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email : ksdpltd@gmail.com Website : www.ksdpltd.com fax : 0477-258162 : 0477-258262

### **Supplier's Copy**

## USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	LVP (BFS) packing
Equipment and Code No.	:	Visual Inspection Conveyor – 4 operators  For 500 and 100 ml /PE PP IV flexible bottles (BFS) (Manual Inspection – After leak test )
Scope	:	Supply, Installation and commission of this machine for 500 & 100 ml filled bottles, at site of M/s. KSDPL-Kerala for LVP packing section at ground floor.
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.	i	1 No.



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# VISUAL INSPECTION CONVEYOR (MANUAL INSPECTION)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION					
(To be specified by the supplier, if any variation)					
Machine	:	Visual Inspection Conveyor for manual inspection of 500 and 100 ml filled PE/PP IV flexible bottles of BFS			
Inspection Type	:	Manual Inspection against black & white board under light			
Model	:	GMP			
Output	•	500 ml : 60 to 65 bottles/min			
Output		100 ml : 100 to 110 bottles/min			
Bottle fill volume	•	500ml &100ml, (I.V. Bottle)			
Conveyor Belt Width	•	455mm			
Both Side Working Space	•	230mm			
No. of operators	:	4 nos. ( 2 x 2 at both side – 4 person)			
Working Height	•	900mm <u>+</u> 50mm (Adjustable)			
Inter-connection from Inlet	•	Inter connection from leak test machine to inspection conveyor should be included along with inter connection from inspection machine to labelling machine, excluding seating arrangement and with VFD *			
Utility connections	•	Any utility required to this machine will be connected by supplier from the point arranged by vendor at site.			





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ANNEXURE - II : CGMP FEATURES

DESCRIPTION				
( To be specified by the supplier, if any variation)				
	:	Visible Parts /Non-contact : SS 304		
	:	Contact part : SS 316		
MOC		SS sheet thickness : 16 swg		
		Any MS parts : SS 304 16 swg cladded		
		Conveyor Belt : Endless Nylon Rubberized Sandwich		
		Belt*		
Finish	:	External : Matt Finish*		
The equipment should besmooth finished without any sharp edges and crevices. *				





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#### ANNEXURE - III : OPERATIONAL FEATURES

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

#### The machine to include:

- > SS 304 hood for internal lighting with black and white stations.
- ➤ Guide provision for transferring of bottles into initial 2 tracks and final 3<sup>rd</sup> track for conveying the tested products.
- > Hard chrome roller with self-aligned bearings.
- Bowl for dust cap at both side of the conveyor
- > Tension mechanism for adjusting the belt tension.
- > AC variable drive fitted in the control panel below the conveyor
- Emergency stop
- > VFD

### Operation of the Machine

- Manual loading of the bottles onto the conveyor.
- > Bottles to be automatically bifurcated into two adjoining tracks with the help of guide
- > Operators to pick the bottles from two side tracks and to visually inspect the bottles with the help of black and white booth with tube light on conveyor for any breakage, leakage, proper volume filled and sealed and any strange particles in filled bottles.
- > After inspection the bottles to be placed in central track for further operation.

### \* To be specified by the end user





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#### ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION				
( To be specified by the supplier, if any variation)				
Standard Operating Frequency		50 Hz		
Standard Operating Voltage	:	230 V single phase *		
Motorrating	•	0.75 to 1 HP		
VFD details	•	*		
Major Cabling details				
Cable size required for input of	:	*		
machine as per connected load				
Starter details (if provided)	:	Star/Delta		
Earthing requirement	:	To be provided with machine by vendor		
An Isolator Circuit breaker	:	To be supplied with machine at power supply in		
All Isolator Circuit breaker		point of appropriate capacity by vendor. *		
Cables and connection from machine panel, or switch or starter should be in scope of				
vendors, client will arrange only incoming cable to this machine's panel or up to starter *				
Any other detail not mentioned above, but required for operation of machine should be				
included in scope of supply				





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ANNEXURE - V : PHYSICAL DETAILS

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Dimension (In mm)	•	*		
Net Weight (In Kgs.)	•	*		
Type of Packing	•	*		
Case Dimension (In mm)	•	*		
Gross Weight (In Kgs.)	•	*		
Foundation details if required	•	*		





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ANNEXURE - VI

LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

### Vendors should provide the following with estimate

- > Recommended Spares list
- > List of Bought out components if any.
- > Any other ancillary or accessories required
- > Optional items -if any
- > Any other items which is required but not mentioned should be informed.
- All items that is required for successful commission and working of machine should be included in scope of supply. \*
- \* To be specified by the supplier





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### ANNEXURE - VII : DOCUMENTATION

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment	2 sets	
	catalogues		
16	DQ, IQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC,	2 sets	
	transmitters, indicators etc.		
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine	2 sets	
	control / monitoring system.		

