





DATASHEET		
HLL LIFECARE LIMITED, Chennai		
	REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI	
	HTM TEST KIT	
	PROJECT #:	110729
	EQ. ID #:	FG-HTM 01
	DOCUMENT # :	DS/FG-HTM 01
		
1	Process requirements	
1.1	The Test Kit shall be used for the testing the quality of steam for non-condensable gases, dryness value and superheat, as per HTM 2010, EN 285 & EN 554.	
2	Technical Specification	
2.1	<p>The equipment shall consist of:</p> <ul style="list-style-type: none"> • Non-condensable gas test condenser • Non-condensable gas separation apparatus • Memory Stick with instruction manual and calculations on spreadsheet. • Temperature probe • Pump assembly • Water connection elbow ½”BSP×6mm push fit • Stainless steel Steam connection elbow 1/4”BSP×6mm • Flexible steam hose • Burette & rubber filler • 250 ml measuring cylinder • Thermocouple connecting cable • Pitot tubes (0.4mm,0.6mm,0.8mm and 1.0mm) • Stainless steel vacuum flask • Connection tube and clips • Measuring cup and flask holder • Superheat expansion tube • Mounting Tripod • Pair of gloves 	
3	Specific requirement	
3.1	The equipment should meet the technical specifications of the kit.	
3.2	The equipment should function consistently and the results should meet the accuracy of + 1.0%.	
3.3	The instruments should be calibrated and have a traceability as per the prescribed standards.	
3.4	Installation and operation manual with calculation sheet should be provided with the kit.	
3.5	For dryness value test of steam, the flask has to be connected within 0.5m of the sampling point; therefore feasibility of incorporation of flask holder in the kit should be provided for convenience. A dryness value of 1.0 is equivalent to Dry Saturated Steam. For sterilization purposes, a factor of 0.9 is acceptable for nonmetal sterilizer loads. For loads containing metal, a factor of 0.95 is considered to be acceptable as referred in guidelines; therefore the kit assembly should be susceptible to measurement for this range.	
3.6	For Superheat value test, temperature is measured by a thermo-couple placed at the centre of an expansion tube placed over the pitot tube as steam passes through its orifice. The temperature is considered to be acceptable if it is less than 25°C above that of the local temperature of boiling water; therefore the thermocouples in kit assembly should be susceptible to measurement.	
3.7	For non condensable gases test, gas and steam condensate volumes are measured by 'zero-adjustable' calibrated scales mounted behind the sight glasses. The temperature of the condensate is maintained above 80°C by controlling the steam flow through the inlet needle valve while measuring the condensate temperature from a thermocouple probe on the outlet of the condenser. The non-condensable gas test is considered to be acceptable for sterilization purposes on sterilizers if the percentage of gas to condensate is less than 3.5% therefore the kit assembly should be susceptible to measurement.	
3.8	For purpose of BET testing Clean/pure steam shall be sampled using sanitary cooler/condenser, therefore it should be able to maintain the close system integrity to facilitate minimum exposure.	
4	Other requirements	
4.1	NA	
5	Regulatory guidelines / standards	
5.1	HTM 2010, EN 285 & EN 554.	
6	Safety requirement	
6.1	NA	

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7	Documents					
7.1	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.					
7.2	Guarantee/ warranty certificate for each equipment and major bought-out items and comprehensive 1 year warranty					
7.3	Vendor to provide the Maintenance manual.					
8	Timelines					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.					
	AFI Approved for Enquiry			AFO Approved for Ordering		
0	2013-03-04	NHSG	NVNG	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/1