

# INTERTECH TECHNOLOGIES PVT. LTD.

*Engineers to Healthcare Industry®*

PHARMA \* FOOD \* COSMETICS \* CHEMICAL \* PACKAGING

**QUALITY ASSURANCE PROTOCOL  
(QAP)**

[www.intertechglobal.com](http://www.intertechglobal.com)

## PREFACE

This Standard details the level of documentation that **INTERTECH TECHNOLOGIES PVT.LTD** (ITPL) will provide during a contract for fabricating tank(s) or portable equipment's. Extensive documentation is required for this system to assist in the validation of critical services to comply with FDA / EU regulatory authorities. This documentation will be compiled in the form of a Quality Assurance manual, the format of which is outlined in this specification. It will contain all necessary information regarding design, construction, installation and validation undertaken by IET.

## INTRODUCTION

### **Document and file:**

- *Brief scope of work / Project Description.*
- *Equipment schedule (including make, model, size, serial numbers)*
- *Tank & Equipment's i.e. Reactor et . data sheets / specification.*
- *Process & Instrumentation Diagram (If applicable).*
- *Details of any departures from the design specifications at installation including materials of construction and key equipment.*
- *Functionality Testing reports.*
- *Warranty on parts and workmanship.*

## QUALITY SYSTEM

The design and fabrication of portable and fixed hygienic tanks will comply with the following standards and specifications:

- *Design Specification*
- *Good Engineering Standards*

### ➤ **Quality Records**

The direct contractor shall operate to a quality system for all works in this contract, inc. Materials and workmanship. The quality system will comply with cGMP norms or equivalent.

Full details of the Quality System will be submitted to client prior to the commencement of manufacture. A final and signed copy will be included with the final documentation submission. Throughout the project, IET will maintain records to verify that quality procedures and standards have been adhered to. Variations or modifications must be documented and approved by client prior to implementation.

### ➤ **Quality Assurance Representative**

After the contract is let and a minimum of **14 days before** the work is to commence, IET shall nominate the person responsible for insuring that the quality assurance requirements are implemented and maintained.

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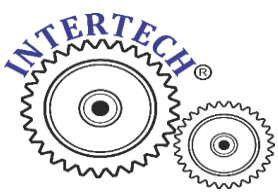
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#### **WORKS - 1**

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Survey No. 36, Hissa No. 10, Dhumal Nagar, Waliv,  
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Plot No. 5 and 6, Intertech Industrial Estate, Survey No. 62  
Hissa No. 2 and 3, Behind Verma Shell Petrol Pump, Waliv,  
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## ➤ **Inspection & Test Plans**

Full details of the quality system, including inspection and test plans will be submitted to client for approval prior to the commencement of manufacture. Inspection, test and hold points shall be prepared and presented to client for approval prior to commencement of manufacture. A copy of this will be provided in the QA manual.

## ➤ **Commonly Inspected Items Include:**

- *Raw material Inspection*
- *Individual component inspection i.e. Dish, cone, Shell after forming.*
- *Inspection of completed weld set up as per approved fabrication drawing*
- *Weld Quality inspection (NDT testing e.g. Radiography)*
- *Grinding and polishing of internal welds.*
- *Individual Nozzle inspection with end connection*
- *Nozzle set up verification on vessel*
- *Pre-polish inspection*
- *Agitator Assembly balancing verification*
- *Inspection of internal tank surfaces*
- *Pressure gauge calibration certificate (if applicable)*
- *Finishing verification*
- *Passivation*
- *Witnessing of pressure testing(e.g. Hydro testing )*
- *Final inspection of tank*
- *Application trial of vessel*
- *Tank documentation*
- *Pressure vessel certification*

Independent tank inspection reports will also be incorporated into the Quality Assurance manual.

## ➤ **Hold Points**

The following designated production hold points shall be incorporated into the Inspection and Test Plan.

The IET shall give client a minimum of 72 hours prior to reaching any hold point inspection stage:

- *Qualification of weld procedures/operators (WPS, PQR.)*
- *critical Fabrication set up*
- *Assembly stages as approved as per QAP*
- *Hydrostatic test;*
- *Roughness testing for surface finish*
- *Functional trial of equipment as approved in QAP*

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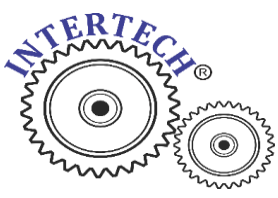
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- *At completion of final polishing prior to packing.*

Will Client waive the right to the nominated inspection IET shall carry out internal checks and document the same for future verification by the client.

