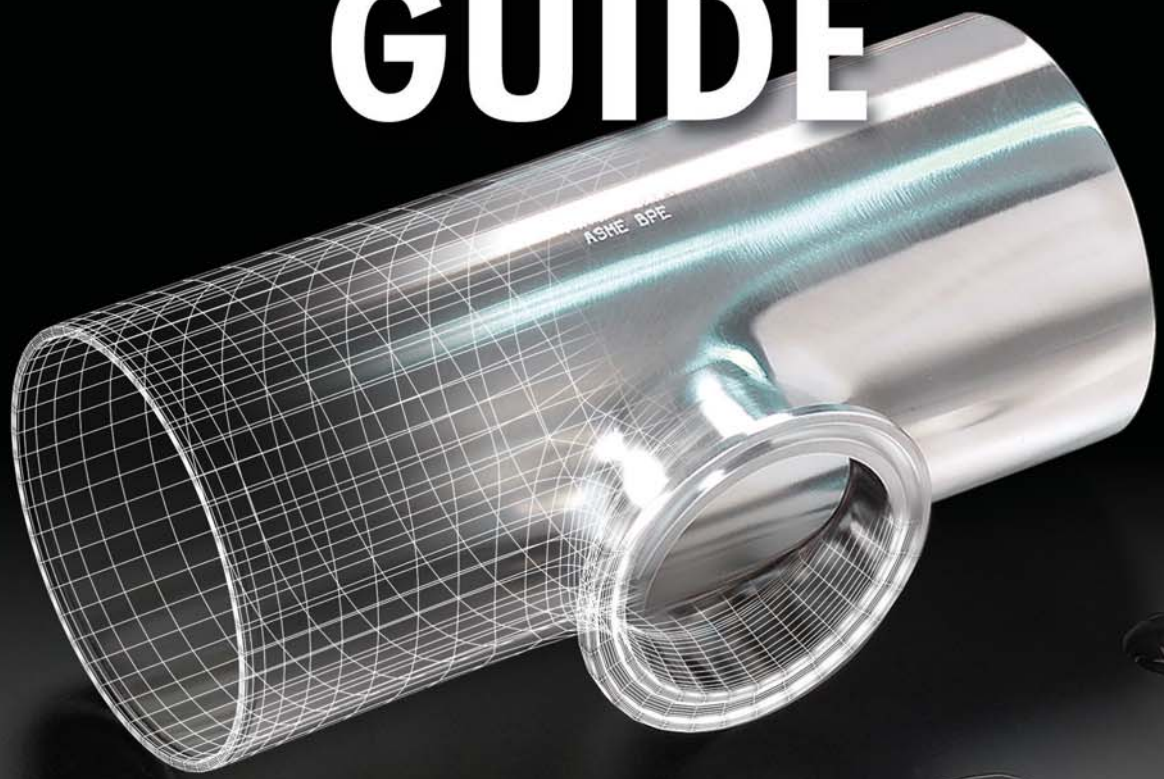
Maximum Purity with Guaranteed Ra

MaxPure

BPE

Bio Processing Equipment

GUIDE



NEUMO VNE EGMO

Neumo Ehrenberg Group

MaxPure - Maximum Purity with Guaranteed Ra

Where cleanability of fittings is the issue, every step in the production process must be carefully controlled. Our production methods insure that no mechanical damage or flaws occur during manufacturing. The cleaning procedures incorporate multi-process degreasing and washing steps provided to eliminate any residues of hydrocarbons and stains, using pure 18 MΩ deionized water. Our procedures and process capabilities result in the formation of a stabilized passive layer and increased corrosion resistance.

Our products proudly offer:

Maximum Cleanability

Cleanability defines how easily contaminants can be removed from a surface.
Our process guarantees the correct finish requirements, chemical composition and passivity state, with no major physical and /or metallurgical flaws.

Full Traceability

We provide full traceability for each of our products by supplying all necessary production process data. Starting from certifications and incoming inspection of raw materials, through in-process quality control, final inspection, marking and packaging. The process is also completely documented with a unique job number for each BPE process component.

Every Fitting is Quality Inspected

All around quality and meticulous inspection insures that every fitting will be of the highest quality and in total compliance with all ASME-BPE standards.

The Neumo Ehrenberg group

The Neumo Ehrenberg Group, a diversified multi-national organization headquartered in Germany, was founded by Senator Henry Ehrenberg in 1947.
Over the last decade, the Group has become a leading manufacturer for worldwide Biopharmaceutical process fittings and components. With its three leading companies, NEUMO, VNE and EGMO, the group has developed a worldwide distribution network supporting major Biopharmaceutical multinational accounts.
The Neumo Ehrenberg Group's synergy and strategy toward the Biopharmaceutical sectors provide customers with innovation, all around quality and efficiency.
Through our Group's volunteer participation in leading standards organizations, we are actively involved in shaping the future for a cleaner, safer and more productive workplace in the Biopharmaceutical Processing Industry.

NEUMO VNE EGMO

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Introduction to BPE (BioProcessing Equipment) Standard

This Standard deals with the requirements applicable to the design used in the bioprocessing, pharmaceutical, and personal care product industries, covering directly or indirectly the subjects of materials, design, fabrications, pressure systems (vessels and piping), examinations, inspections, testing, and certifications. Items or requirements that are not specifically addressed in this Standard cannot be considered prohibited.

- International standard established in 1997 under ASME Boiler & Power Piping Codes and Standards.
- Recognized in over 30 countries
- Requirements applicable to the design used in the bioprocessing, pharmaceutical & personal care product industries

Covering directly or indirectly the subjects of:

- Materials
- Design
- Fabrications
- Pressure systems (vessels and piping)
- Examinations
- Inspections
- Certifications
- Testing

Provides designer & a process engineers a reliable requirements & measurable way of specifying Hygienic Tubes, Valves & Fittings for:

a) Components that are in contact with the product, raw materials, or product intermediates during manufacturing, development, or scale-up.

b) Systems that are a critical part of product manufacture: Water-For-Injection (WFI), steam, filtration & intermediate product storage.

- **Installation, validation & maintenance are:**
  Easier to manage
  Minimize overall project & maintenance costs

Main Advantages of the ASME BPE Standard

- Controlled Sulfur content of 0.005-0.017% contributes to repeatability in the orbital automatic welding process. **(See Table DT-3, Standard ASME BPE.)**
- Clear quantitative recognition between various surface treatments and surface finish. **(See Table SF-4 - Standard ASME BPE.)**
- Additional requirement for surface quality to Ra-max in addition to RA average. **(See Table SF-4, Standard ASME BPE.)**
- Stipulation of required measurements and tolerances. **(See Table DT-4, Standard ASME BPE.)**
- Quantitative definition for measuring different types of flaws arising from various sources:
  a) raw material quality
  b) mechanical process
  c) welding flaws
  (See Table SF-3, Standard ASME BPE.)
- Clear definition of standard marking and packaging for accessories. **(See Table DT-3, Standard ASME BPE.)**
- Clear definition of “Maximum pressure ratings”. **(See Table DT-2, Standard ASME BPE.)**
- Accurate definition of basic concept of systems and elements. **(See Table GR-10, Standard ASME BPE.)**
- General requirements for design of hygienic and sterile accessories and different pipe elements such as: valves, pumps, filters and heat exchangers. **(See Chapter SD, Standard ASME BPE.)**
- Categories of different seal types, definition of structure, and mechanical and physical requirements for various applications. **(See Chapter SG, Standard ASME BPE.)**

MaxPure

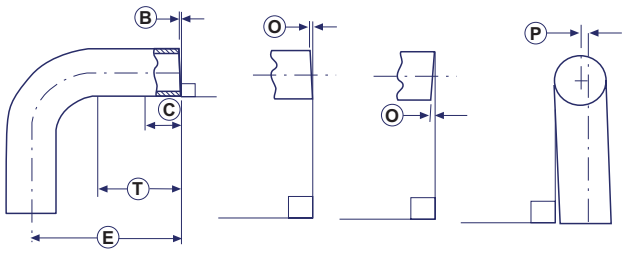
Fittings Specifications

Product:
Stainless Steel fittings comply with ASME BPE standards.
Gaskets are made from compounds which are
FDA approved and USP24 Pharmaceutical Class VI certified.

