

Equipment Specification Data Sheet

Equipment Name: Cell Factory Hand Manipulator

Document No.: DS-CSM 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies Bulk Block	B4-CSM 01, 02	-	2

**NNE Pharmaplan India Limited**

Name	Designation	Signature	Date
<b>Prepared by</b>			
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<b>Checked by</b>			
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<b>Approved by</b>			
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**HLL Biotech Limited**

Name	Designation	Signature	Date
<b>Reviewed by</b>			
User department: Rabies Bulk Block <i>P. NAGAN KUMAR</i>	DEPUTY MANAGER (NVP)	<i>P. Nagan</i>	16/02/2016
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Project Authority <i>RAMAN K. R.</i>	C.E.O.	<i>Raman K.R.</i>	19.2.16



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HLL Biotech Limited, Chennai			
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED            Subsidiary of HLL Life Sciences Limited            H. Government of India, Chennai</small>
	Equipment Name	Cell Factory Hand Manipulator	
	Project #	120310	
	Document #	DS-CSM 01	
<b>1</b>	<b>Process requirements</b>		
1.1	The hand manipulator is intended to handle Cell Factory 40 (CF40) version manually for loading, cultivation, unloading position.		
<b>2</b>	<b>Equipment ID</b>		
2.1	B4-CSM 01, 02		
<b>3</b>	<b>Technical Specification</b>		
3.1	Model	cGMP Model	
3.2	Type	CF40 Hand Manipulator	
3.3	Manual Tilting	Lever(s) and pedal(s) required	
3.4	CF 40 Size	350 x 250 x 720 mm approximately	
<b>4</b>	<b>Material of Construction</b>		
4.1	Frame MOC	SS 304 or better	
4.2	Wheels	Clean room wheels	
<b>5</b>	<b>Specific Equipment requirement</b>		
5.1	Manipulator must be designed for CF40 specification and appropriate fixing arrangement must be provided		
5.2	Handles at appropriate position must be provided		
5.3	The manual movement of tilting (backward, forward, sideward for filling and emptying) must be manually controlled with lever and pedals		
5.4	Four wheel arrangement along with locking arrangement		
<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	Appropriate closure of all parts.		
8.2	Recommended cleaning agent for the machine must be provided		
<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		



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	Project #	120310	
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**TABLE NO: 1**

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-CSM 01	Rabies Bulk Block	Virus Propagation	B4G046	6625 x 5775	2700
B4-CSM 02	Rabies Bulk Block	Cell Culture - Propagation Lab	B4G036	5850 x 4850	2700

**Table-2: Change Log**

Date	Name	Revision	Section	Change/Comment
29-10-2015	Nihit Singhal	00	-	New document

**Table-3: Annexure**

Not applicable