<sup>\*</sup> To be specified by the supplier





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#### ANNEXURE - VIII : TERMS AND CONDITIONS

Delivery Period	•	As per tender		
Payment Terms	:	As per tender		
Packaging and Forwarding	:	As per tender		
GST	:	As per actuals		
Unloading and placing of machine at particular position at site	=	By vendor or to be arranged by the vendor at site		
Installation and Commissioning	:	By vendor		
Submission of documents and drawings	i			
Response to URS and submission of quotation	:	As per tender		
Submission of detail functional design specification and schematic drawings	÷	Within a week after order finalization		
Submission of FAT / SAT specification	:	2 weeks before FAT		
Submission of IQ AND OQ documents	:	With equipment delivery		
Drawings / diagrams	:	Within one week of receiving PO		
The supplier should notify customer 2 weeks in	adva	ance of the beginning of FAT		
Catalogue, Equipment drawing, List of clients and year of establishment to be submitted along with technical bid.				
Any other terms, not mentioned above, also to be specified.				





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### ANNEXURE -IX : ABBREVIATION

1.	URS	:	User Requirement Specification.	
2.	KSDPL	:	Kerala State Drugs & Pharmaceuticals Ltd.	
3.	DQ	:	Design Qualification	
4.	IQ	:	Installation Qualification	
5.	OQ	:	Operational Qualification	
6.	PQ	:	Performance Qualification	
7.	SS	:	Stainless Steel	
8.	RHS	:	Right Hand Side	
9.	MOC	:	Material of Construction	
10.	KW	:	Kilo Watt	
11.	HP	:	Horse Power	
12.	RPM	:	Rotation Per Minute	
13.	FLP	:	Flame Proof	
14.	cGMP	:	Current GoodsManufacturing Practices	
15.	O&M	:	Operation and Maintenance	
16.	GA	:	General Arrangement	
17.	SLD	:	Single Line Diagram	
18.	HOD	:	Head of Department	
19.	QA	:	Quality Analysis	
20.	MRP	:	Maximum Retail Price	
21.	NMT	:	Not more than	
22.	VFD	:	Variable frequency drive	

Any other details, not mentioned in Annexure I to VIII, to be specified in the quotation/specification by the vendor.



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### Supplier's Copy

## **USER REQUIREMENT SPECIFICATION**

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	LVP (BFS) Packing
Equipment and Code No.	:	Automatic Horizontal (Top) Sticker Labeling Machine for 500 and 100 ml PE/PP (IV - flexible bottles) with TIJ printer & accessories
Scope	:	Supply, Installation and commission of labelling machine with TIJ printer for 500 ml PE /PP IV flexible bottles along with change parts of 100 ml bottles, at site of M/s. KSDPL-Kerala for LVP packing section at ground floor.
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.	:	1 no.



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# AUTOMATIC HORIZONTAL (TOP) STICKER LABELING MACHINE FOR IV FLEXIBLE BOTTLES OF 500 & 100 ML

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Machine	:	Automatic Horizontal top Sticker Labeling Machine for PE/PP flexible bottles of IV		
Bottle fill volume	:	500ml and 100ml, (I.V. Bottle)		
Output Speed	:	500 ml : 60 to 65 bottles/min 100 ml : 100 to 110 bottles/min		
Label Size	:	For 500 ml bottles : L x B 5.5x7.0 cm and 5.0x5.0 cm For 100 ml : 3.5x5.7 cm		
		Label roll diameter: Maximum OD 280 to 300 mm And ID: 76 mm		
Maximum Label size in this machine	:	Vendor to specify their standard		
Working Height	:	875 <u>+</u> 5mm adjustable		
Inter-connection with Inspection machine	•	Inter-connection should be provide from inspection machine to this labelling machine		
TIJ printer	:	Printer with accessories to print on white background paper labels, without varnish and lamination for printing ,lot no, Mfg. date , expiry date, MRP etc.		
Room height	:	2.4 mt false ceiling height		