Sizes:
Stainless Steel fittings are available in sizes ½" - 6" O.D. tube size.

Material:
Fittings are fabricated in AISI 316L Stainless Steel with sulfur content of 0.005-0.017% achieving superior repeatability for automatic orbital welding process.

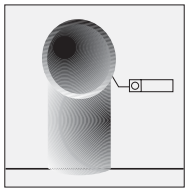
Dimensions & Tolerances:
Dimensions as specified in ASME BPE Part DT.



General Note:
Tolerance on (E)
End-to-End
Center-to-End:
0.050 in. (=1.27 mm)

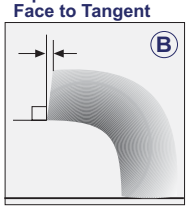
Nominal OD Size	½"	¾"	1"	1½"	2"	2½"	3"	4"	6"
O.D. Tolerance	±.005	±.005	±.005	±.008	±.008	±.010	±.010	±.015	±.030
Nominal Wall Thickness	.065	.065	.065	.065	.065	.065	.065	.083	.109
Wall Thickness Tolerance before EP	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.005 - .008	+.008 - .010	+.015 - .015
Wall Thickness Tolerance after EP	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.005 - .010	+.008 - .012	+.015 - .017
Control Length (C)	.750	.750	.750	.750	.750	.750	.750	.750	.750
Tangent Length (T)	1.500	1.500	1.500	1.500	1.500	1.500	1.750	2.000	2.500
Squareness Face to Tangent (B)	.005	.005	.008	.008	.008	.010	.016	.016	.030
Off Angle (O)	.014	.018	.025	.034	.043	.054	.068	.086	.135
Off Plane (P)	±.030	±.030	±.030	±.050	±.050	±.050	±.050	±.060	±.060

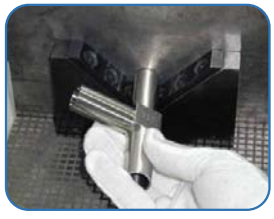
• Roundness



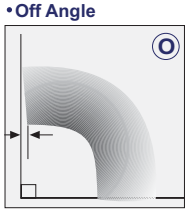
• Wall Thickness

• Squareness Face to Tangent

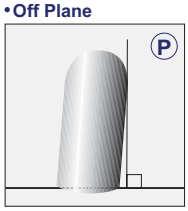




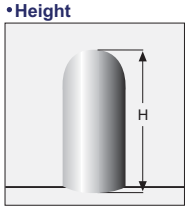
• Off Angle



• Off Plane



• Height



Fittings Specifications

Surface Finish:

Reference: ASME BPE Part SF, table SF-4.

Surface Finish Code	ASME BPE Surface Designation	Inside Surface			Outside Surface
		Ra Maximum		Surface Treatment	Surface Treatment
		µ-in.	µm		
PC	SFF1	20	0.51	Mechanically Polished	Unpolished
PL	SFF1	20	0.51	Mechanically Polished	Mechanically polished to 32 Ra µ-in.
PF	SFF3	30	0.76	Mechanically Polished	Unpolished
PT	SFF3	30	0.76	Mechanically Polished	Mechanically polished to 32 Ra µ-in.
PD	SFF4	15	0.38	Mechanically Polished & Electropolished	Unpolished
PR		10	0.25	Mechanically Polished & Electropolished	Mechanically polished to 32 Ra µ-in.
PM	SFF4	15	0.38	Mechanically Polished & Electropolished	Mechanically polished to 32 Ra µ-in.
PO	SFF5	20	0.51	Mechanically Polished & Electropolished	Mechanically polished to 32 Ra µ-in.

General Notes: **1.** All Ra readings are taken across the lay, wherever possible.
2. Other customized finishes are available on request.

Cleaning:

A multi step cleaning cycle is conducted to ensure that fittings are cleaned with a perfect passivation layer.
The cleaning process involves degreasing, pickling, electro polishing (as required) and passivation. During the final stage, the fittings are double-rinsed using hot DI water.

Cleaning

Inspection Procedures:

All fittings produced by EGMO production are 100% visually inspected for any surface finish imperfections, as mentioned in Table SF-3 in the ASME BPE specification. All dimensional characteristics are inspected 100% for tolerances listed in Table DT-5 in the ASME BPE specification.

Inspection Procedures

Marking:

Each BPE fitting is marked with the following:

- Heat number
- Job number
- Material grade
- Standard
- Surface finish (SFF), as specified in ASME BPE, Part DT.
  Brand name

Marking

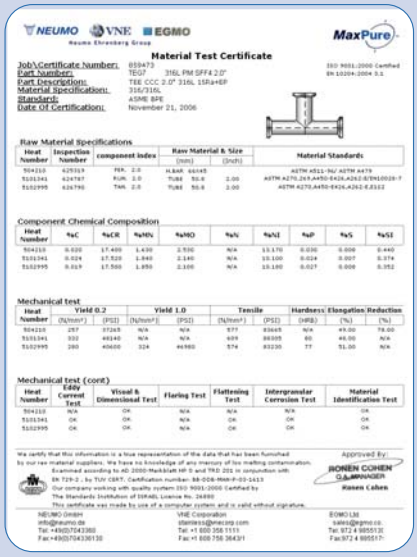
Packaging:

Each fitting is capped, bagged and labeled in full compliance with the ASME BPE standard.

Packaging

Documentation:

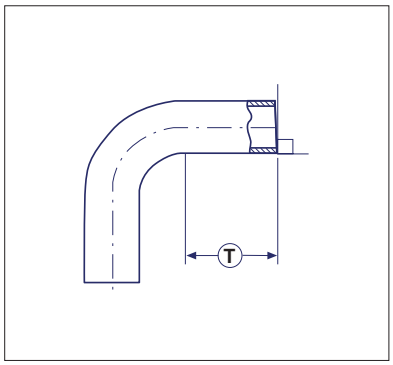
Full Material Test Reports are supplied with the finished products and are also accessible on line through our interactive internet website.
The only input parameter necessary to generate the MTR is the product's job number.
The job number is the product identification number which represents all processes and raw materials related to the specific item.



Documentation

Table DT-4 Tangent Lengths

Nominal OD Tube Size, in.	Tangent, T	
	in.	mm
¼	1.50	38.10
⅜	1.50	38.10
½	1.50	38.10
¾	1.50	38.10
1	1.50	38.10
1½	1.50	38.10
2	1.50	38.10
2½	1.50	38.10
3	1.75	44.45
4	2.00	50.80
6	2.50	63.50



*** Specifications per ASME BPE.**

GENERAL NOTE:
Minimum tangent lengths for ferrules do not apply.

Table DT-5 Tolerances for Mechanically Polished Fittings and Process Components

Nominal Size, in.	O D		Wall Thickness		Squareness Face to Tangent, B		Off Angle, O		Off Plane, P	
	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm
¼	±0.005	±0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.009	0.23	0.030	0.76
⅜	±0.005	±0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.012	0.30	0.030	0.76
½	±0.005	±0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.014	0.36	0.030	0.76
¾	±0.005	±0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.018	0.46	0.030	0.76
1	±0.005	±0.13	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.025	0.64	0.030	0.76
1½	±0.008	±0.20	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.034	0.86	0.050	1.27
2	±0.008	±0.20	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.043	1.09	0.050	1.27
2½	±0.010	±0.25	+0.005/-0.008	+0.13/-0.20	0.010	0.25	0.054	1.37	0.050	1.27
3	±0.010	±0.25	+0.005/-0.008	+0.13/-0.20	0.016	0.41	0.068	1.73	0.050	1.27
4	±0.015	±0.38	+0.008/-0.010	+0.20/-0.25	0.016	0.41	0.086	2.18	0.060	1.52
6	±0.030	±0.76	+0.015/-0.015	+0.38/-0.38	0.030	0.76	0.135	3.43	0.060	1.52

*** Specifications per ASME BPE.**

Table SF-3 Acceptance Criteria for Interior Surface Finishes of Fittings

Anomaly or Indication	Acceptance Criteria
Cluster of pits	No more than 4 pits per each 1/2 in. x 1/2 in. inspection window. The cumulative total of all relevant pits shall not exceed 0.040 in.
Demarcation	If <5% of total area when visually inspected and Ra max. is met.
Dents	None accepted.
Grit lines	If Ra max. is met.
Welds	If polished smooth, blended, and Ra max. is met.
Nicks	None accepted.
Pits	If diameter <0.020 in. and bottom is shiny. Pits <0.030 in. diameter are irrelevant and acceptable.
Scratches	If length <0.25 in., depth <0.030 in. and Ra max. is met.
Star burst	None accepted.
Surface cracks	None accepted.
Surface inclusions	If Ra max. is met. and there is no liquid penetrant indication.
Surface residuals	None accepted, visual inspection.
Surface roughness (Ra)	See Table SF-4.
Weld slag (per tube length)	None accepted.
Weld porosity	None accepted.

