG Life Sciences

DONG-A PHARM.

JEIL PHARM. CO., LTD.

JW 중외제약

ILDONG

PHARMAGEN

6. Customer_Domestic

Chemical Industry

Food Industry



2012





2013



2014





2015

EXHIBITION
Interphex Japan

JUNGHYUN PLANT


2016



2017



2018







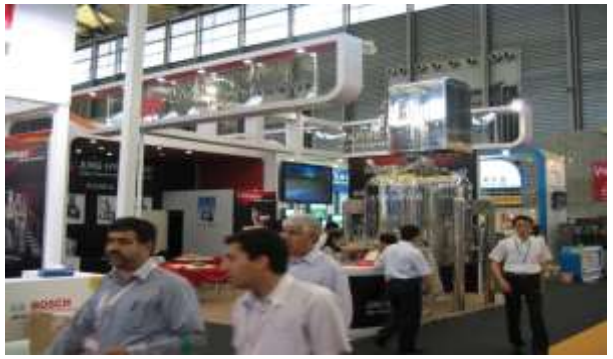
2019

EXHIBITION
Interphex Japan

JUNGHYUN PLANT

CPhI & P-Mec

P-Mec





2011 P-Mec / China
2015 CPhI / COEX





CPhI

JUNGHYUN PLANT

Interphex Japan 2019







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KOREA CHEM 2018





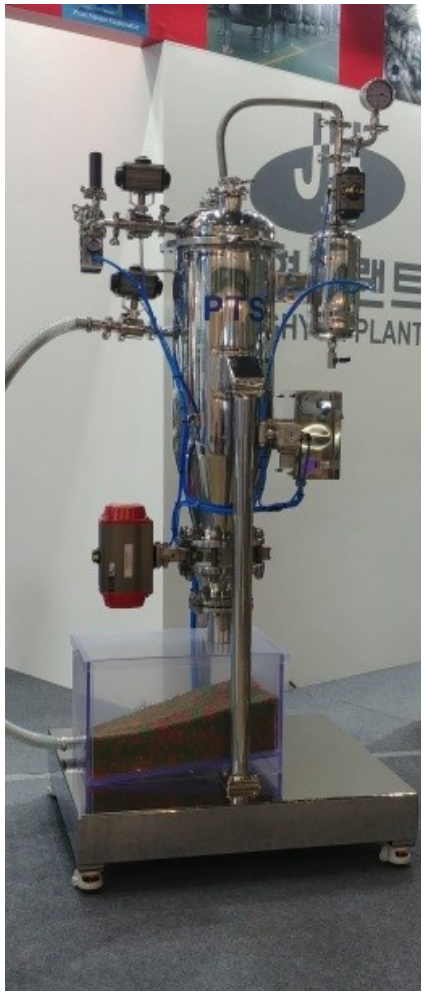


2018 (KINTEX KOREA)

JUNGHYUN PLANT

KOREA CHEM 2019





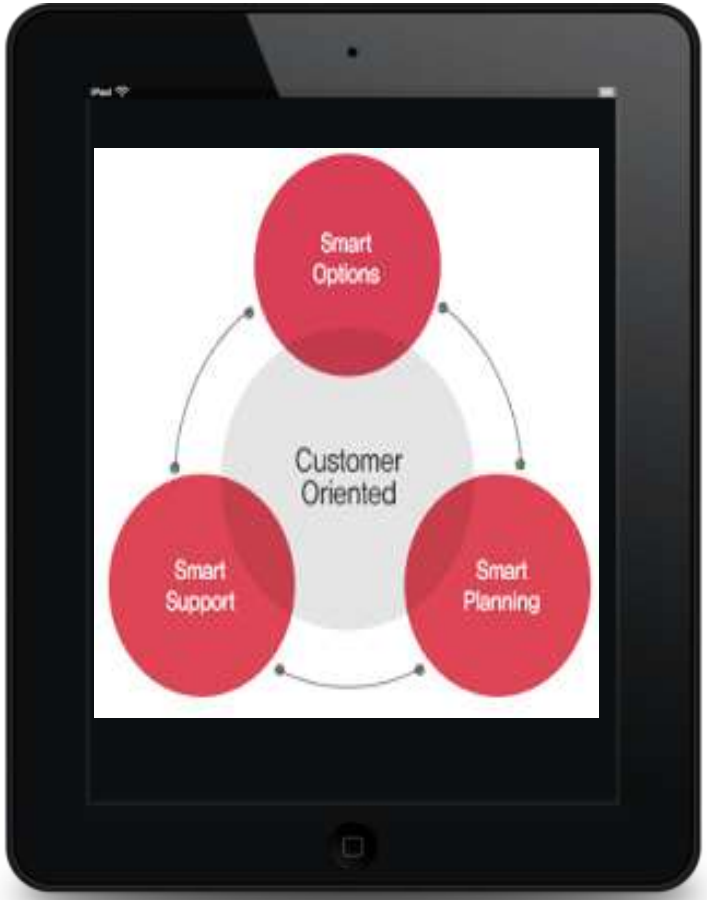




2019 (KINTEX KOREA)

JH JUNGHYUN PLANT

JUNGHYUN PLANT CO., LTD.



- CUSTOMER FOCUS
- TECHNOLOGY-ORIENTED
- QUALITY CONTROL & ASSURANCE
- TRUSTWORTHY

JUNGHYUN PLANT





THANK YOU
JUNGHYUN PLANT

Experiences, Technology,

Perfect Applying URS,

Strict Safety & Quality Control

“PARTNER FOR YOUR SUCCESS”