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ANNEXURE - II : CGMP FEATURES

DESCRIPTION				
( To be specified by the supplier, if any variation)				
	:	Visible Parts : SS 304		
	:	Belt : Endless Nylon Rubberized Sandwich Belt		
MOC	:	Conveyor Belt : Single track SS Slat		
		Safety Guards: SS 304		
		SS sheet thickness : 16 SWG		
		All MS parts should be cladded with SS 304 sheet of		
		16 swg		
Finish	:	Matt		
The equipment should be smooth finished without any sharp edges and crevices *				





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#### ANNEXURE - III : PROCESS CONTROL FEATURES

DESCRIPTION				
( To be specified by the supplier, if any variation)				
Variation in speed of the machine : By VFD		By VFD		
Machine Operation Control	:	By Programmable Logic Controller (PLC)		
Machine Operational Interface	:	By Pre-programmed HMI screen with function keys.		
Control Panel	:	In built Control Panel to be provided with isolator		

#### The machine should include:

- ➤ No Product No Labeling
- > Sensor to sense the product
- Over current / temperature protection
- > Labeling dispensing speed to be set digitally through HMI.
- > Motor unlock facility changing the label roll.
- > Total counter facility with password protected reset button.
- Multiple program facility\*
- ➤ Label break/roll end/missing label (02 label) Machine stop. HMI to display the same\*

	:	Any utility required to this machine will be
Utility connections		connected by supplier from the point arranged
		by vendor at site.





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#### ANNEXURE - IV : OPERATIONAL FEATURES

#### **Operational Features**

- > Products coming from onward conveyor of inspection machine to be loaded in horizontal position manually to the labeling machine conveyor.
- > Speed of the conveyor to be synchronized with the help of PLC.
- > Label roll to be fitted on the roll disc and guided by guide rolls.
- Label dispenser to be fixed on top of the conveyor. \*
- Product sensor to sense the product, PLC to command the label dispensing motor to rotate at desired revolution which is to be controlled by label gap sensor which will sense the gap between two labels and accordingly label will be released from the dispenser and applied on the product.
- > Labels to be pasted on the product with the help of nylon brush and sponge roller.
- > Labeled products shall then proceed for further operation and to be collected manually on SS table ( Table to be arranged by client)





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### ANNEXURE - V : ELECTRICAL DETAILS

DESCRIPTION			
( To be specified by the supplier, if any variation)			
Standard Operating Frequency	:	50 Hz	
Standard Operating Voltage	:	230 single phase	
Electrical load	:	1 to 1.25 kw	
AC drive details	:	*	
PLC/HMI details	:	*	
VFD Details	:	*	
Major Cabling details			
Cable size required for input of	:	*	
machine as per connected load			
Starter details (if provided)	:	Star/Delta	
Earthing requirement	:	To be provided with machine by vendor	
An Isolator Circuit breaker	:	To be supplied with machine at power supply in	
All Isolator Circuit breaker		point of appropriate capacity by vendor. *	
Cables and connection from machine panel, or switch or starter should be in scope of			
vendors, client will arrange only incoming cable to this machine's panel. *			





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#### ANNEXURE - VI : SAFETY FEATURES

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

Safety of machine operation is of utmost importance.

To ensure safety, all guards to be fitted with interlock switches.

The machine to be provided with motor overload safety relay.

In the event of machine malfunction or stoppage of utilities, the unit must contain all necessary protection devices to ensure that machine and product remain in safe condition.

Machine settings should not get disturbed due to power failure. Machine should not restart without human intervention.

Machine should indicate fault through audio / visual signal with details on Control panel/PLC (Failure mode detection)

An easily accessible emergency stop to be provided on main control panel door. \*

Lubricant should not come in product contact. \*

Wherever possible, warning symbols should be provided.

Electrical wiring must be concealed





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ANNEXURE - VII : CLEANING TECHNIQUE

DESCRIPTION			
( To be specified by the supplier, if any variation)			
Mode of machine cleaning	:	*	
Use of Lubricants	:	*	
All contact parts should be easily dismantled and cleanable.			
Easy washing and cleaning facility should be available.			