*** Specifications per ASME BPE.**

Table SF-4 Ra Readings for Fittings

Surface Designation	Mechanically Polished Ra Maximum	
	µ-in.	µm
SFF1	20	0.51
SFF2	25	0.64
SFF3	30	0.76
Surface Designation	**Mechanically Polished and Electropolished Ra Maximum**	
	µ-in.	µm
SFF4	15	0.38
SFF5	20	0.51
SFF6	25	0.64

*** Specifications per ASME BPE.**

GENERAL NOTE:
(a) All Ra readings are taken across the lay, wherever possible.
(b) No single Ra reading shall exceed the Ra max. value in this table.
(c) Other Ra readings are available if agreed upon between owner/ user and manufacturer, not to exceed values in this table.

NOTE:
(1) On any other finishing method that meets the Ra max.

MaxPure recommendation - MTR

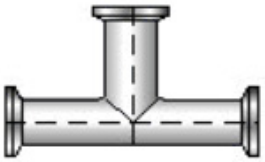
NEUMO VNE EGMO
Neumo Ehrenberg Group

MaxPure

Material Test Certificate

ISO 9001:2000 Certified
EN 10204:2004 3.1

Job\Certificate Number:	859473
Part Number:	TEG7 316L PM SFF4 2.0"
Part Description:	TEE CCC 2.0" 316L 15Ra+EP
Material Specification:	316/316L
Standard:	ASME BPE
Date Of Certification:	November 21, 2006



Raw Material Specifications

Heat Number	Inspection Number	component index	Raw Material & Size (mm)	(Inch)	Material Standards
504210	625319	FER. 2.0	H.BAR 66X45		ASTM A511-96/ ASTM A479
5101341	624787	RUN. 2.0	TUBE 50.8	2.00	ASTM A270,269,A450-E426,A262:E/EN10028-7
5102995	626790	TAN. 2.0	TUBE 50.8	2.00	ASTM A270,A450-E426,A262:E,E112

Component Chemical Composition

Heat Number	%C	%CR	%MN	%MO	%N	%NI	%P	%S	%SI
504210	0.020	17.400	1.630	2.530	N/A	13.170	0.030	0.008	0.440
5101341	0.024	17.520	1.840	2.140	N/A	10.100	0.024	0.007	0.374
5102995	0.019	17.500	1.850	2.100	N/A	10.180	0.027	0.008	0.352

Mechanical test

Heat Number	Yield 0.2 (N/mm²)	Yield 0.2 (PSI)	Yield 1.0 (N/mm²)	Yield 1.0 (PSI)	Tensile (N/mm²)	Tensile (PSI)	Hardness (HRB)	Elongation (%)	Reduction (%)
504210	257	37265	N/A	N/A	577	83665	N/A	49.00	78.00
5101341	332	48140	N/A	N/A	609	88305	80	48.00	N/A
5102995	280	40600	324	46980	574	83230	77	51.00	N/A

Mechanical test (cont)

Heat Number	Eddy Current Test	Visual & Dimensional Test	Flaring Test	Flattening Test	Intergranular Corrosion Test	Material Identification Test
504210	N/A	OK	N/A	N/A	N/A	OK
5101341	OK	OK	N/A	OK	OK	OK
5102995	OK	OK	N/A	OK	OK	OK

We certify that this information is a true representation of the data that has been furnished by our raw material suppliers. We have no knowledge of any mercury of low melting contamination.

Examined according to AD 2000-Merkblatt HP 0 and TRD 201 in conjunction with EN 729-2 , by TUV CERT. Certification number: BB-DDB-MAN-P-03-1613
Our company working with quality system ISO 9001:2000 Certified by The Standards Institution of ISRAEL Licence No. 26880
This certificate was made by use of a computer system and is valid without signature.

Approved By:
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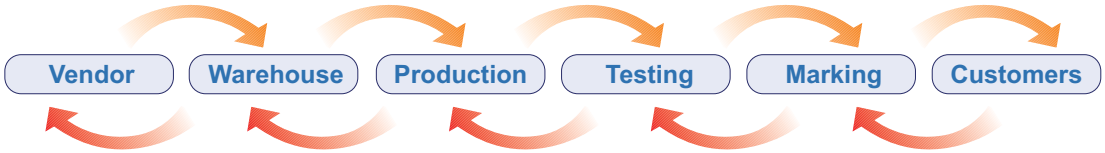
MTR - Material Test Report

The MTR is a document required by ASME BPE for all metallic equipment and components produced according to this standard. The MTR is the reference document for the entire history of the production processes and the raw materials used to make the BPE component.



The MTR document is easily generated on-line via **MaxPure.net** using only the job number as input. The job number is the product identification number which represents all processes and raw materials related to the specific item.

The MTR format provides the following information:

1. Part number, part description, job number, drawing and associated BPE DT table number
2. ASME BPE standard.
3. Material type: 316L 316L with Sulphur content of 0.005-0.017%
4. Heat Number per each component describing the fitting and it's associated properties:
   a. Tube dimensions and standards
   b. Chemical composition
   c. Mechanical tests
   d. Visual, dimensional, corrosion, EDDY current testing, flaring and flattening, PMI Test
5. Certificate of Compliance

Tube Specifications

Standards:

- ASTM A-269/270
- ASME BPE

Tubing Dimensional Tolerances: Tubing specifications, ASTM A-269/270

Tubing Diameter	Gauge (wall- thickness)	OD dimensional specification	Length	Wall
		ASTM Spec.	ASTM Spec.	ASTM Spec.
1/2"	16g (.065" wall)	+.002/-.008	-0+1/8	+/-10%
3/4"	16g (.065" wall)	+.002/-.008	-0+1/8	+/-10%
1"	16g (.065" wall)	+.002/-.008	-0+1/8	+/-10%
1 1/2"	16g (.065" wall)	+.002/-.008	-0+1/8	+/-10%
2"	16g (.065" wall)	+.002/-.011	-0+1/8	+/-10%
2 1/2"	16g (.065" wall)	+.002/-.011	-0+1/8	+/-10%
3"	16g (.065" wall)	+.002/-.012	-0+1/8	+/-10%
4"	14g (.083" wall)	+.002/-.015	-0+1/8	+/-10%

Technical Supplement For Stainless Steel Tubing (Pharmaceutical Industries) Seamless Tubing

1. **Product:** Seamless Austenitic Stainless Steel Sanitary Tubing.

2. **Specification:** ASTM A269.
   Referenced documents: ASTM A450/ASTM E112.

3. **Intended use:** Tubing intended for use in the dairy, food and pharmaceutical industries.

4. **Material:** Stainless Steel 316L with sulfur content of 0.005-0.017%.

5. **Manufacturing:** In accordance with **ASME BPE** requirements.

6. **Length:**

   6.1 Conventional cargo - wooden box packing - 6.00 meters (19.68 feet) long.

   6.2 Container cargo - packed bundles 5.80 meters (19.02 feet) long (including packing).

7. **Nominal outside diameter:** ½" (12.7 mm); ¾" (19.05 mm); 1" (25.4 mm).

8. **Wall thickness (mm):**

   8.1 **Tolerances:**
   (0.065" $^{+10\%}_{-10\%}$) 1.65 $^{+0.165}_{-0.165}$

   All other tolerances in accordance with ASTM A269.

   8.2 The measured wall-thickness of each tubing batch should be reported in the Certificate of Test Results.

   8.3 Each separate package should contain tubing with the same wall thickness, produced from the same coil (i.e. a "BATCH") and the same nominal size (i.e. same O.D.).

9. **Testing:** Testing procedure in accordance with ASTM A-450.

