



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
MULTI-MIX MANUFACTURING PLANT**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
MULTI-MIX MANUFACTURING PLANT
MANUFACTURING LINE**

DATE OF QUALIFICATION

SUPERSEDES PROTOCOL No.

NIL



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1.0 PROTOCOL PRE- APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on basis of Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Multi-Mix Manufacturing Plant with Model MP 250 procured Propack Technologies Pvt. Ltd. The equipment used to manufacture Toothpaste/ointment/cream.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none"> • Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol after Execution
Engineering	<ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification . <ul style="list-style-type: none"> • GA Drawing • Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. • Details of utilities • Identification of components for calibration • Material of construction of all components • Brief Process Description • Safety Features and Alarms • Post Approval of Qualification Protocol after Execution



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5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the equipment from the supplier Site. To ensure that no un-authorized and/or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

The **Multi-Mix Manufacturing Plant** is meant for manufacturing of Toothpaste /ointment/ creams / as per cGMP requirement.

6.0 BRIEF PROCESS DESCRIPTION:

The Multi Mix Plant with load cell is used to Heat / Cool, Mix & Stir Water Phase & Wax Phase by using Bottom Stirrer. A Bottom Stirrer is controlled by VFD. A stirrer is engaged to check continuous homogenized mixing of element when in cycle of duty. Steam is provided for heating. A layer of mineral glass wool wrapped around control the heat loss into atmosphere due to dissipation of the heat. Multi Mix Plant with load cell contain temperature sensor for sensing the inside temperature.

The temperature is set through the control panel. Steam is passed through the steam inlet and the desired temperature is achieved. The wax phase vessel contains a Drain through which the condensed steam will come out in form of water. A pressure gauge & safety valve is also provided on jacket, so that the steam pressure does not exceed the set value, for safety. The stirrer motor of 1 HP is mounted on the stand which is made of SS 304. Mixing is start – (by means of push button provided at control panel) stirrer which will run with a help of a motor Check whether wax is ready for mixing. The wax is transferred by means of Vacuum by opening the outlet valve to the main manufacturing vessel through conical filter.

7.0 EQUIPMENT SPECIFICATION (URS):

Equipment Specification is a document provided to manufacturer for engineering equipment as per the specifications mentioned in PO.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<p>Application: The Multi-Mix Plant with load cell should be able to Manufacture cosmetic / Lotions / Creams & Gel</p>	<p>Multi-Mix Plant with load cell should meet the requirement for Manufacture cosmetic / Lotions / Creams & Gel. (To be assured by Supplier).</p>	<p>Process & cGMP Requirement</p>
<p>Working: Working of Multi-Mix Plant with load cell</p>	<p>Working is Vibration Free & free from any unwanted sound.</p>	<p>Process Requirement</p>
<p>Electrical Control Panel</p>	<p>The system should have Electrical Control Panel.</p> <p>AC Frequency Controller (For 3 HP Anchor Agitator)</p> <p>DOL Starter (For 7.5 HP High Shear Emulsification Head)</p> <p>Digital Timer (High Shear Emulsification Head)</p> <p>DOL Starter (For 1 HP Wax Phase Agitator)</p> <p>DOL Starter (For 1 HP Water Phase Agitator)</p> <p>DOL Starter (For 3 HP Vacuum Pump)</p> <p>Digital Temperature PID (3 Nos-for controlling Temperature in Vessels)</p> <p>DOL Starter (For 1.5 HP Transfer Pump)</p> <p>Indication Lamps (For mains ON and equipment ON)</p> <p>Emergency OFF (For Safety and Emergency).</p> <p>Mimic Operation Diagram (For Process Know-how).</p> <p>Electrical Diagram (For Easy fault rectification).</p> <p>Interconnecting Pipelines: All Pipelines are electro polish & joint are TC fitting for easy dismantling & cleaning.</p>	<p>Design & Process Requirement</p>



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8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	3 Phase Plus Earthing, 5 Wire Line Up To The Panel Board Terminal. Voltage- 440 ± 10% V -18.5 HP Frequency- 50 ± 3% Hz (To be assured by Engineering Department)	cGMP & Design Requirement
Steam	¾" BSP Header at 3 Kg.cm ²	Process Requirement
Cooling Water	1 ½" BSP Header at 7000 Ltrs./Hr	Process Requirement
Service Water	¾" BSP line at 2 Kg./cm ² pressure for cleaning	Process Requirement
Room Condition	Temperature: NMT 25 °C RH: NMT 55%	Process Requirement
Compressed Air	6.0 kg/cm ²	Process Requirement
Vacuum	650 to 760 mm. /Hg	Process Requirement