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ANNEXURE - VIII : PHYSICAL DETAILS

DESCRIPTION		
(To be specifie	d by t	he supplier, if any variation)
Dimension (In mm)	:	*
Net Weight (In Kgs.)	•	*
Type of Packing	:	*
Case Dimension (In mm)	•	*
Gross Weight (In Kgs.)	:	*
Foundation details if required	•	*





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ANNEXURE - IX : LIST OF ANGILLARY / ACCESSORIES / OPTIONAL ITEMS

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

### Vendors should provide the following with estimate

- > Recommended Spares list
- List of Bought out components if any.
- > Any other ancillary or accessories required
- Optional items -if any
- > Any other items which is required but not mentioned should be informed.

All items that is required for successful commission and working of machine should be included in scope of supply. \*





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ANNEXURE - X : TRAINING REQUIREMENT

Training to all concern of KSDPL, Kerala for Installation, Operation, Maintenance and Cleaning of Automatic Horizontal Sticker Labeling Machine should be provided by vendor and training record will be documented.



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### ANNEXURE - XI : DOCUMENTATION

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment catalogues	2 sets	
16	DQ, IQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC,	2 sets	
	transmitters, indicators etc.		
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	



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### ANNEXURE - XII : TERMS AND CONDITIONS

Delivery Period	:	As per tender				
Payment Terms	:	As per tender				
Packaging and Forwarding	:	As per tender				
GST	:	As per actuals				
Unloading and placing of machine at	:	By vendor or to be arranged by the				
particular position at site		vendor at site				
Installation and Commissioning	:	By vendor				
Submission of documents and drawings						
Response to URS and submission of quotation	:	Within 1 week				
Submission of detail functional design	:	Within a week after order finalization				
specification and schematic drawings						
Submission of FAT / SAT specification	:	2 weeks before FAT				
Submission of IQ AND OQ documents	:	With equipment delivery				
Drawings / diagrams : Within one week of receiving PO						
The supplier should notify customer 2 weeks in advance of the beginning of FAT						
Catalogue, Equipment drawing, List of clients and year of establishment to be submitted alongwith technical bid						
Any other terms, not mentioned above, also to be specified.						

### \* To be specified by the supplier



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### ANNEXURE - XIII : ABBREVIATION

1.	URS	:	User Requirement Specification.	
2.	KSDPL	:	Kerala State Drugs & Pharmaceuticals Ltd.	
3.	DQ	:	Design Qualification	
4.	IQ	:	Installation Qualification	
5.	OQ	:	Operational Qualification	
6.	PQ	:	Performance Qualification	
7.	SS	:	Stainless Steel	
8.	RHS	:	Right Hand Side	
9.	MOC	:	Material of Construction	
10.	KW	:	Kilo Watt	
11.	HP	:	Horse Power	
12.	RPM	:	Rotation Per Minute	
13.	FLP	:	Flame Proof	
14.	cGMP	:	Current Goods Manufacturing Practices	
15.	O&M	:	Operation and Maintenance	
16.	GA	:	General Arrangement	
17.	SLD	:	Single Line Diagram	
18.	HOD	:	Head of Department	
19.	QA	:	Quality Analysis	
20.	MRP	:	Maximum Retail Price	
21.	NMT	:	Not more than	
22.	VFD	:	Variable frequency drive	

Any other details, not mentioned in Annexure I to XII, to be specified in the quotation/specification by the vendor.



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### Supplier's Copy

## USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	LVP (BFS) Packing (Ground Floor)
Equipment and Code No.	:	SS 304 Packing Conveyor
		(After labelling of IV flexible bottle) Length: 7 feet long
Scope	:	Supply, Installation and commission of packing conveyor for 500 and 100 ml PE /PP IV flexible bottles, at site of M/s. KSDPL-Kerala for LVP packing section at ground floor.
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.	:	1 no.