## ➤ **Drawing Approvals**

Records of new or modified drawings will be maintained as part of the quality assurance manual. All new drawings and modifications will be approved by Client prior to distribution or implementation.

## ➤ **Equipment s Construction**

### ✓ **Surface Finish**

The internal surface of the vessel is to be mechanically polished to a surface finish as per Client specifications. The surface will be free of surface defects, tarnishing, scuff marks or burrs. Provision of surface roughness measurements will be at the discretion of the Project engineer pending the nature of the vessel application.

### ✓ **Test Samples**

The Client can request to submit a surface finish sample. The sample shall consist of two pieces of the vessel material (approx. 6" x 6"), double butt welded and polished on one side to the surface finish specified.

### ✓ **Water Quality Report**

Required to determine the quality of water used during any stage of fabrication, final cleaning and hydrostatic testing. High concentrations of certain chemicals, such as chlorides, may adversely affect the surface of the vessel and result in long term problems.

## ➤ **Site Installation**

Any standard procedures followed in order to meet industry / Client standards must be referred to. If appropriate, Quality Procedures will be incorporated into the quality assurance documentation. Quality procedures will apply to the following aspects:

- *Vessel, Jacket & insulation*
- *Welding*
- *Equipment inspection & installation*
- *Cleaning of tanks & fittings*

The installation work is to be performed to the best industry standards. Inspections are to be carried out during installation to ensure that IET is working in accordance with specifications and is performing work to the best industry practices. Any reports generated from such inspections must be included.

## ➤ **Commissioning & Testing**

Commissioning and testing procedures will comply with industry & Client standards. Details of procedures, testing methods & final test results will be included in the QA manual.

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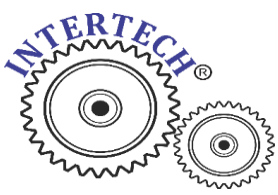
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## ➤ Completion

After delivery on site, documented proof shall be provided to verify that the vessel meets industry & Client standards. Other documents such as non-conformance report, rectification lists and Handover Inspection reports will also be incorporated into an appropriate section of the Quality Assurance manual.

## **MATERIALS OF CONSTRUCTION**

Materials of construction will be shown to comply with Client specifications. Evidence in the form of check sheets, material certificates or letters of conformity, shall be provided for 'critical' materials. i.e. those that impact on the quality of the final product.

### **Incoming Materials Inspection Records**

Upon delivery to ITPL work shop and Client site, all equipment & materials will be inspected to ensure that the item is of appropriate quality and complies with purchase specification & has not been damaged during fabrication or handling.

### **Materials Certificates / Letters of Conformity**

Required to validate the authenticity of materials used during construction. Several companies may be approached to test component materials and supply documentation to support the claim. These certificates ensure that the construction material meets the same specifications and quality standards specified by Client.

Vessel: To verify the correct material composition, heat or mill certificates will be provided by the supplier.

Valves, Fittings & Piping: Material Certificates or Letters of Conformity shall be provided for all components in contact with product. All pipeline valves and fittings in contact with product will be of stainless steel construction; the tubing will comply with ASTM A270 grade 316L. Valve diaphragms, gaskets, o-rings etc will comply with Codes of GMP ie. Teflon / EPDM.

#### **File:**

- *Materials list referenced and indexed to drawings and certificates*
- *Material Safety Data Sheets for any insulation used*
- *Letters of Conformity / Material certificates / Certificate of Analysis*
- *Purchase orders, quotations, specifications and equipment changes.*

## **WELDING**

## ➤ Welding Quality System

To assure the welding quality the workman welder has to be qualified as per ASME code the procedures and record includes following

- *QW-482 Welding Procedure Specification(WPS) (Section IX, ASME )*
- *QW-483 Procedure qualification record (PQR) (Section IX, ASME )*
- *QW-484A Welder Performance qualification (WPQ) (QW-301 ,Section IX, ASME )*

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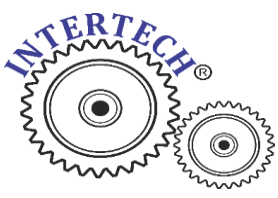
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➤ **A Welding Quality Record will include:**

The method of welding used to fabricate the tank and associated piping will be clearly stated. Details of Company Welding Quality systems will also be given. A Welding Quality system will identify the following areas:

