Lifelong MEDITECH PVT. LTD.

ANNEXURE – 01
REFERENCE: MPR/QA/001
TEMPLATE FOR SPECIFICATION

FINISHED PRODUCT SPECIFICATION			
PRODUCT NAME : NON-STERILE HYPODERMIC SYRINGES FOR SINGLE USE (BULK PACK)			
SPECIFICATION NO.	REVISION NO.	EFEECTIVE DATE	PAGE NO.
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S. No.	PARAMETER	SPECIFICATION			REFERENCE
1	Extraneous Matter (Cleanliness)	When inspected by normal vision or corrected to-normal vision, without magnification, the surface of syringe which comes into contact of the injection fluid during normal use, should be free from particles and extraneous matter.			ISO 7886-1
2	Limits for Acidity or Alkalinity	The pH value of an extract prepared with the Syringes should be within ±1 unit of that of control fluid.			ISO 7886-1
3	Limits for Extractable Metals	In extract of syringes the combined amount of lead, tin, zinc & iron should not be greater than 5mg/Kg and 0.1mg/kg of cadmium.			ISO 7886-1
4	Lubricant	The lubricant should not be reach the Luer channel of the Nozzle & it should be optimized to minimize the visibility. The amount of lubricant should not be exceeded 0.25mg/cm^2.			ISO 7886-1
5	Tolerance on graduated capacity	**Capacity less than half of nominal capacity (ml)**			ISO 7886-1
		Size	**Volume tested**	**Tolerance**	
		2 ml	0.5	0.460-0.540	
		3 ml	1	0.935-1.065	
		5 ml	2	1.905-2.095	
		10 ml	2	1.830-2.170	
		20 ml	5	4.650-5.350	
		30 ml	10	9.450-10.550	
		50 ml	10	9.150-10.850	
		60 ml	20	18.900-21.100	

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ASSISTANT MANAGER QA	ASSISTANT MANAGER QC	AGM QUALITY

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		Capacity greater than half of nominal capacity (ml)			ISO 7886-1
		Size	Volume tested	Tolerance	
		2 ml	1.5	1.425-1.575	
		3 ml	2	1.900-2.100	
		5 ml	4	3.840-4.160	
		10 ml	8	7.680-8.320	
		20 ml	15	14.400-15.600	
		30 ml	20	19.200-20.800	
		50 ml	40	38.400-41.600	
		60 ml	50	48.000-52.000	
		Nominal Capacity			
		Size	Minimum (mL)	Maximum (mL)	
		2 ml	1.900	2.100	
		3 ml	2.850	3.150	
		5 ml	4.800	5.200	
		10 ml	9.600	10.400	
		20 ml	19.200	20.800	
		30 ml	28.800	31.200	
		50 ml	48.000	52.000	
		60 ml	57.600	62.400	
6	Dead Space	Nominal capacity of syringe		Maximum dead space	ISO 7886-1
		2 ml		0.07 ml	
		3 ml		0.07 ml	
		5 ml		0.07 ml	

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		10 ml	0.10 ml		
		20 ml	0.15 ml		
		30 ml	0.17 ml		
		50 ml	0.20 ml		
		60 ml	0.20 ml		
7	Graduated Scale	The graduation lines should be uniform thickness, at right angles to the axis of barrel, they evenly spaced, similar length vertically beneath each other and approx. half (length) of long graduation lines.			ISO 7886-1
8	Scale Numbering	The scale should be numbered at minimum increment given in the table (At least or can be less {finer})			ISO 7886-1
		Nominal capacity of syringe, V	Scale Interval	Increment between graduation lines	
		2 ml	0.2 ml	1.0 ml	
		3 ml	0.2 ml	1.0 ml	
		5 ml	0.5 ml	1.0 ml	
		10 ml	1.0 ml	5.0 ml	
		20 ml	2.0 ml	10.0 ml	
		30 ml	2.0 ml	10.0 ml	
		50 ml	5.0 ml	10.0 ml	
		60 ml	5.0 ml	10.0 ml	
9	Scale Length up to Nominal Capacity	**Nominal Capacity**	**Minimum scale length**		ISO 7886-1
		2 ml	27 mm		
		3 ml	27 mm		
		5 ml	36 mm		