   9.1 Grain size to be between 6 to 7, per ASTM E112.

   9.2 Hardness: Maximum 80 HRB.

   9.3 Test results should be reported as part of the certificate.

10. **Marking:** Heat number should be marked on each tubing.

11. **Documentation / Certification:**

    11.1 Full Mill-Tests Report to be provided with the material, to verify the above requirements and test results.

    11.2 The above certificates should be the actual test results and not Certificates of Compliance.

    11.3 Test documents must be furnished in English.

12. **Packaging:**
    Each tube to be packaged using protective 6 mil. poly sleeving within air tight end caps. The tubing is then packaged in wooden boxes for maximum protection during shipment.

13. **Surface finish:**
    According to table SF-2

MaxPure

Technical Supplement For Stainless Steel Tubing (Pharmaceutical Industries) Welded Tubing

1. **Product:** Welded Austenitic Stainless Steel Sanitary Tubing.

2. **Specification:** ASTM A270.
   Referenced documents: ASTM A450/ASTM E112.

3. **Intended use:** Tubing intended for use in the dairy, food and pharmaceutical industries and needs to withstand secondary cold forming operations.

4. **Material:** Stainless steel 316L with sulfur content of 0.005-0.017%.

5. **Manufacturing:** In accordance with **ASME BPE** requirements.

6. **Length:**

   6.1 Conventional cargo - wooden box packing - 6.00 meters long.

   6.2 Container cargo - packed bundles 5.80 meters long (including packing).

7. **Nominal outside diameter:** 1" (25.4 mm); 1½" (38.1 mm); 2" (50.8 mm).

8. **Wall thickness (mm):**

   8.1 **Tolerances:**

   (0.065" $^{+10\%}_{-10\%}$) 1.65 $^{+0.165}_{-0.165}$

   All other tolerances in accordance with ASTM A270.

   8.2 The measured wall-thickness of each tubing batch should be reported as part of the Certificate of Test Results.

   8.3 Each separate package should contain tubing with the same wall thickness, produced from the same coil (i.e. a "BATCH") and the same nominal size (i.e. same O.D.).

9. **Testing:** Testing procedure in accordance with ASTM A-450.

   9.1 Grain size to be between 6 to 7, per ASTM E112.

   9.2 Hardness: Maximum 80 HRB.

   9.3 Test results should be reported as part of the certificate.

10. **Seam:**

   10.1 The seam should be uniform, having "full penetration" with no "under-cut", "protrusions", etc.

   10.2 The seam should be free of "oxidation" and "porosity", with no evidence for "lack of fusion" or "incomplete fusion".

   10.3 The seam should be "internally bead rolled" in order to have a uniform wall-thickness across the weld area.

11. **Form testing:**

11.1 Two samples per each lot of tubing size to be subjected to the “flange test” or “reverse flattening test”.

11.2 The test samples to be shipped along with the tube.

12. **Marking:** Heat number should be marked on each tube.

13. **Documentation / Certification:**

13.1 Full Mill-Tests Report to be provided with the material, to verify the above requirements and test results.

13.2 The above certificates should be the actual test results and not Certificates of Compliance.

13.3 Test documents must be furnished in English.

14. **Packaging:**

Each tube to be packaged using protective 6 mil. poly sleeving within air tight end caps.
The tubing is then packaged in wooden boxes for maximum protection during shipment.

15. **Surface Finish:**

According to table SF-2

Table DT-1 Nominal OD Tubing Size

Nominal Size, in.	Tube OD		Tube Wall Thickness		Hygienic Clamp Size, in.
	in.	mm	in.	mm	
¼	0.250	6.35	0.035	0.89	¾
⅜	0.375	9.53	0.035	0.89	¾
½	0.500	12.70	0.065	1.65	¾
¾	0.750	19.05	0.065	1.65	¾
1	1.000	25.40	0.065	1.65	1½
1½	1.500	38.10	0.065	1.65	1½
2	2.000	50.80	0.065	1.65	2
2½	2.500	63.50	0.065	1.65	2½
3	3.000	76.20	0.065	1.65	3
4	4.000	101.60	0.083	2.11	4
6	6.000	152.40	0.109	2.77	6

*** Specifications per ASME BPE.**

Table SF-1 Acceptance Criteria for Interior Surface Finishes of Tubing

Anomaly or Indication	Acceptance Criteria
Cluster of pits	No more than 4 pits per each 1/2 in. x 1/2 in. inspection window. The cumulative total of all relevant pits shall not exceed 0.040 in.
Demarcation	If longer dimension is less than the tube diameter and Ra increases <50%.
Dents	None accepted.
Grit lines	If Ra max. is met.
Welds	If polished smooth, blended, and Ra max. is met.
Nicks	None accepted.
Pits	If diameter <0.020 in. and bottom is shiny [Note (1)]. Pits <0.030 in. diameter are irrelevant and acceptable.
Scratches [Note (2)]	If depth <0.030 in.
Star burst	If <75% of the width of the weld bead.
Surface cracks	None accepted.
Surface inclusions	If Ra max. is met.
Surface residuals	None accepted, visual inspection.
Surface roughness (Ra)	See Table SF-2.
Weld slag (per tube length)	Up to 3, if <75% of the width of the weld bead [Note (3)].
Weld porosity	If no liquid penetrant indication.

*** Specifications per ASME BPE.**

NOTES:
(1) Black bottom pit of any depth is not acceptable (2) 12 in. of cumulative length per tube length (3) Tube length is 20 ft.

Table SF-2 Ra Readings Tubing

Surface Designation	As Drawn and/or Mechanically Polished	
	Ra Maximum	
	µ-in.	µm
SFT1	20	0.51
SFT2	25	0.64
SFT3	30	0.76
Surface Designation	**Mechanically Polished and Electropolished, or Electropolished**	
	Ra Maximum	
	µ-in.	µm
SFT4	15	0.38
SFT5	20	0.51
SFT6	25	0.64

*** Specifications per ASME BPE.**

GENERAL NOTE:
(a) All Ra readings are taken across the lay, wherever possible.
(b) No single Ra reading shall exceed the Ra max. value in this table.
(c) Other Ra readings are available if agreed upon between owner/ user and manufacturer, not to exceed values in this table.

NOTE:
(1) On any other finishing method that meets the Ra max.

Pharmaceutical Vessels (PV) Characteristics

Following are the guidelines for Presentation/Discussion of the construction of **PV** based on EGMO's experience and Good Manufacturing Practice.

1.0 Vessel specification:

It is very important when preparing a PV Specification to include actual data for:

- Working / Design Pressure - Vessel.
- Working / Design Pressure - Heating/ Cooling Jacket.
- Working / Design Temperature.
- Surface Finish Inside/ Outside.

Each value requested that is higher than necessary, increases costs. In many cases, after the customer receives a quotation, the specification is modified to a lesser standard that meets the customer's product requirements.

1.1 Manholes:

- Most PV vessels use manholes for working pressure Full Vacuum/ 3-6 bar, 150°C.
- We use standard manholes from leading manufacturers.
- On small vessels, the manhole diameter is equal to vessel diameter.
- On each vessel, a manhole is required for entry into the vessel to enable grinding and polishing of the last weld.

1.2 Heating / cooling jacket:

Generally, there are three jacket types:

- Double jacket (D/J) - Manufactured as two vessels of different sizes, installed one into the other. In between, a spiral guide directs the water flow pattern. If specification calls for high water pressure, very thick plates are required, up to 10-12 mm. Therefore, this system is used for small vessels only.

- Dimple Type - Used on small and large-size vessels.

- Half Pipe Coils - Used on larger vessels with demand for high pressures/ temperatures. Limited to minimum diameter of 800 mm.

A good combination is D/J at bottom and dimple on cylinder.

1.3 Vessel insulation:

- For vessels where product must be cooled to 2-5°C, we use foamed Polyurethane of 50 mm thickness.

- Vessels where product must be heated from 10-140°C, we use mineral wool / glass wool. In both cases, the insulated material is covered and protected with a Stainless Steel sheet, welded all around.

1.4 Nozzles:

- Most common fittings used on pharmaceutical vessels are Ferrules. It is important that the nozzle has a minimum "dead volume" and it should be as short as possible.

