



**PERFORMANCE QUALIFICATION REPORT  
FOR  
STERILIZING & DEPYROGENATING TUNNEL**

**PROTOCOL No.:**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
STERILIZING & DEPYROGENATING  
TUNNEL**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Ampoule Washing and De-Pyrogenation Tunnel</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES REPORT No.</b>	<b>NIL</b>



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION REPORT  
FOR  
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**PROTOCOL No.:**

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**PROTOCOL No.:**

**1.0 REPORT PRE – APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

The objective of this Report is to establish that Sterilization & Depyrogenating tunnel meets the following criteria:

- The Sterilization and Depyrogenating tunnel performs as per the pre-defined parameters and/or quality attributes.

**3.0 SCOPE:**

- The Report covers all aspects of Performance Qualification for the Sterilizing and Depyrogenating Tunnel (**Make – TruKing Technologies Ltd.**) installed in the Ampoule Washing & Depyrogenating of .....
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples



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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 verification and evaluation of performed tests results.

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation, Approval Compilation of the Performance Qualification.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Analytical Support (Microbiological Testing / Analysis)</li></ul>
<b>External Qualification Agency ( if Applicable)</b>	<ul style="list-style-type: none"><li>• Provide Raw Data of qualification activity as per protocol</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Reviewing of qualification Report for correctness, completeness and technical excellence</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li></ul>

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Sterilizing and De-pyrogenating Tunnel
<b>Equipment ID.</b>	.....
<b>Manufacturer's Name</b>	Truking Technologies Ltd.
<b>Supplier's Name</b>	Truking Technologies Ltd.
<b>Model</b>	KSZ620/60B
<b>Location of Installation</b>	Ampoule Washing and Depyrogenating Tunnel



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**6.0 PRE – QUALIFICATION REQUIREMENTS:**

**6.1 Training of Qualification Team:**

- All the persons involved in the execution of qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

**6.2 Calibration of all Components of System and Test Instruments:**

- Calibration of all the instruments used for Qualification should be mentioned along with Calibration Certificates.

S.No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
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**PROTOCOL No.:**

**7.0 TESTS AND CHECKS:**

**7.1 Air velocity measurement:**

<b>Date of Test</b>	
<b>Name of Instrument Used for Testing</b>	<b>Digital Anemometer</b>
<b>Calibrated on</b>	
<b>Calibration due on</b>	

HEPA Filter No.	Location	Velocity [FPM]					Average Velocity [FPM]
		V1	V2	V3	V4	V5	
1.	In feed Zone						
2.	Preheating Zone						
3.	Heating Zone						
4.	Cooling Zone						

**Acceptance Criteria**

The Average measured clean air velocity at downstream of filter face.

**Infeed Zone:** 90-110 feet/min., **Preheating Zone:** 90-110 feet/min.,  
**Heating Zone:** 120-150 feet/min., **Cooling Zone:** 90-110 feet/min.

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**PROTOCOL No.:**

**7.2 Filter Integrity Test (PAO Test) Of HEPA Filter :**

<b>Date of Test</b>	
<b>Name of Instrument</b>	<b>Aerosol Photometer</b>
<b>Calibrated on</b>	
<b>Calibration due on</b>	

<b>S.No.</b>	<b>HEPA Filter Location</b>	<b>Filter ID</b>	<b>Observed Downstream Concentration</b>
1.	In feed Zone		
2.	Preheating Zone		
3.	Heating Zone		
4.	Heating Zone		
5.	Heating Zone		
6.	Cooling Zone		
7.	Cooling Zone		

**Acceptance Criteria:**

The PAO Penetration Leak Through HEPA Filters Should not Be Greater Than 0.01% of The Upstream PAO Concentration

**Checked By  
(Engineering)**

**Sign/Date:** .....

**Verified By  
(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By  
(Manager QA)**

**Sign/Date:** .....





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**PROTOCOL No.:**

**7.3 Non – viable particle count test:**

<b>Date of Test</b>	
<b>Name of Instrument used for Testing</b>	
<b>Calibrated on</b>	
<b>Calibration due on</b>	