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		10 ml	44 mm	
		20 ml	52 mm	
		30 ml	67 mm	
		50 ml	75 mm	
		60 ml	75 mm	
10	Scale position	When plunger fully inserted, The zero graduation line should coincide with the fiducial line on the piston to achieve the graduated capacity tolerance.		ISO 7886-1
11	Barrel Dimensions	The length of barrel should be such that the syringe has a maximum usable capacity of at least 10% more than the nominal capacity.		ISO 7886-1
12	Barrel Flanges	The syringe should not roll more than 180° on a flat surface at an angle of 10° to horizontal; the flange should be adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use, free from flash & sharp edges.		ISO 7886-1
13	Plunger stopper/ Plunger Assembly (Design)	The design of the plunger and push button of the syringe should be such that, when the barrel held in one hand, the plunger can be depressed by the thumb of that hand. And when the Fiducial line coincides with zero graduation lines, the minimum length of the plunger from surface of the barrel flanges nearer to push button shall be at least 8mm		ISO 7886-1
14	Nozzle conical Fitting	Should be 6% taper and conical fitting of hypodermic syringe nozzle shall meet the requirements of ISO 80369-7 as describe in S. No. 22, 23, 24, 25, 26 & 27.		ISO 7886-1, ISO 80369-7

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15	Nozzle Position	Nominal capacity of syringe	Nozzle position		ISO 7886-1
		2ml to 3ml	Should be centrally		
		5 ml and more than 5 ml	Either centrally or eccentrically		
		If the nozzle is eccentric than the distance between the axis of nozzle and nearest point on the internal surface of bore of the barrel should not greater than 4.5 mm			
16	Nozzle lumen	Inner diameter of nozzle lumen should not be less than 1.2 mm			ISO 7886-1
17	Freedom from liquid leakage past piston	There should be no leakage past piston, when a pressure applied as per below table at the plunger of filled syringe up to 30s to 35s.			ISO 7886-1
		Nominal Capacity of syringe	Forces for leakage testing		
			Side Forces (±5%)	Axial Pressure (±5%)	
		2 ml	1.0Newton	300kPa	
		3 ml	1.0Newton	300kPa	
		5 ml	2.0Newton	300kPa	
		10 ml	2.0Newton	300kPa	
		20 ml	3.0Newton	200kPa	
		30 ml	3.0Newton	200kPa	
		50 ml	3.0Newton	200kPa	
		60 ml	3.0Newton	200kPa	
18	Freedom from air past piston (Aspiration test)	Should be no leakage at -88kPa up to 60s and plunger stopper should not be detached from plunger.			ISO 7886-1

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19	Force to operate the piston	The syringe should be complies with force to operate the piston as per below:			ISO 7886-1
		Syringe Volume V	Initial forces Maximum (F_S)	Mean forces Maximum (F)	Max. Force (F_{max})
		V<2 ml	10N	5N	< (2.0X measured F) or measured F+1.5N), whichever is higher
		2≤V<50ml	25N	10N	
		50≤V ml	30N	15N	
20	Fit of plunger stopper/plunger in barrel	When the syringe is filled with water and held vertically with first one end and then the other end uppermost, the plunger should not move by reason of its own mass and the water contained.			ISO 7886-1
21	Fluid Leakage by positive pressure method	Should be no sign of leakage sufficient to form a falling drop of water from Luer connectors over a hold period 30s to 35s while being applied pressure between 300 to 330kpa			ISO 80369-7
22	Sub-atmospheric pressure Air Leakage	Luer connectors shall not leak by more than 0.005Pa.m^3/s, while being applied sub-atmospheric pressure between 80 to 88kpa, over a hold period between 15s to 20s			ISO 80369-7
23	Stress Cracking	Luer connectors shall be evaluated for stress cracking and shall meet the requirements of fluid leakage as describe in S. No. 22.			ISO 80369-7

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24	Resistance to Separation from axial load	Luer connector shall not separate from reference connector, over a hold period between 10s for Luer Slip and 15s for Luer Lock, while being applied disconnection axial force between 23N to 25N for slip and 32N to 35N for Luer lock.	ISO 80369-7
25	Resistance to separation from Unscrewing (Luer Lock only)	Luer lock connectors shall not separate from reference connector for a hold period between 10s to 15s, while applied an unscrewing torque between 0.0198N.m to 0.0200N.m	ISO 80369-7
26	Resistance to overriding (Luer Lock only)	Luer lock connectors shall not override the threads or lugs of the reference connector, while applied torque between 0.15N.m to 0.17N.m for a hold period between 05s to 10s	ISO 80369-7
27	Bacterial Endotoxin test	Should pass the test	IP, USP & NF

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