**CONSULTANT: M/S. KNACK TECHNOCRATS** 

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### PACKING CONVEYOR

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

<b>DESCRIPTION</b> (To be specified by the supplier, if any variation)			
Machine	<b></b>	Packing Conveyor Belt  (To be connected after labelling machine)	
Model	:	GMP	
Conveyor Length	:	7 feet long (2100 mm)	
Conveyor Width	:	300 mm	
Type of Belt	•	Endless belt	
Speed		Variable speed (VFD)	
Operating height	:	875 mm ( <u>+</u> 50 mm )	
Stand with wheel	:	With castor wheel to remove when not in use.	
Qty.	:	1 no.	

\* To be specified by the supplier

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ANNEXURE - II : CGMP FEATURES

DESCRIPTION					
(To be specified by the supplier, if any variation)					
МОС					
Main Body And Top Plate	:	SS 304			
Pipe Structure & Platform	:	SS 304			
Conveyor Side Channel	:	SS 304 sheet of 16 swg			
Conveyor material	•	Endless Nylon rubberized sandwich belt			
General Nut & Bolts	:	SS 304			
Working Area Environment	:	Classified area			
Finish for side tables		Matt Finish *			
The equipment should be smooth finished without any sharp edges and crevices					

### \* To be specified by the supplier



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#### ANNEXURE - III : OPERATIONAL FEATURES

DESCRIPTION				
( To be specified	( To be specified by the supplier, if any variation)			
Features				
Adjustable bolt to be provided for belt	tighte	ning		
Adjustable height of conveyor belt, to align with other machine.				
Specially designed hard chrome roller with self-aligned bearing				
Tension mechanism for adjusting the belt tension				
Stopper arrangement at the end of conveyor				
Utility connections	:	Any utility required to this machine will be connected by supplier from the point arranged by vendor at site.		

\* To be specified by the supplier



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#### ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Standard Operating Frequency	:	50 Hz		
Standard Operating Voltage	:	230 V		
VFD	:	*		
Motor Details	:	AC variable drive		
Gear Box Details	:	*		
VFD Details	:	*		
Starter	:	DOL		
Major Cabling details				
Cable size required for input of	:	*		
machine as per connected load				
Starter details (if provided)	:	Star/Delta		
Earthing requirement	:	To be provided with machine by vendor		
An Isolator Circuit breaker	:	To be supplied with machine at power supply in		
All Isolator Circuit breaker		point of appropriate capacity by vendor. *		
Cables and connection from machine panel, or switch or starter should be in scope of				
vendors, client will arrange only incoming cable to this machine's panel. *				

\* To be specified by the supplier



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ANNEXURE - V : PHYSICAL DETAILS

DESCRIPTION			
(To be specified by the supplier, if any variation)			
Dimension (In mm)		*	
Floor Space		*	
Net Weight (In Kgs.)	•	*	
Type of Packing	:	*	
Case Dimension (In mm)	:	*	
Gross Weight (In Kgs.)	:	*	
Foundation Details (If required)	•	*	

<sup>\*</sup> To be specified by the supplier



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ANNEXURE - VI : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

### Vendors should provide the following with estimate

- > Recommended Spares list
- > List of Bought out components if any.
- > Any other ancillary or accessories required
- > Optional items -if any
- > Any other items which is required but not mentioned should be informed.

All items that is required for successful commission and working of machine should be included in scope of supply.



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ANNEXURE - VII : DOCUMENTATION

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment catalogues	2 sets	
16	IQ, OQ, DQ and PQ documents.	2 sets	
	1		



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#### ANNEXURE - VIII : TERMS AND CONDITIONS

Delivery Period	:	As per tender
Payment Terms	:	As per tender
Packaging and Forwarding	:	As per tender
GST	:	As per actuals
Unloading and placing of machine at particular position at site	:	By vendor or to be arranged by the vendor at site
Installation and Commissioning	:	By vendor
Submission of documents and drawings	<b></b>	
Response to URS and submission of quotation	:	Within 1 week
Submission of detail functional design specification and schematic drawings	:	Within a week after order finalization
Submission of FAT/SAT specification	:	2 weeks before FAT
Submission of DQ, IQ, OQ, PQ documents	:	With equipment delivery
Final Drawings / Diagrams	:	Within one week of receiving purchase order
The supplier should notify the end user 2 week	s in a	advance of the beginning of FAT
Catalogue, Equipment drawing, List of clients a alongwith technical bid.	ınd y	ear of establishment to be submitted
Any other terms, not mentioned above, also to	be s	pecified.