- *Welding process;*
- *Welding machine;*
- *Grade of material used;*
- *Grade of Welding consumables: used gas, tungsten type and filler type;*
- *Tubing diameter & wall thickness*
- *Weld records (inc. Date, Job No., Drg. No., Operator etc)*
- *Weld Inspection reports*
- *Radiography report for all weld joints (As per approved QAP)*

## **TESTING & VALIDATION**

The Equipment's will be tested as fully as possible prior to installation on site. Installation and Operational checks (where applicable) shall be undertaken and full documentation provided. Where applicable, the following items shall be tested and documented during the testing & installation phases. These tests and inspections may be conducted by an independent third party as agreed to by Client.

➤ **Mechanical**

❖ Document and file evidence that the following items have been adequately function tested:

- *Inlet / outlet valves*
- *drainage*
- *sample ports*
- *jacket services (inc. relief valves & non-return valves)*
- *stirrer / agitator*
- *spray balls*
- *load cells*
- *vent filters (inc. Integrity test reports of Letters of Conformity from manufacturer)*
- *Light glasses etc.*
- *Nozzle end connection fitment*

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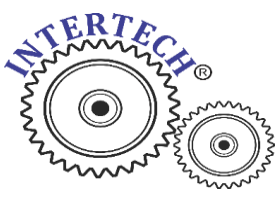
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❖ Document and file evidence that the following items have been inspected and shown to meet Client specifications:

- *Bearings and seals*
- *Hinges*
- *Gaskets*
- *Insulation & cladding*
- *Baffles, if any*

File test certificates for all above mentioned components

#### ➤ **Instrumentation & Calibration**

All indicating, recording and controlling instruments need to be calibrated against certified instruments.

This includes:

- *Test results for instrumentation used during hydrostatic pressure testing of tanks;*
- *Calibration of load cells*
- *Calibration of temperature/ pH/ conductivity probes Velocity ,transmitters , level sensors.*
- *Calibration of pressure gauges, vacuum gauge , differential pressure gauges.*

**File:** a calibration report containing details of all findings, adjustments and tolerances, calibration procedures & records.

#### ➤ **Passivation and Hydrostatic Test and surface finish**

Following polishing, the tank will be passivated and hydrostatically tested to an agreed documented procedure.

File: Test results / reports.

### **AS-BUILT DRAWINGS**

The following 'As-built' drawings must be provided in hard copy and as soft copy.

- *General assembly drawings*
- *Layout drawings*
- *Process & Instrumentation diagram (if applicable)*
- *Records of new & developing or modified drawings shall be maintained as part of this section.*

A full drawing register must also be provided as part of this section.

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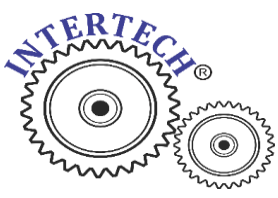
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## **OPERATION AND MAINTENANCE**

This section will contain a technical description of each component together with all associated maintenance recommended by the manufacturer or supplier. The following information will be provided.

- *Equipment technical data (including manufacturers' literature and suppliers' reference list) of all components will be provided.*
- *Complete Operation overview*
- *If PLC operated system, complete system overview with operation sequencing. Alarm and safety interlock , I/O list details covered in Functional design specification(FDS) documents*
- *Any safety precautions necessary to protect personnel and equipment during maintenance.*
- *General Cleaning Procedure*
- *Repair, overhaul, disassembly and reassembly procedures, wear components spare parts, part numbers.*
- *Clear and specific maintenance instructions with illustrations to explain procedures and showing replacement parts and quantities required.*
- *Any special tool requirements necessary tolerance fits, alignments, tensions, adjustments, and testing procedures if correct settings are not made.*
- *The expected service life of normal wear items or replacement frequency of services items in operating hours.*
- *A recommendation of all spare parts to be maintained at Client.*

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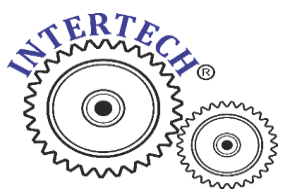
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## QUALITY ASSURANCE PLAN