Date	Area / Location	Observation		Acceptance Criteria
		≥0.5μ	≥5.0μ	
	In feed Zone L-01			1. NMT 3520/m <sup>3</sup> particles of 0.5μ. 2. NMT 20/m <sup>3</sup> Particles of 5.0μ
	Preheating Zone L-02			
	Heating Zone L-03			
	Heating Zone L-04			
	Heating Zone L-05			
	Cooling Zone L-06			
	Cooling Zone L-07			

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**PROTOCOL No.:**

**7.4 Conveyor Belt speed Verification test:**

$$\text{Belt Speed in mm} = \frac{(\text{Ampoule Diameter})^2 \times \cos 30 \times \text{Washing M/C Out put}}{\text{Tunnel Conveyor Width}}$$

**For 1 ml**

Ampoule Diameter-10.5 mm  
Washing M/C Output – 500 ampoule/minute  
Tunnel width- 600mm

**For 2 ml**

Ampoule Diameter-11.5 mm  
Washing M/C Output – 500 ampoule/minute  
Tunnel width- 600mm

**For 3 ml**

Ampoule Diameter-12.5 mm  
Washing M/C Output – 500 ampoule/minute  
Tunnel width- 600mm

**For 5 ml**

Ampoule Diameter-14.5 mm  
Washing M/C Output – 420 ampoule/minute  
Tunnel width- 600mm

<b>Date of Test</b>				
<b>Ampoule Size</b>	<b>1 ml</b>	<b>2ml</b>	<b>3ml</b>	<b>5ml</b>
<b>Set Speed</b>	76 mm/minute	92 mm/minute	110 mm/minute	120 mm/minute
<b>Actual Speed</b>				

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....



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**PROTOCOL No.:**

**7.5 Heat Distribution Study For Empty Chamber:**

<b>Test Instrument Name</b>	
<b>Sensors type &amp; Qty.</b>	
<b>Model No</b>	
<b>Make</b>	
<b>Calibration done Date</b>	
<b>Calibration due Date</b>	

**Empty Heat Distribution Cycle Parameter:**

<b>Parameters</b>	<b>Set Value</b>	<b>Observed Value</b>		
		<b>1<sup>st</sup> Cycle</b>	<b>2<sup>nd</sup> Cycle</b>	<b>3<sup>rd</sup> Cycle</b>
<b>Cycle Start Date / Time</b>				
<b>Relative Humidity of Area</b>				
<b>Temperature of Area</b>				
<b>No. of In - built Temp. Sensors</b>	05			
<b>No. of external placed Temp. Sensors</b>	12			
<b>Heater Bank 1 cut off</b>	340 <sup>0</sup> C			
<b>Heater Bank 2 cut off</b>	338 <sup>0</sup> C			
<b>Heater Bank 3 cut off</b>	336 <sup>0</sup> C			
<b>Conveyor Start Temp.</b>	320 <sup>0</sup> C			
<b>Conveyor Belt Speed</b>	80 mm/minute			
<b>Differential Pressure between Drying Zone and room</b>	05-10 Pascal			
<b>Differential Pressure between Heating Zone and room</b>	06-12 Pascal			
<b>Differential Pressure between Cooling Zone and room</b>	05-10 Pascal			



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**PROTOCOL No.:**

Parameters	Set Value	Observed Value		
		1 <sup>st</sup> Cycle	2 <sup>nd</sup> Cycle	3 <sup>rd</sup> Cycle
Minimum Avg. Temperature (Sensor No)				
Maximum Avg. Temperature (Sensor No.)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By  
(Engineering)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

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**Reviewed By  
(Manager QA)  
Sign/Date: .....**



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**PERFORMANCE QUALIFICATION REPORT  
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**PROTOCOL No.:**

**7.6 Heat Distribution Study For Loaded Chamber:**

<b>Test Instrument Name</b>	
<b>Sensors type &amp; Qty.</b>	
<b>Model No</b>	
<b>Make</b>	
<b>Calibration done Date</b>	
<b>Calibration due Date</b>	
<b>Ampoule Size</b>	