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8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Equipment	<ul style="list-style-type: none"> Multi-Mix Plant with load cell 	Supplier
Model No.	<ul style="list-style-type: none"> MP 250 	Design Requirement
Working Capacity	<ul style="list-style-type: none"> 250 Kg 	Process Requirement
Overall Dimension	<ul style="list-style-type: none"> Height : 2550 mm (Approx) Width : 2100 mm (Approx) Length : 5600 mm (Approx) 	Design Requirement
Manufacturing Vessel	<ul style="list-style-type: none"> Qty : 1 Nos. Capacity : 250 Kg. 	Design & Process Requirement
	Manufacturing Vessel	
	<ul style="list-style-type: none"> Shell : 5 mm thick AISI SS 316 with flange Bottom: 5 mm thick AISI SS 316 terrispherical type welded with shell. TOP: Terrispherical Dish end type welded with flange SS 316. Flange: 19 mm thick made of AISI SS 316L (2 Nos). Gaskets :Silicon gasket (Food grade) Jacket: 4 mm thick SS 304. 	
	Vessel Connection on Top Dish End:	
	<ul style="list-style-type: none"> Light Glass: 4" Dia. with Lamp Sight glass: 6" Dia. toughen glass. Extra Connection: 1"Dia TC 1 Nos. Ingredient Suction: 1"Dia TC with flexible hose & Butterfly valve CIP Connection: 1"Dia TC 2 Nos. for spray ball with common pipe line Stirrer: Mounted on centre of the dish. 	
	Vessel Connection on side of the top shell:	
<ul style="list-style-type: none"> Wax Inlet: 1" Dia with TC Union. Water Inlet: 1" Dia with TC Union. Recirculation: 1 ½" Dia with TC Union 		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	<p>Vessel Connection on bottom of the top shell:</p> <ul style="list-style-type: none"> • Outlet: 1 ½” Dia. flush bottom valve with TC Union. • Product Sensor: PT- 100 with temperature indicator. • Homogenizer: On conical portion <p>Vessel Design:</p> <ul style="list-style-type: none"> • Temperature: 150°C • Pressure: 2 kg/cm² • Vacuum: 650-700 mm/hg. <p>Jacket Connection:</p> <ul style="list-style-type: none"> • Steam Inlet : 1” Dia. TC Flanged End • Cooling Outlet : 1 ½” Dia. TC or Flanged End • Cooling Inlet : 1 ½” Dia. TC or Flanged End • Steam Condensate : 1” Dia. TC or Flanged End • Drain : 1 ½” Dia. TC or Flanged End • Connection for : Safety valve, Pressure gauge & Air vent is provided <p>Jacket Design:</p> <ul style="list-style-type: none"> • Temperature : 150°C • Pressure : 4 kg/cm² working & 6 kg/cm² Hydraulic Test <p>Agitator:</p> <ul style="list-style-type: none"> • Type: Teflon Scrappers Floating Type. • Speed: Frequency controller is provided for vary speed.5 to 48 RPM. • Speed Regulation: Variable frequency drive provided for speed variation. (Delta) • Shaft Seal: Dry mechanical seal. • Motor: 3 HP / 440 V/1500 RPM. • Gear Box: Size-W-110. Ratio-30:1 	