### \* To be specified by the supplier



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#### ANNEXURE - IX : ABBREVIATION

1.	URS	:	User Requirement Specification.
2.	KSDPL	:	Kerala State Drugs & Pharmaceuticals Ltd.
3.	DQ	:	Design Qualification
4.	IQ	:	Installation Qualification
5.	OQ	:	Operational Qualification
6.	PQ	:	Performance Qualification
7.	SS	:	Stainless Steel
8.	RHS	:	Right Hand Side
9.	MOC	:	Material of Construction
10.	KW	:	Kilo Watt
11.	HP	:	Horse Power
12.	RPM	:	Rotation Per Minute
13.	FLP	:	Flame Proof
14.	cGMP	:	Current Goods Manufacturing Practices
15.	O&M	:	Operation and Maintenance
16.	GA	:	General Arrangement
17.	SLD	:	Single Line Diagram
18.	HOD	:	Head of Department
19.	QA	:	Quality Analysis
20.	NMT	:	Not more than
21.	VFD	:	Variable frequency drive

Any other details, not mentioned in Annexure I to VIII, to be specified in the quotation/specification by the vendor.

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### **Supplier's Copy**

## **USER REQUIREMENT SPECIFICATION**

Name of the Company	i	
Contact Person	•	
Address	:	
Contact Details	:	
Department	:	LVP (BFS- Packing)
Equipment and Code No.	:	Pressure Leak Check Machine (Leak Test Machine) for flexible IV bottles of 500 and 100 ml fill volume
Scope	:	Supply, Installation and commission of this machine for 500 ml bottles along with change parts of 100 ml bottles, at site of M/s. KSDPL-Kerala for LVP packing section at ground floor.
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.	•	1 No.



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### PRESSURE LEAK CHECK MACHINE (FOR IV BOTTLES)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION			
(To be specifie	d by th	ne supplier, if any variation)	
Machine	:	Pressure Leak Check Machine for PE/PP flexible IV bottles after autoclaving	
Model	•	*	
Bottle fill volume	:	500 ml and 100ml, ( flexible IV Bottle)	
Output	:	For 500 ml :60 to 65 bottles/min For 100 ml : 100 to 110 bottles/min	
Conveyor Belt Width	:	80 to 100 mm *	
Both Side Working Space	:	About 7" *	
Working height	:	950 mm <u>+</u> 50 mm *	
Scope	:	Supply , installation and commission of this machine at packing of LVP section (ground floor) of M/s. KSDPL including interconnection arrangement of this machine to inspection machine	
Utility connections	:	Any utility required to this machine will be connected by supplier from the point arranged by vendor at site.	
Room height	:	2.4 mt (false ceiling height)	

\* To be specified by the supplier



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ANNEXURE - II **CGMP FEATURES** 

DESCRIPTION				
(To be	spe	cified by the supplier, if any variation)		
	:	Visible Parts : SS 304		
	:	Contact part : SS 316		
MOC	:	Belt : Endless Nylon Rubberized Sandwich Belt		
		Conveyor Belt : Single track SS Slat		
		Safety Guards: SS 304		
SS sheet thickness : 16 SWG		SS sheet thickness : 16 SWG		
		All MS parts should be cladded with SS 304 sheet of 16 swg		
Finish	:	Matt Finish *		
The equipment should be smooth finished without any sharp edges and crevices*				

\* To be specified by the supplier





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#### ANNEXURE-III : OPERATIONAL FEATURES

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

#### The machine to include:

- > Moving parts of the machine to be covered with SS safety guards of 16 swg\*
- Single track SS slat conveyor
- Conveying system to convey the product with easy adjustable side guide.
- > Star plate and rotary plate (partially) covered with acrylic cover.
- > Back side mirror for leak check of bottle's bottom.
- Pressure alignment level for different size of bottles (500 and 100 ml)
- > Star plate to lift the bottle.
- > Star plate and rotary plate
- Adjustable pressure rod.
- Collection tray at the bottom, for collecting liquid from leaked bottles.
- Drive motor and gear mechanism
- Any other parts which is required but not mentioned here. \*

