

Equipment Specification Data Sheet

Equipment Name: Karl fisher autotitrator  
 (Volumetric)

Document No.: DS-KFA 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines  
 Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-KFA 01	-	1

**NNE Pharmaplan India Limited**

Name	Designation	Signature	Date
<b>Prepared by</b>			
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<b>Checked by</b>			
Mr. Yogesha M J	Process Engineer		11/02/2016
<b>Approved by</b>			
Dr. Harshad Mali	Lead - Process Engineer	for	11/02/2016

**HLL Biotech Limited**

Name	Designation	Signature	Date
<b>Reviewed by</b>			
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HLL Biotech Limited, Chennai			
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED            Publicly Traded Company of HLL Group Limited            In Government of India's Category</small>
	Equipment Name	Karl fisher autotitrator (Volumetric)	
	Project #	120310	
	Document #	DS-KFA 01	
<b>1</b>	<b>Process requirements</b>		
1.1	Karl fisher autotator colourimetric titration is a classic titration method in analytical chemistry that uses coulometric titration to determine trace amounts of water in sample.		
<b>2</b>	<b>Equipment ID</b>		
2.1	Q1- KFA 01		
<b>3</b>	<b>Technical Specification</b>		
3.1	Model	Vendor to specify	
3.2	Titration Type	Karl Fischer Volumetric	
3.3	Determination Range	100 ppm to 100%	
3.4	Choice of end point indication	bi- volumetric or bi- amperometric	
3.5	Burette Resolution	1/10000 of Burette cylinder volume	
3.6	Titration Dimension	Vendor to specify	
3.7	Ambient Temperature	+5 to +40° C	
<b>4</b>	<b>Material of Construction</b>		
4.1	Main body	vendor to specify	
<b>5</b>	<b>Specific Equipment requirement</b>		
5.1	Should have the facility to STOP the titration by Delay time or the novel "drift stop", where titration stops when a preset drift value is reached		
5.2	The equipment should not have a separate method for drift determination and the drift compensation should be automatic		
5.3	10 ml Burette complete set to be offered along with the system. The burette should have a zero dead volume or close to it and preferably a positive displacement type for safety in case of spillage		
5.4	Automatic recognition of cylinder volume should be built into the instrument preferably with a unique serial number		
5.5	The instrument should be equipped with an intelligent burette capable of storing the complete information on the Titrant like the Titer history, Value, and serial number.		
5.6	Result can be displayed or printed in a choice of units as %, ppm, g/L, mg/L, mol/L, g, mg, ml, mg/pc, no unit & unit programmable		
5.7	Possibility to connect host of accessories for automation		
5.8	A suitable stirrer along with a pump for handling the solvent and the waste should be provided with the system		
5.9	The instrument shall have the facility to measure pH of a solution using a suitable electrode if required.		
5.10	The instrument shall have the facility to do parallel titration if required		
5.11	The instrument should be compatible with an autosampler, for automation of sample analysis if required in the future		
5.12	Latest windows based software should be provided		
<b>6</b>	<b>Other requirement</b>		
6.1	Training and demo for user on operation and cleaning to be provided		
<b>7</b>	<b>Regulatory aspects</b>		
7.1	CE certification		
<b>8</b>	<b>Safety requirements</b>		
8.1	Proper earthing is necessary		
8.2	Appropriate closure of all parts.		

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<b>9</b>	<b>Documents</b>		
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file		
9.1	IOQ documents		
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site		
9.3	Warranty Letter for Minimum 1 year from the date of supply.		
9.4	Vendor should provide list of standard spare parts with ordering information.		
9.5	NPL traceable calibration certificates and calibration procedures		
9.6	Vendor should provide list of change parts (if applicable) with ordering information		
<b>10</b>	<b>Timelines</b>		
10.1	Not Applicable		
<b>11</b>	<b>Preferred list of Makes</b>		
11.1	Metrohm, Mettler toledo		

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TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1- KFA 01	QC	Chemical Lab	Q1S022	-	-

Table-2: Change Log				
Date	Name	Revision	Section	Change/Comment
09-09-2015	Tushar Shinde	00	-	New document

Table-3: Annexure
Not applicable