- Nozzles penetrating the insulated wall must be clear of Insulation (conical) to allow instrumentation installation.

Pharmaceutical Vessels (PV) Characteristics

2.0 Vessel accessories:

2.1 Agitators:

Can be divided into two groups:

- Agitators designed to be mounted on top of the vessel.
- Other applications require bottom entry or side entry design.
- Magnetic drive agitators designed for bottom mounting.

All agitators are tailor made. The agitating elements vary from marine type propeller, Rushton turbine, tooth disc, and pitch blade turbine to anchor shape with scrapers.

The speed varies according to the product.
The best way to adjust speed is to use an electronic frequency controller.

2.2 Sight Glass:

- On vessel top, a sight glass is installed.
- On sight glass, a Halogen lamp can be installed.
- On bigger vessels there are two sight glasses, one for lamp, the other for viewing into the vessel.

2.3 Manholes:

There are manholes for atmospheric vessels and for pressure vessels.
There are round manholes installed on top of the vessels, and oval manholes installed on the side.

When ordering a manhole, the following data should be given:

- Working / Test pressure
- Working temperature
- Gasket material
- Tank finish inside / outside vessel

2.4 CIP vessel cleaning:

- Fixed spray ball
- Removable spray ball
- Rotating spray device
- Rotating spray device - moves in / out

2.5 Vessel bottom valve:

- Valves with zero dead volume
- Piston valves that can open into the tank or outside
- Diaphragm valves

Both types can be hand operated, or automatically operated with a pneumatic actuator.

2.6 Sampling valves:

- Welded to the vessel wall with zero dead volume
- Ferrule end / Threaded end
- Keofitt sampling valves
- Egmo sampling valves
- Needle / Gasket sampling device

All valves can be delivered with CIP port.

Pharmaceutical Vessels (PV) Characteristics

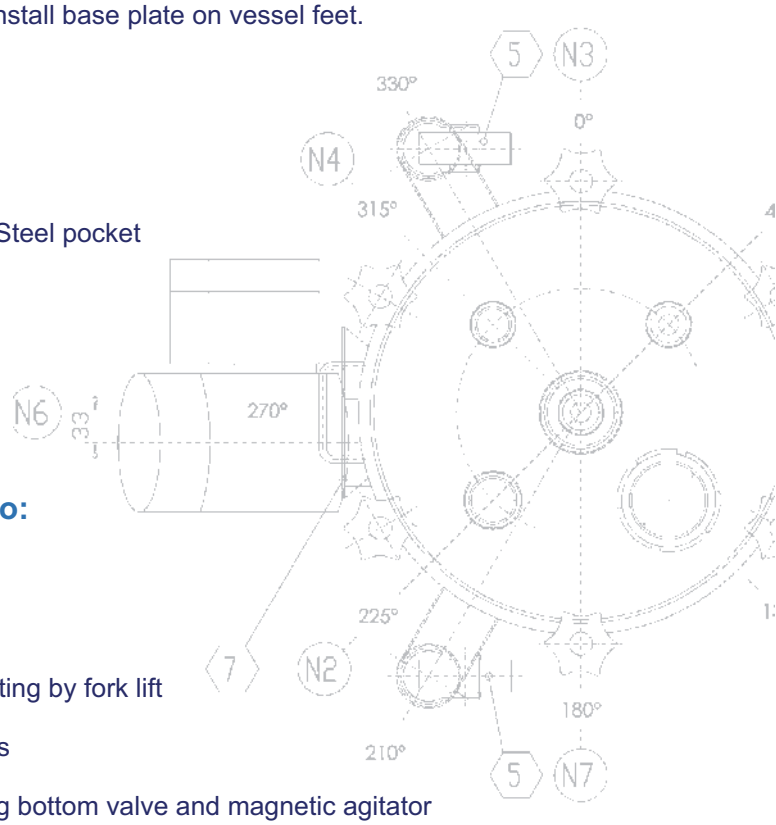
2.7 Load cells:

In addition to ordering the load cells, it is necessary to install base plate on vessel feet.

- Stainless Steel pipe for cable
- Base plate for control panel

2.8 Temperature detection:

PT 100 sensor is protected and installed in a Stainless Steel pocket



2.9 Mobile vessels:

- On wheels 2+2 or all 4 swiveled
- Tank to be lifted by forklift

3.0 Different vessels manufactured by Egmo:

3.1 70 ltr. vessel on wheels with “Dimple” jacket

3.2 120 ltr. vessel on Load Cell with Double jacket

3.3 700 ltr. vessel on wheels and provision for transporting by fork lift

3.4 500 ltr. vessel with D/J heating, including 3 agitators

3.5 960 ltr. vessel with half pipe spiral heating, including bottom valve and magnetic agitator

3.6 1,500 ltr. vessel with combination of D/J heating at the tank bottom and “Dimple” heating on the tank cylinder

4.0 Mobile CIP trolley:

- The trolley is used for cleaning vessels and pipes.
- In some plants, the trolley is used for passivating pipe systems and tanks.

5.0 Heat exchangers:

- Tubular heat exchangers, one pass or more
- Tube U-shape
- Double tube sheet construction for contamination protection and easy leak detection

6.0 Specials:

Egmo can manufacture any Fitting / Tool / Special equipment from Stainless Steel material.
Share your problem with us and we shall find the solution to suit you.

MaxPure

Table SF-7 Acceptance Criteria for Contact Surface Finishes of Vassels

Anomaly or Indication	Acceptance Criteria
Cluster of pits	No more than 4 pits per each 1/2 in. x 1/2 in. inspection window. The cumulative total of all relevant pits shall not exceed 0.040 in.
Demarcation	If on the top head only and Ra max. is met.
Dents	None accepted [Note (1)].
Grit lines	If Ra max. is met.
Welds	If polished smooth, blended, and Ra max. is met.
Nicks	None accepted.
Pits	If diameter <0.020 in. and if shiny, per inspection window [Note (2)].
	Pits <0.003 in. diameter are irrelevant and acceptable.
Scratches	If length <0.50 in. at 0.003 in. depth and if <3 per inspection window
	[Note (2)].
Star burst	None accepted.
Surface cracks	None accepted.
Surface inclusions	If Ra max. is met and there is no liquid penetrant indication.
Surface residuals	None accepted, visual inspection.
Surface roughness (Ra)	See Table SF-8.
Weld slag	None accepted.
Weld porosity	None accepted.

*** Specifications per ASME BPE.**

NOTES:
(1) Dents in the area covered by and resulting from welding dimple heat transfer jackets are acceptable.
(2) An inspection window is defined as an area 4 in. x 4 in.