Sr. NO	ACTIVITIES	CHARACTERISTICS OF CHECK	TYPE OF CHECK	ACCEPTANCE STD	FORMAT OF RECORD	Intertech (AI)	Agency
1	<b>Material Identification:</b> (a) Plates. (b) Pipes For Nozzles. (c) Flanges (d) Fittings (e) Rods (f) Flats	To ensure the quality of the material specified. Correlate the properties specified with relevant code specification.	(i) Dimensional and visual Inspection. (ii) Co-relation between test certificate and marking on material. (ii) Finish of raw material.	ASME/ASTM	Material test certificates	P	H/W
2	<b>Material Identification and sample collection</b>	Material Identification with MTC and sample collection	Identification and testing of material (Chemical & Mechanical Tests)	ASME/ASTM	Material Identification Report and Sample analysis report	P	H/W
3	<b>All Brought item</b>	Reputed make as per Technical Specification	Instruction manual TC Review	Related standards	Details product specification	P	H/W
4	<b>Welding Procedure specification</b>	Welding procedure	Document	ASME Sec IX	Document	P	H/W
5	<b>Welding operator performance qualification</b>	Welder Performance Qualification	Visual, NDE/ Mechanical	ASME Sec IX	Approved WPQ & PQR	P	H/W
<b>MAIN VESSEL</b>							
1	<b>Dished end formation</b>	Dimensional & DP	DP Test on knuckle portion of dished ends	ASTM-E-165	DP test Report & Dimensional report	P	H/W
2	<b>Weld setup of shell, dish ends, flanges and nozzles</b>	Visual	(i) Visual Inspection (ii) Dimensional check.	Drawing	Approved drawing and reports.	P	H/W
3	<b>Welding of seam joint, flanges and nozzles</b>	DP Test	ASTM-E-165	DP Test Report	To be recorded in stage wise inspection report.	P	H/W
4	<b>Welding quality examination (NDT)</b>	100% Radiography Film Test (As per approved in contract )	Film	ASME SEC VIII Div1	Report	P	H/W

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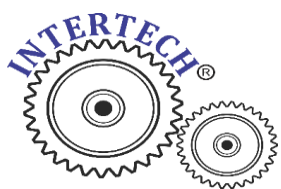
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Sr. NO.	ACTIVITIES	CHARACTERISTIC OF CHECK	TYPE OF CHECK	ACCEPTANCE STD	FORMAT OF RECORD	Intertech (AI)	Agency
5	<b>Mark Leg orientation on cone/shell, Set-up, Welding, Visual examination.</b>	Markings of Leg locations	(i) Visual Inspection As per Drawing (ii) Dimensional check.	Approved Fabrication Drawing	Report	P	H/W
<b>AGITATOR ASSEMBLY</b>							
1	Agitator	i) Drawing approval of agitator assembly with support	Dimension as per technical specification	Approved Fabrication Drawing	Report	P	H/W
		ii) Drawing approval of mechanical seal	TC and approval of drawing	As per Approved Drawing	Report	P	H/W
		ii) Dynamic balancing of agitation shaft	Balancing	ISO 1940 Grade 6.3	Inspection Report	P	H/W
2	Final Dimensional verification as per As build drawing (With All Nozzle Fitment)	Alignment Orientation Dimensions	Visual Visual Measurement	Final Approved Dwg.	Inspection Report	P	H/W
		Hydro-Testing	Integrity/ HT as per ASME Sec VIII Div 1 procedure	ASME Sec VIII Div 1	Test reports	P	H/W
		Leak Testing	Leak test as per ASME Sec VIII Div 1 procedure	Soap Bubble Test	Test reports	P	H/W
3	<b>Inspection of surface finish' (Int./Ext.) before testing 'of equipment. Free from foreign particle, rust dust and grease.</b>	Surface finish	Visual & Surface roughness meter	Approved Drawing. (RA value Range)	Surface finish inspection report	P	H/W
4	<b>Functionality testing</b>	(i) Ensure Operations and functions as per specified requirement	(i) Operating panel functions verification (ii) Interlock verification (iii) RPM verification (iv) With Load functioning trial (v) Load cell calibration Pipeline verification	Approved Fabrication drawing.	FAT report.	P	H/W
	AI	Authorized Inspector (From Intertech Technologies Pvt. Ltd )					
	Agency	Customer Authorized Third Party inspection Agency or Customer representative					
	H (HOLD):	Stage of Inspection beyond which work shall not progress unless accepted by AI/Agency					
	W (WITNESS)	Stage of Inspection for which AI /Agency shall be notified in advance, However work may proceed with AI's/Agency's consent if AI is unable to undertake the inspection.					
	P(Perform)	AI to perform the activity, document all results					

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