**Loaded heat distribution cycle parameter:**

Parameters	Set Value	Observed Value		
		1 <sup>st</sup> Cycle	2 <sup>nd</sup> Cycle	3 <sup>rd</sup> Cycle
<b>Cycle Start Date / Time</b>				
<b>Relative Humidity of Area</b>				
<b>Temperature of Area</b>				
<b>No. of external placed Temp. Sensors</b>	12			
<b>No. of In - built Temp. Sensors</b>	05			
<b>Heater Bank 1 cut off</b>	340 <sup>0</sup> C			
<b>Heater Bank 2 cut off</b>	338 <sup>0</sup> C			
<b>Heater Bank 3 cut off</b>	336 <sup>0</sup> C			
<b>Conveyor Start Temp.</b>	320 <sup>0</sup> C			
<b>Conveyor Belt Speed</b> (mm/minute)				
<b>Differential Pressure between Drying Zone and room</b>	05-10 Pascal			
<b>Differential Pressure between Heating Zone and room</b>	06-12 Pascal			



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**PROTOCOL No.:**

Parameters	Set Value	Observed Value		
		1 <sup>st</sup> Cycle	2 <sup>nd</sup> Cycle	3 <sup>rd</sup> Cycle
Differential Pressure between Cooling Zone and room	05-10 Pascal			
Minimum Avg. Temperature & Sensor No.				
Maximum Avg. Temperature & Sensor No.				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**PERFORMANCE QUALIFICATION REPORT  
FOR  
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**PROTOCOL No.:**

**7.7 Heat penetration study for loaded chamber:**

<b>Test Instrument Name</b>	
<b>Sensors type &amp; Qty.</b>	
<b>Model No</b>	
<b>Make</b>	
<b>Calibration done Date</b>	
<b>Calibration due Date</b>	
<b>Ampoule Size</b>	

**LOADED HEAT PANETRATION CYCLE PARAMETER:**

Parameters	Set Value	Observed Value		
		1 <sup>st</sup> Cycle	2 <sup>nd</sup> Cycle	3 <sup>rd</sup> Cycle
<b>Cycle Start Date / Time</b>				
<b>Relative Humidity of Area</b>				
<b>Temperature</b>				
<b>No. of external placed Temp. Sensors</b>	12			
<b>No. of In - built Temp. Sensors</b>	05			
<b>Heater Bank 1 cut off</b>	340 <sup>0</sup> C			
<b>Heater Bank 2 cut off</b>	338 <sup>0</sup> C			
<b>Heater Bank 3 cut off</b>	336 <sup>0</sup> C			
<b>Conveyor Start Temp.</b>	320 <sup>0</sup> C			
<b>Conveyor Belt Speed</b>				
<b>Differential Pressure between Drying Zone and room</b>	05-10 Pascal			
<b>Differential Pressure between Heating Zone and room</b>	06-12 Pascal			
<b>Differential Pressure between Cooling Zone and room</b>	05-10			



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**PROTOCOL No.:**

Parameters	Set Value	Observed Value		
		1 <sup>st</sup> Cycle	2 <sup>nd</sup> Cycle	3 <sup>rd</sup> Cycle
	Pascal			
Minimum Avg. Temperature (Sensor No.)				
Maximum Avg. Temperature (Sensor No.)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....





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**PROTOCOL No.:**

**F<sub>H</sub> Calculation & Endotoxin Test Report:**

Probe No.	De-pyrogenating Temperature		Duration of Depyrogenating Temp. (300°C & Above)		F <sub>H</sub> Value	Reduction of Endotoxin	Remarks
	Min	Max	From	To			

**Acceptance Criteria:**  
Reduction of Endotoxin NLT 3 log

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**PERFORMANCE QUALIFICATION REPORT  
FOR  
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**PROTOCOL No.:**