Table SF-8 Ra Readings for Vessels

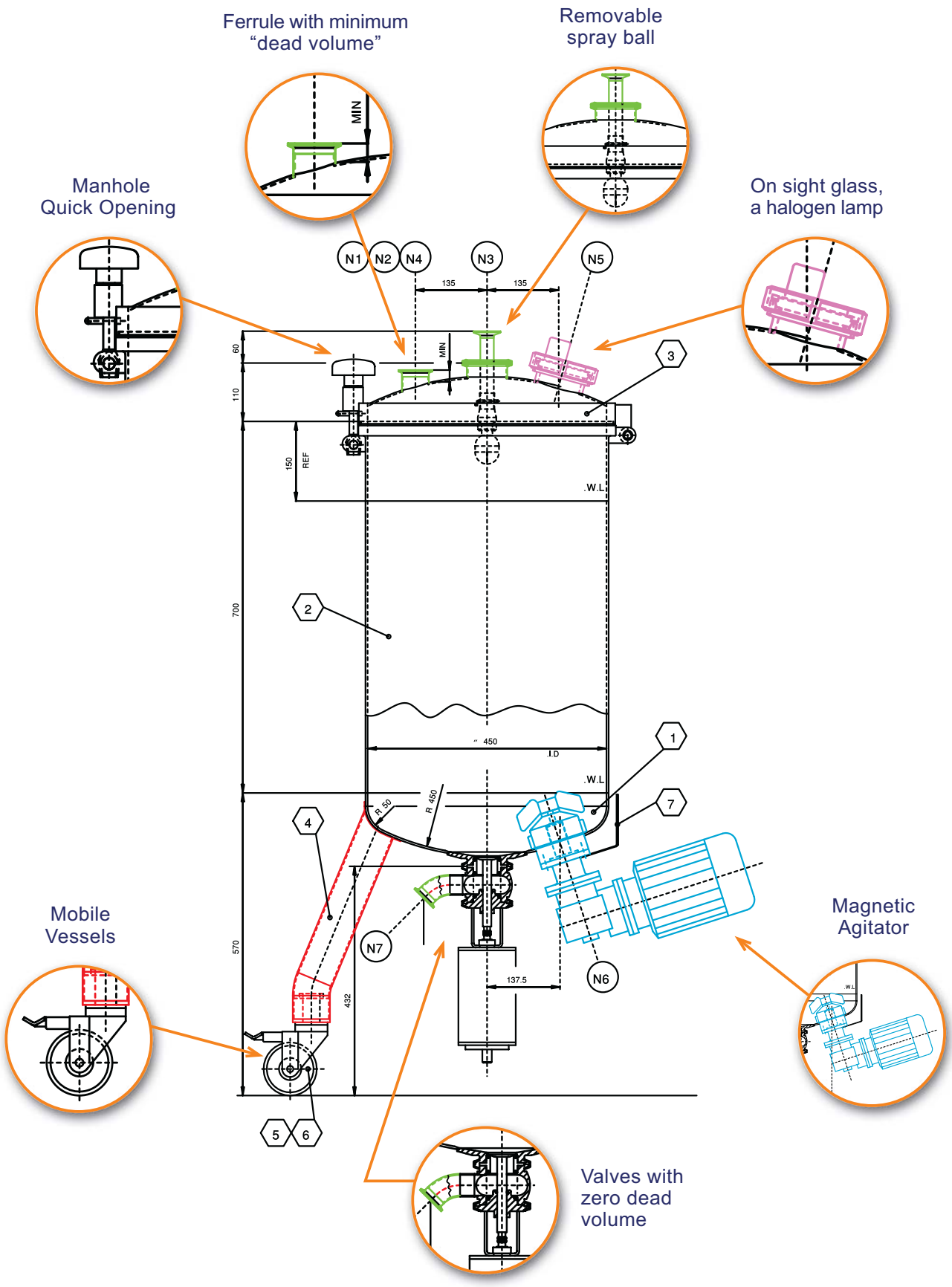
Surface Designation	Mechanically Polished [Note (1)]	
	Ra Maximum	
	µ-in.	µm
SFVV1	20	0.51
SFVV2	25	0.64
SFVV3	30	0.76
Surface Designation	**Mechanically Polished and Electropolished**	
	Ra Maximum	
	µ-in.	µm
SFVV4	15	0.38
SFVV5	20	0.51
SFVV6	25	0.64

*** Specifications per ASME BPE.**

GENERAL NOTE:
(a) All Ra readings are taken across the lay, wherever possible.
(b) No single Ra reading shall exceed the Ra max. value in this table.
(c) Other Ra readings are available if agreed upon between owner/ user and manufacturer, not to exceed values in this table.

NOTE:
(1) On any other finishing method that meets the Ra max.

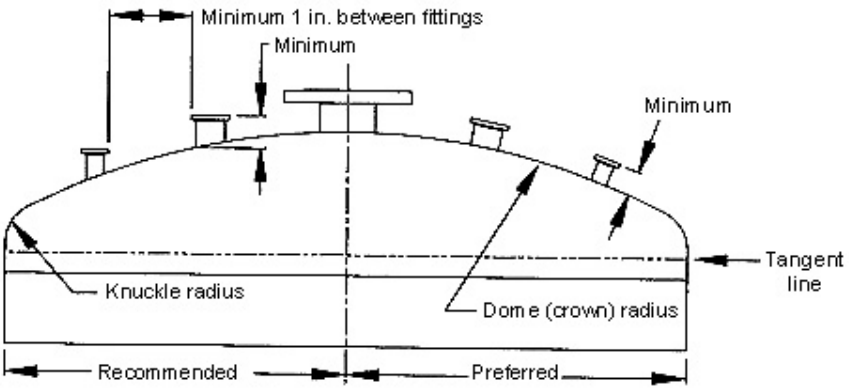
Pharmaceutical Vessels

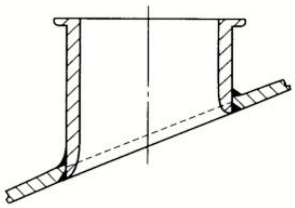


Pharmaceutical Vessels

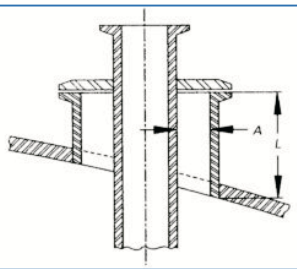
Top view

General Notes:
a) Less dead space
b) Better CIP/SIP capabilites

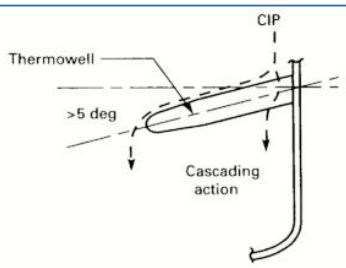




Full Penetration Fillet Design (Recommended)
General Notes:
a) All *L / D* ratios to be calculated on long-side dimensions for vessel heads
b) *D* = inside diameter
c) *L/D* = L_3 / *D* (Target 2:1)



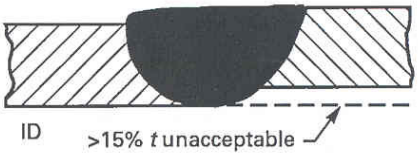
Acceptable: Better Design
General Notes:
a) Less dead space
b) Better CIP/SIP capabilities
c) *L/A* Target of 2:1 more easily obtained



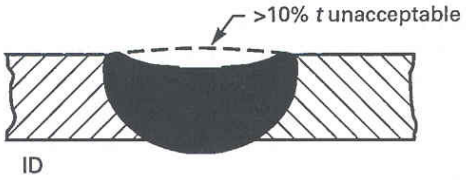
Positive slope in all directions (preferred)

Acceptable and Unacceptable Weld Profiles for Tube Welds

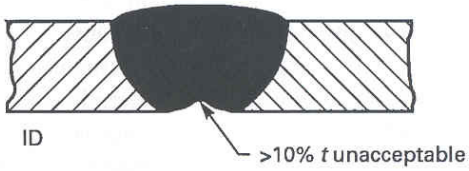
(a) Acceptable



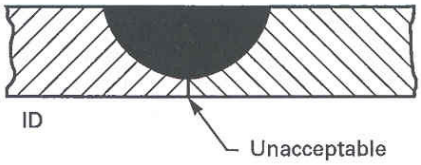
(b) Misalignment (Mismatch)



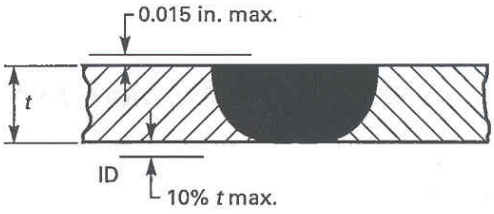
(c) OD Concavity



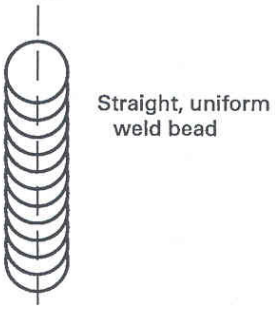
(d) ID Concavity (Suckback)