#### Operation of the Machine

- > Bottles to be loaded manually to the conveyor.
- > Bottles to move on conveyor and at the end of conveyor bottles to be lifted up with the help of star plate.
- > Through the star plate bottle to move on rotary plate with pressure rod where the operator can check for leakages in bottles with the mean of pressure.
- Operators to remove the leaked bottles manually.
- After process of leak testing the bottles to be transferred to Inspection machine.
  Required inter-connection should be included in supply. \*

#### \* To be specified by the supplier





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ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Standard Operating Frequency	:	50 Hz		
Standard Operating Voltage	:	415V , 3 phase		
Motor Connected load	:	1 to 1.5 kw		
Gear Box Details	:	*		
VFD Details		*		
Major Cabling details				
Cable size required for input of	:	*		
machine as per connected load				
Starter details (if provided)	:	Star/Delta		
Earthing requirement	:	To be provided with machine by vendor		
		To be supplied with machine at power supply in		
An Isolator Circuit breaker		point of appropriate capacity by vendor. *		
Cables and connection from machine panel, or switch or starter should be in scope of				
vendors, client will arrange only incoming cable to this machine's panel. *				
Any other detail not mentioned above, also to be included.				





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ANNEXURE - V : PHYSICAL DETAILS

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Dimension (In mm)	:	*		
Floor Space	:	*		
Net Weight (In Kgs.)	<b>:</b>	*		
Type of Packing	•	*		
Case Dimension (In mm)	•	*		
Gross Weight (In Kgs.)	:	*		
Foundation Details (If required)	•	*		





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ANNEXURE - VI : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

#### **DESCRIPTION**

( To be specified by the supplier, if any variation)

### Vendors should provide the following with estimate

- > Recommended Spares list
- List of Bought out components if any.
- > Any other ancillary or accessories required
- Optional items –if any
- > Any other items which is required but not mentioned should be informed.

All items that is required for successful commission and working of machine should be included in scope of supply. \*





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ANNEXURE - VII TRAINING REQUIREMENT

Training to all concern of KSDPL, Kerala for Installation, Operation, Maintenance and Cleaning of Pressure leak check Machine should be provided by vendor and training record will be documented.



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ANNEXURE - VIII **DOCUMENTATION** 

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment	2 sets	
	catalogues		
16	IQ, OQ, DQ and PQ documents.	2 sets	



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#### ANNEXURE - IX : TERMS AND CONDITIONS

Delivery Period	:	As per tender			
Payment Terms	:	As per tender			
Packaging and Forwarding	:	As per tender			
GST	:	As per actuals			
Unloading and placing of machine at particular position at site	:	By vendor or to be arranged by the vendor at site			
Installation and Commissioning	:	By vendor			
Submission of documents and drawings					
Response to URS and submission of quotation	:	Within 1 week			
Submission of detail functional design specification and schematic drawings	:	Within a week after order finalization			
Submission of FAT/SAT specification	:	2 weeks before FAT			
Submission of DQ, IQ, OQ, PQ documents	•	With equipment delivery			
Drawings / Diagrams	:	Within one week of receiving PO			
The supplier should notify the end user 2 weeks in advance of the beginning of FAT					
Catalogue, Equipment drawing, List of clients and year of establishment to be submitted alongwith technical bid.					
Any other terms, not mentioned above, also to be specified.					

### \* To be specified by the supplier



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#### ANNEXURE - X : **ABBREVIATION**

1.	URS	:	User Requirement Specification.
2.	KSDPL	•	Kerala State Drugs & Pharmaceuticals Ltd.
3.	DQ		Design Qualification
		:	
4.	IQ	:	Installation Qualification
5.	OQ	:	Operational Qualification
6.	PQ	:	Performance Qualification
7.	SS	:	Stainless Steel
8.	RHS	:	Right Hand Side
9.	MOC	:	Material of Construction
10.	KW	:	Kilo Watt
11.	HP	:	Horse Power
12.	RPM	:	Rotation Per Minute
13.	FLP	:	Flame Proof
14.	cGMP	:	Current Goods Manufacturing Practices
15.	O&M	:	Operation and Maintenance
16.	GA	:	General Arrangement
17.	SLD	:	Single Line Diagram
18.	HOD	:	Head of Department
19.	QA	:	Quality Analysis
20.	NMT	:	Not more than
21.	VFD	:	Variable frequency drive
	_i		<u> </u>

Any other details, not mentioned in Annexure I to VIII, to be specified in the quotation/specification by the vendor.



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