**7.8.1 Differential Pressure Record:**

Pressure Differential Gauge	Preheating Zone and room	Heating Zone and room	Cooling Zone and room
Magnehelic Gauge Id. No.			
Date of Calibration			
Calibration due date			
Acceptance Criteria	05-10 Pascal	06-12 Pascal	05-10 Pascal

Date	Time	Pressure Differential		
		Preheating Zone and room	Heating Zone and room	Cooling Zone and room

**Checked By**  
**(Engineering)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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## PERFORMANCE QUALIFICATION REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

PROTOCOL No.:

### 7.8.2 Differential Pressure Record:

Pressure Differential Gauge	up and down of HEPA filter in preheating zone	up and down of HEPA filter-1 in heating zone	up and down of HEPA filter-2 in heating zone
Magnehelic Gauge Id. No.			
Date of Calibration			
Calibration due date			
Acceptance Criteria	100-300 Pascal	150-350 Pascal	150-350 Pascal

Date	Time	Pressure Differential		
		up and down of HEPA filter in preheating	up and down of HEPA filter-1 in heating zone	up and down of HEPA filter-2 in

Checked By  
(Engineering)  
Sign/Date: .....

Verified By  
(Quality Assurance)  
Sign/Date: .....

Inference:

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Reviewed By  
(Manager QA)  
Sign/Date: .....



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FOR  
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**PROTOCOL No.:**

**7.8.3 Differential Pressure Record:**

Differential Pressure Gauge	up and down of HEPA filter-3 in heating zone	up and down of HEPA filter-1 in cooling zone	up and down of HEPA filter-2 in cooling zone	Washing room and filling room
Magnehelic Gauge Id. No.				
Date of Calibration				
Calibration due date				
Acceptance Criteria	150-350 Pascal	80-250 Pascal	80-250 Pascal	15-30 Pascal

Date	Time	Pressure Differential			
		up and down of HEPA filter-3 in heating zone	up and down of HEPA filter-1 in cooling zone	up and down of HEPA filter-2 in cooling zone	Washing room and filling room

**Checked By  
(Engineering)  
Sign/Date: .....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**  
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 .....

**Reviewed By  
(Manager QA)  
Sign/Date: .....**



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FOR  
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**PROTOCOL No.:**

**7.9 AIR FLOW PATTERN**

<b>Date of Testing</b>		<b>Make/Model</b>	
<b>Instrument Name</b>		<b>Calibration Date</b>	
<b>Instrument ID.</b>		<b>Calibration Due Date</b>	

<b>Area</b>	<b>Air Flow Pattern Should Be Moving In Downward Direction</b>	<b>The Air Flow Pattern should not travelling Dying and Cooling Zone to Sterilization zone.</b>	<b>Verified By (Sign &amp; Date)</b>

**8.0 CHECKLIST OF ALL TESTS & CHECKS**

<b>S. No.</b>	<b>Name of Test or Check</b>	<b>Execution (Yes/No.)</b>	<b>Remark</b>	<b>Verified By (Sign &amp; Date)</b>
1.	Air Velocity Measurement			
2.	HEPA Filter Integrity Test (PAO Test) Report			
3.	Differential Pressure Record			
4.	Speed verification set value			
5.	Non – Viable Particle Count			
6.	Air Flow Pattern			
7.	Heat Distribution Study 1. Empty 2. Loaded			
8.	Heat Penetration Study Loaded Chamber			

**Inference:**

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**Reviewed By  
(Manager QA)  
(Sign & Date):.....**



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**PROTOCOL No.:**

**9.0 DOCUMENTS TO BE ATTACHED:**

- Calibration Certificates of test instruments.
- Calibration Certificate of Data logger.
- Calibration Certificate of Sensors.
- Any other relevant document.

**10.0 NON COMPLIANCE:**

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**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**PROTOCOL No.:**

**16.0 ABBREVIATIONS:**

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
mm	:	Millimeter
Amp.	:	Ampere
PQ	:	Performance Qualification
DTM	:	Depyrogenating Tunnel Machine
SOP	:	Standard Operating Procedure





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**PROTOCOL No.:**

**17.0 REPORT POST 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)			