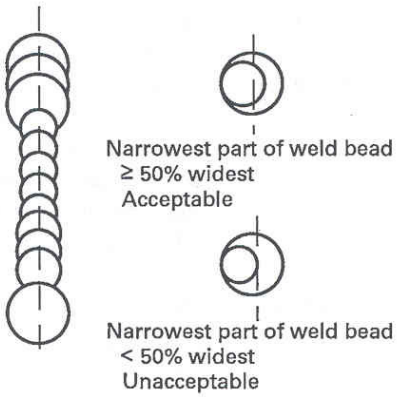
(e) Lack of Penetration: None Allowed



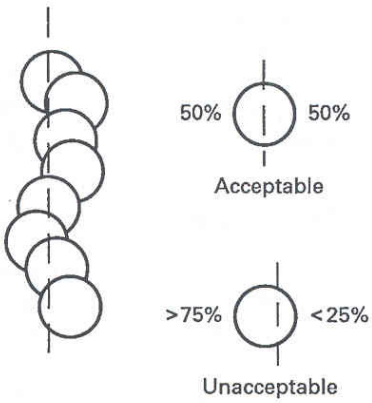
(f) Convexity



(g) Acceptable Weld Bead



(h) Excessive Weld Bead Width Variation



(i) Excessive Weld Bead Meander

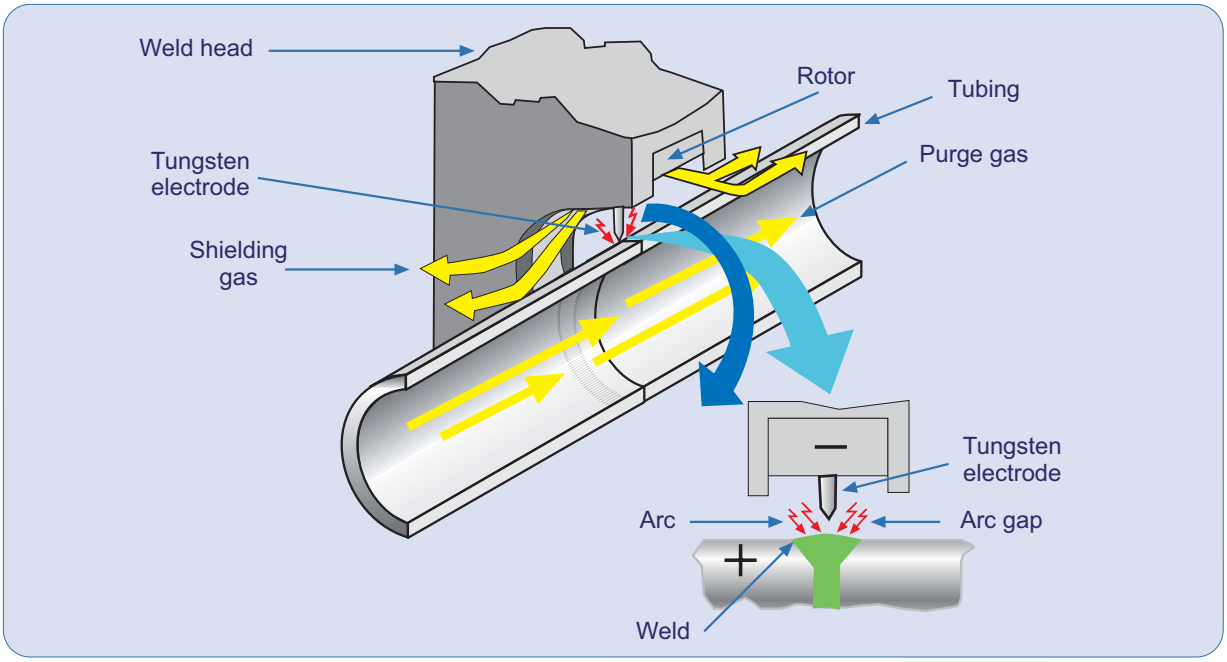
Welding - Definitions

Manual Arc Welding - A welding process where the arc and the filler metal feeding operations are performed manually. The employee is a welder.

Semi Automatic Welding - A welding process where the arc is manipulated manually and the filler metal is mechanically fed into or close to the arc. The employee is a welder.

Automatic Welding - A welding process where the arc and the filler feeding mechanism are mechanically manipulated. The employee is an operator.

AOW - An automatic machine which moves the arc around an orbital path.
Modern day orbital welding systems offer computer control where welding parameters can be stored in memory and called up. The skills of a certified welder are thus built into the welding system, producing enormous numbers of identical welds and leaving significantly less room for error or defects.



Orbital Welding Equipment

An orbital welding system consists of a power supply and an orbital weld head. In the orbital welding process, tubes/pipes are clamped in place and an orbital weld head rotates an electrode and electric arc around the weld joint.

Power Supply: The power supply/control system supplies and controls the welding parameters according to the specific weld program created or recalled from memory. The power supply provides the control parameters, the arc welding current and pulsation, the power to drive the motor in the weld head, and switches the shield gas(es) on/off as necessary.

Weld Head: Orbital weld heads are usually of the enclosed type and provide an inert atmosphere chamber that surrounds the weld joint. Standard enclosed orbital weld heads are practical in welding tube sizes from 1/16 inch (1.6mm) to 6 inches (152mm) with wall thickness of up to .154 inches (3.9mm). Bigger diameters and wall thickness can be accommodated with open style weld heads.

Reasons for Using Orbital Welding Equipment

- Productivity
- Quality
- Consistency
- Code (FDA) requirements

Additional Neumo Ehrenberg Group Products

The pharmaceutical industry has the most stringent specifications for its fittings and fixtures which is why their choice is **Neumo Ehrenberg Group** quality Stainless Steel tube fittings, valves and vessels. From design, through production, to customer service, the **Neumo Ehrenberg Group** production team works to give its pharma customers all over the world only the very best.

Specials: Custom-made process design for the pharmaceutical industry

Aseptic Valves

Heat Exchangers

Process Observation

Aseptic Sampling Valves

Reactors

Diaphragm Valves

Vessels Cleaning Systems

In-Line Instrumen-tation

Tubes: ASTM A269 / 270

BioConnect® Screwed Version

BioConnect® Clamp Version

Connect S® Flanged Version

BioControl® Manometer with blind flange

BioControl® Transmitter with G25

BioControl® Inline housing type Neumo G50

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The Neumo Ehrenberg Group Pharma Reference List

- Abbott Laboratories
- Abic
- Agis
- Akzo-Nobel
- Alexion
- Allpharma
- Amgen
- Astra
- Aventis
- BASF AG
- Baxter
- Bayer
- Biochemie Kundl
- Biofarma
- BTG
- Celltrion BASF Korea
- Chilu Antibioticos
- Dankos Laboratories
- Dexon
- Egis
- Eli Lilly
- Ferron pharmaceutical
- Genentech
- Genzyme
- Glaxo Smith Kline
- Interpharm
- Kamada
- Kinetics
- Knoll AG
- LAPI Pharmaceutical
- Lonza
- Merck
- Merckle
- Novartis
- Novo Nordisk
- Pfizer
- Pharmacia
- Pharmaplan
- Rafa
- Rekah
- Reliance Life Science
- Roche
- S & A
- Sanbe Farma
- Schering-Plough
- Taro
- Teva Pharmaceuticals
- Wyeth
- Yang-Tse Pharma

Industry Terms Glossary

Term	Acronym	Definition
A		
Alloy	**----**	A material composed of two or more metals which are mixed and united - usually when they are in a molten state. Alloys are created to improve properties such as the appearance, strength and durability of metals. Common alloys include cast iron, stainless steel, brass, bronze, sterling silver and alpha cellulose, that part of a material made of cellulose that is insoluble in a 17.5% solution of sodium hydroxide at 20°c under specified conditions. While alpha cellulose consists principally of cellulose, it does include other components that are insoluble under the test conditions.
American Society of Mechanical Engineers	**ASME**	Creates consensus standards for Mechanical Engineering.
American Society for the Testing & Materials	**ASTM**	Creates consensus standards for material quality and material quality testing methods
Aseptic	**----**	Free of pathogenic (disease causing) micro-organisms.
ASTM-A 269	**ASTM-A 269**	Specification titled "Seamless and Welded Austenitic Stainless Steel Tubing for General Service". This specification covers a variety of grades of austenitic stainless steel tubing.
ASTM-A 270	**ASTM-A 270**	Specification titled "Welded Austenitic Stainless Steel Tubing" for use in the pharmaceutical industries and need to withstand secondary cold forming operations. This specification covers a variety of grades of austenitic stainless steel tubing.
B		
Bio Processing Equipment	**BPE**	ASME Standard is intended for the design, materials, construction, inspection and testing of vessels, piping and related process components used in the biopharmaceutical industry and other aseptic applications.
Bio Processing Equipment Committee	**BPEC**	A sub-committee of the ASME BPE Main committee working to develop the ASME BPE standard while meeting three times per year.
B31.3 ASME Process Piping	**B31.3**	American National Standard that covers piping typically found in pharmaceutical, semiconductor, and cryogenic plants, and related processing plants and terminals. It must be noted that B31.3 does not address hygienic tubing and/or piping; it applies mostly to inspection, examination, and testing of systems.