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Homogenizer	<ul style="list-style-type: none">• Type: Bottom of the vessel in conical portion.• HSEH Design: Especially Design HSEH with Rotor and Stator Principle for breaking mass into Micron size particles. Also works as a pump to re-circulate the product externally during the processing & discharge the product after the batch is completed.• Shaft Seal: Double cartridge mechanical seal with TC/TC seal Face with cooling water arrangement for the mechanical seal and an electronic water detection sensor to trip the motor if the flow of water to the mechanical seal is stopped, ensuring thorough safety of the seal.• Motor: 7.5 HP /2800 RPM/440V• Safety: safety of mechanical seal flow switch is provided.• Weld and Finish details: Vessel will be argon arc welded.• Internally: 0.5 Ra 210 grit (Mirror polish)• Externally: 180 grit (Matt polish)• Vessel is 650 to 760 mm. /Hg. Vacuum Tight.	Process Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<p>Wax Phase Vessel</p>	<ul style="list-style-type: none"> • Capacity: 150 Liters. • Shell: 4mm Thick, Cylindrical type. • Bottom: 4mm Thick, Dish Type welded with shell. • Top: 16 SWG thick, loose with 1/3rd Open able type. • Flange: 12 mm thick SS 304 with openable type • Jacket: 4 mm thick , spiral type stiffeners for uniform heating and cooling • “0” Ring: Silicon food grade. • Legs: made of SS304 pipe legs 03 Nos. • Cladding: made of 14 SWG welded type. • Inline Conical Filter: Made of SS 316 L ,100mesh (for filtration of WAX Phase) 	<p align="center">Design & Process Requirement</p>
	<p>Vessel Connection on Top LID:</p>	
	<ul style="list-style-type: none"> • Stirrer: Mounted on centre of the Lid. 	
	<p>Vessel Connection on bottom of the Vessel:</p>	
	<ul style="list-style-type: none"> • Outlet: 1” Dia. flush bottom valve with TC fittings. • Product Sensor: P.T. 100 with temperature indicator. 	
	<p>Vessel Design:</p>	
	<ul style="list-style-type: none"> • Temperature: 150°C • Pressure: 2 kg/cm² • Vacuum : 650 – 700 mm/Hg 	
	<p>Jacket Connection :</p>	
	<ul style="list-style-type: none"> • Steam Inlet : 1” Dia. TC or Flanged End • Steam Condensate: 1” Dia. TC or Flanged End • Drain: 1 ½” Dia. TC or Flanged End • Connection for: Safety valve, Pressure gauge & Air vent is provided. 	
	<p>Jacket Design:</p>	



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	<ul style="list-style-type: none"> • Temperature: 150° C • Pressure: 4 kg/cm² working & 6 kg/cm² Hydraulic Test <p>Agitator:</p> <ul style="list-style-type: none"> • Type: Saw Cutter type • Motor: 1 HP / 440 V/ 960 RPM. • Weld and Finish details: Vessel will be argon arc welded. • Internally: 0.5 Ra 210 grit (Mirror polish) • Externally: 180 grit (Matt finish) 	
<p>Water Phase Vessel</p>	<ul style="list-style-type: none"> • Capacity: 150 ltrs. • Shell: 4mm Thick, Cylindrical type. • Bottom: 4mm Thick, Dish Type welded with shell. • Top: 16 SWG thick, Loose with 1/3rd Open able type. • Flange : 16 mm thick • Jacket: 4 mm thick, Spiral type stiffeners for uniform heating and cooling. • “0”Ring : silicon food grade. . • Legs : pipe legs (3 Nos.) • Cladding : made of 14 SWG welded type. • Inline Conical Filter: 100mesh (for Filtration of Water Phase) <p>Vessel Connection on Top LID:</p> <ul style="list-style-type: none"> • Stirrer : Mounted on centre of the dish <p>Vessel Connection on bottom of the Vessel:</p> <ul style="list-style-type: none"> • Outlet: 1” Dia. flush bottom valve with common pipe line fittings. • Product Sensor: P.T. 100 with temperature indicator. <p>Vessel Design:</p>	<p>cGMP & Design Requirement</p>



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	<ul style="list-style-type: none"> • Temperature : 150°C • Pressure : 2 kg/cm². • Vacuum : 650 – 700 mmHg. <p>Jacket Connection:</p> <ul style="list-style-type: none"> • Steam Inlet : 1” Dia. TC or Flanged End • Steam Condensate: 1” Dia. TC or Flanged End • Drain : 1 ½” Dia. TC or Flanged End • Connection for : Safety valve, Pressure gauge & Air vent is provided <p>Jacket Design:</p> <ul style="list-style-type: none"> • Temperature : 150°C • Pressure : 4 kg/cm sq. working & 6 kg/cm sq Hydraulic Test <p>Agitator:</p> <ul style="list-style-type: none"> • Type: Propeller type/Saw cutter type • Motor: 1 HP / 440 V/ 960 RPM. • Weld and Finish Details: Vessel will be argon arc welded. • Internally: 0.5 Ra 220 grit (Mirror polish) • Externally: 180 grit (Matt finish) <p>Interconnecting Pipelines:</p>	
	<ul style="list-style-type: none"> • Pipeline from wax melting vessel to Cosmetic Manufacturing Vessel with conical Filter (100mesh) • All pipelines are electro polished and joints are TC fitting for easy dismantling & cleaning 	