Industry Terms Glossary

Term	Acronym	Definition
C		
Chemical reaction	**----**	The process by which chemicals combine with each other to form products, which differ from, or alter, the original substances.
Clean in Place	**CIP**	The technique of cleaning process line components without the need for disassembly.
Conductivity	**----**	Measurement of a substance's ability to conduct an electric current.
current Good Manufacturing Practice	**cGMP**	Written and enforced by the FDA. Consists of some specific, but mostly "umbrella" regulations covering personnel, records, and equipment, leaving much to the interpretation of the Inspector and the court system. cGMP's are evolutionary, reflecting the least common denominator of practices in the industry at present (hence the term "current").
D		
Dead Leg	**----**	A section of pipe in a closed recirculation loop that does not have a continuous flow through it.
Deutsches Institut fur Normung (German Institute for Standardization)	**DIN**	Creates engineering standards for Germany Contributing body to CEN and ISO. Other countries and companies give adopted DIN standards.
E		
Electron Spectroscopy for Chemical Analysis	**ESCA**	A procedure that uses electron beams to characterize the extreme outer surface of a metal. Typically used to determine levels of chromium oxide on the surface of austenitic stainless steel.
Electro-Polish	**EP or E/P**	Polishing process for metal components where the part is placed in an acid bath (typically sulfuric or phosphoric) containing a cathode. As current is passed through the cathode, metal ions are removed from the surface of the metal.
Epidemiology	**----**	Study of the distribution and determinants of diseases in populations.
European Hygienic Equipment Design Group	**EHEDG**	Comprised of representatives from research institutes, equipment manufacturers, the food and bio-pharm industry and legislative bodies . The group's objective is to provide standardization organizations (CEN and ISO) with specialist views on hygienic and aseptic design by publishing requirements and test methods.

Industry Terms Glossary

Term	Acronym	Definition
F Fermentation	**----**	The biochemical synthesis of organic compounds by microorganisms or cultivated cells.
Food and Drug Administration (USA)	**FDA**	Enforcement agency of the U.S. government for food, drug and cosmetics manufacturing. Author of the U.S. cGMP's. Responsible for new product approvals, plant inspections and product recalls.
G Gas Tungsten Arc Welding	**GTAW**	(a.k.a. TIG) A welding process where the welding arc is maintained between a non-consumable tungsten electrode and the base metal to be welded. The arc is shielded with an inert gas, typically argon.
Good Manufacturing Practices	**GMP**	Refers specifically to FDA cGMP's (see cGMP) or to the standards of manufacturing in a particular country and industry (e.g.:EU GMP). Generally refers to standards that are written and enforced.
H Heat Tracing	**----**	Permanent identification used to trace a part back to the mill heat (batch) from which the part was manufactured. Each heat number traces back to an MTR (see MTR).
I International Standards Organization	**ISO**	Creates consensus standards for engineering and quality systems.
International Society for Pharmaceutical Engineering	**ISPE**	A global not-for-profit membership organization that provides education, training and technical publications to pharmaceutical manufacturing professionals.
J Joining Techniques	**----**	Connections between tube and tube or tube and fitting, and even tube/fitting to equipment during system fabrication and/or construction can be accomplished by diverse means.

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Industry Terms Glossary

Term	Acronym	Definition
M		
Mill Test Report or Material Test Report	**MTR**	(a.k.a. "Mill Certs"). A document certifying the composition of a metal from a particular heat batch.
O		
Orbital Welding	**----**	An automated TIG (or GTAW) welding process that is designed to produce repeatable fusion welds for tubular components. A system consists of a programmable power supply and weld head. The power supply controls the weld parameters of current and electrode speed. The weld head holds the two parts, purges the weld and moves the electrode using an electric motor.
Ovality	**----**	A quantitative measurement of how 'round' a tube is by comparing width to height. Limits are specified on the appropriate ASTM specification of a product.
P		
Parenteral Drug Association	**PDA**	Association for manufacturers of injectable drug products. Publishes technical reports and other publications of interest to the industry.
Passivation	**----**	The process of rinsing stainless steel with acid (typically nitric) to form a corrosion resistant chromium-oxide layer on the surface.
Pharma-coepidemiology	**----**	The study of the utilization and effects of drugs in large numbers of people. To accomplish this study, pharmacoepidemiology borrows from both pharmacology and epidemiology.
Point of Use	**POU**	A valved branch in a recirculating utility system (typically a water system).
Process Qualification/ Process Validation	**PQ/PV**	The demonstration and documentation that the various units and procedures of a process operate as they should. This logically establishes that the product is of the quality the system is purported to yield. Performed after the IQ/OQ has been executed and approved. Typically, the acceptance criteria is the same as the product acceptance criteria, and the product run is considered product-for-sale. Executed by the manufacturing personnel of the operating company according to the SOP.

Industry Terms Glossary

Term	Acronym	Definition
R		
Roughness Average (Ra)	**Ra**	An expression of measured surface roughness or texture, typically, of a polished or machined metal surface. The arithmetic average value of the departure (peaks and valleys) of a surface profile from the center-line throughout the sampling length, generally expressed in micro-inch(µin) or micro-meter(µm) units and measured with profilometers and/or orescopes.
S		
Seamless Pipe	**----**	Pipe produced from a solid billet that is heated and rotated under pressure. This rotating pressure creates a hole in the middle of the billet, which is then formed into a pipe by a mandrel.
Solvent Cleaning	**----**	The removal of contaminants such as oil, grease, dirt, salts, etc. by cleaning with a solvent, steam, vapor, alkali, or emulsion.
Standard Operating Procedure	**SOP**	(a.k.a. EOP, OP) A controlled document that outlines the procedure for operating equipment/ systems. An operator's adherence to a written SOP is an integral part of the validation process. It is the connecting link between the initial validation process and the daily manufacturing operation.
Steam in Place	**SIP**	Sanitization of process line components by the use of steam without the need for disassembly.
Sterile	**----**	Free of living organisms.
Sulfur	**----**	A non-metallic element that exists in several forms-the ordinary one being a yellow, rhombic, crystalline solid-and which burns with a blue flame and a suffocating smell. Some sulfur compounds, particularly sulphides and oxides, can cause severe chemical deterioration in objects.
Surface Finish	**SFF**	Surface finishes are all interior surface finishes accessible and inaccessible, that directly or indirectly come in contact with the designated product in bioprocessing equipment and distribution system components. Surface roughness specification and measurement standard shall be determined by Ra values rather than by polishing methods.

MaxPure

Industry Terms Glossary

Term	Acronym	Definition
T		
Tubing Dimensions	**----**	O.D. - outside diameter I.D. - inside diameter Wall thickness or gauge. All tube dimensions are specific; pipe dimensions are nominal. Specific – actual measurements in inches. Nominal – theoretical or stated value of a dimension.
Tungsten Inert Gas	**TIG**	(a.k.a. GTAW) A welding process where the welding arc is maintained between a non-consumable tungsten electrode and the base metal to be welded. The arc is shielded with an inert gas, typically argon.
U		
Ultra Filter or Ultra-Filtration	**UF**	Filters formed from polymer membranes. UFs have the ability to retain larger molecules while permitting the passage of smaller ones. Often used for the separation of proteins.
Ultraviolet Light or Ultraviolet Radiation	**UV**	Radiation in the ultraviolet portion of the spectrum (200 to 400 nm) is used to destroy micro-organisms. Also used to neutralize ozone.
US Pharmaceutical Class VI-XXII	**USP**	An official public standards-setting authority for healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products which are also recognized and used outside the United States.
W		
Water For Injection	**WFI**	Water for use as a solvent for the preparation of parenteral products conforming to USPXXIII (EP and JP) guidelines. Obtained most commonly by distillation. However, other processes are allowed depending on particular pharmacopoeia.
Welded Tubing	**----**	Tubular products, which are rolled, formed and then joined continuously along a longitudinal seam by a material fusion process. The process employed at Gibson Tube is, Gas Tungsten Arc Welding (GTAW). See Gas Tungsten Arc Welding'.

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