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Transfer Pump (LOBE PUMP)	<ul style="list-style-type: none"> • Rotors are accurately machined and located on sturdy shafts • Two mechanical seals are provided on two shafts. • Mounted on stand with geared 1.5 HP / 440v / 760 RPM • Output: 1800 liters/hr • Inlet size: 1½” Dia. TC • Outlet size: 1 ½” Dia. TC 	Design & Process Requirement
Vacuum Pump	<ul style="list-style-type: none"> • Type: Water Ring Type • 3 HP / 440V / 2800 RPM / Water Ring Type • Capacity: 710 mm/hg. • Water inlet flow required: 6-8 Lit/Min • Water Temperature: Ambient • Utility Required: • Soft Water Inlet: 1” Dia. line • Chilled water inlet line: 1” Dia. line • Chilled water outlet line: 1”dia line. • Drain line: 1” Dia. line 	Design & Process Requirement
Meter-in Pump	<ul style="list-style-type: none"> • Purpose/Application: For feeding product from Storage Vessel to the Filling Machine Hopper. The pump shall match the output of the Filling Machine • Type: Reciprocating Plunger type, Volume adjustable. • Motor: 0.5 HP / 440V / 1440 RPM • Head 2.5 meter • Inlet: 1” Dia. line • Outlet: 1 ” Dia. line 	Design & Process Requirement
Batch Storage Vessel	<ul style="list-style-type: none"> • Qty.: 4 Nos. • Capacity: 350 Liters • Inlet: 1 ½” TC • Outlet: 1 ½” Dia. with Butterfly valve 	Design & Process Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Load Cell	<ul style="list-style-type: none">• Model: TWS L Series 4 Legs 250kg x 50 gm• Supplier: Mettler-Toledo India Pvt. Ltd• Operating Environment: Temperature: -10°C-42°C (14°F-107.6°F) RH: 10%-95%• Utility/ Electricity: Voltage: 220V AC±10% Frequency: 50Hz Power: 40W• Working Capacity: Max^m: 250.0 Kg Min^m: 2.0 Kg• PLC Panel: Dimension (WxHxD): Panel Mount	Process Requirement



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8.4 MATERIAL OF CONSTRUCTION :

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	All contact Parts	AISI SS 316
2.	Shell	AISI SS 316
3.	Bottom	AISI SS 316
4.	Top	AISI SS 316
5.	Flange	AISI SS 316L
6.	Gaskets	Food Grade
7.	Jacket	SS 304
8.	Legs	SS 304
9.	Insulation	Fiber Wool (Mineral Wool Asbestos Free)
10.	Transfer Pump (LOBE PUMP)	AISI SS 316 (Product Contact Parts)
11.	Meter-in Pump	SS 316 (Product Contact part)
12.	Working Platform: <ul style="list-style-type: none"> • Square Pipe Frame Work with Top SS 304 • Dimple Sheet Ladder SS 304 • Railing is provided on all three sides of the Platform SS 304 • Legs SS 304 (Round Pipe Legs are provided) • Platform SS 304 (GMP Standard Paint Free) 	SS 304
13.	Batch Storage Vessel: <ul style="list-style-type: none"> • Shell 16 SWG (Cylindrical type) SS 316 • Bottom 16 SWG SS 316 (Conical type welded with shell) • Top 16 SS 316 (Loose type Lid) • Legs with PU Castor wheel with Bracket. 	SS 316 (All Contact Parts) SS 304



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8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling And Balancing	Equipment should be properly balanced & leveled	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
Noise Level	Below 80 db	Safety Requirement
Emergency Switch	Provided easy access position	Safety Requirement
Startup	When top Dish end of Multi-Mix is up then the stirrer will not start, ensuring safety for the operator.	Safety Requirement
Cooling arrangement	Cooling arrangement provided for motor shaft and seal with special flow switch to detect water, so only if cooling water is circulated then only homogenizer will operate, this ensures long life of the equipment.	Safety Requirement
Operating panel	Is provided on platform of the Equipment for operator safety.	Safety Requirement
Dimple sheet	Platform to ensure proper grip during walking and railing is provided as safety feature.	Safety Requirement



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8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Multi-Mix Plant with load cell..	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feed back from market (customers already using the equipment)	Process Requirement

- Reference:**
- (1) The equipment shall confirm to the specifications and requirement as specified in PO.
 - (2) Operating and service manual for **Multi-Mix Plant with load cell.**



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9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

DQ	:	Design Qualification
URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practice
P & ID	:	Piping and Instrumentation Diagram
GA	:	General Agreement
SS	:	Stainless Steel
RPM	:	Revolution per Minute
TC	:	Tri Clover
HP	:	Horse Power
Hz	:	Hertz
NMT	:	Not more Than
RH	:	Relative Humidity
SWG	:	Standard water gauge
NRV	:	Non Return Valve
MCB	:	Miniature Circuit Breaker
Db	:	Decibel
PO	:	Purchase order



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			