


TECHNICAL DATA SHEET

Name	Oral Tip Low-Dose Syringe (Sterile)				
Product Code	OT01LD/OT25LD				
Shelf Life	5 Years				
Lot Number format	HMYyxxx (Y is for year, xxx is a sequential batch number)				
Expiry and Manufactured date format	yyyy/mm				
Appearance	General	All components (product, blister, and boxes) should be free of damage, no tears or holes.			
	Blister	Product is provided in a single blister pack.			
	Box	White shipping carton shall be free of any major damage.			
	Outer Carton	Shipping carton shall be free of any major damage.			
	Syringe	Foreign matter under 3000lx – 700lx Illuminance. Free from foreign particles and matters.			
		Syringe free from defects; fins, burrs, plastic flow and material shortage.			
		Syringe barrel shall be transparent to see fiducial line clearly. Syringe Barrel shall be legible with clear and even lines.			
		All print should be legible and clearly seen.			
	Piston	Plunger will be attached to black piston and shall be intact.			
Shall be free from blooming and foreign matters. The surface shall be free from cracks, cutting, damage and uneven surfaces.					
Labelling and Symbols	Label Information	Shall match the copies in artwork master file.			
	Symbols	Shall match the copies in artwork master file.			
Material Composition	Barrel & Plunger	Polypropylene.			
	Piston	Silicone			
	Lubricant	Silicone Oil.			
Packaging	Bag	Multiple package (see table below). QML (minimum delivery quantity): 1 Box			
		PRODUCT CODE	CAPACITY	BOX QUANTITY	CARTON QUANTITY
		OT01LD	1ml	100	2400
		OT25LD	2.5ml	100	2000
Biological	Sterility	Shall be sterile.			
Chemical Performance	pH Value	pH Value difference between extract and blank solution shall not exceed 1.0 pH <ul style="list-style-type: none"> Extract solution: Purified water + Sample. Blank Solution: Purified water. Note, the quantity of extract solution is based on the nominal capacity of the syringe.			
	Readily Oxidisable substance	The syringe extract solution and equal volume of blank solution to indirect titrations as per Standard GB/T14233.1, the amount of KM_nO_4 consumption shall not exceed 0.5ml.			
	IR Spectra	The spectra of the syringe materials correspond to the reference spectra.			
Physical Performance	Conical Fitting	No evident shaking or movement between standard gauge and conical fitting as per ISO 594.			

	Leakage	There shall be no air leakage when syringe is under negative pressure 88Kpa for 60s + 5s at the contacting position between barrel and piston. The piston will not detach from plunger.			
	Capacity Tolerance	Nominal capacity of syringe, V ml	Tolerance on graduated capacity		Maximum Dead Space ml
			Less than half nominal capacity	Equal to or greater than half nominal capacity	
		V < 2	±(1.5% of V + 2% of expelled volume)	± 5% of expelled Volume	0.07
		2 ≤ V < 5	±(1.5% of V + 2% of expelled volume)	± 5% of expelled Volume	0.07
		5 ≤ V < 10	±(1.5% of V + 1% of expelled volume)	± 4% of expelled Volume	0.075
		10 ≤ V < 20	±(1.5% of V + 1% of expelled volume)	± 4% of expelled Volume	0.10
		20 ≤ V < 30	±(1.5% of V + 1% of expelled volume)	± 4% of expelled Volume	0.15
30 ≤ V < 50	±(1.5% of V + 1% of expelled volume)	± 4% of expelled Volume	0.17		
50 ≤ V	±(1.5% of V + 1% of expelled volume)	± 4% of expelled Volume	0.20		
Sliding Performance	Nominal Capacity of syringe, V ml	Initial Force, Fs Max. N	Mean Force, F Max N	Maximum Force F Max N	Minimum Force, F min N
	V < 2	10	5	(2,0 measured) or (measured+1,5N), whichever is higher	(0,5 measured) or (measured-1,5N), whichever is the lower
	2 ≤ V < 50	25	10	(2,0 measured) or (measured +1,5N), whichever is higher	(0,5 measured) or (measured-1,5N), whichever is the lower
	50 ≤ V	30	15	(2,0 measured) or (measured +1,5N), whichever is higher	(0,5 measured) or (measured-1,5N), whichever is the lower
When syringe is filled with water up to its nominal capacity and kept vertically, the plunger shall not be moved by its own weight.					
Product Drawing					
*Representative Drawing					

Storage	Normal storage procedures and conditions (5°C - 35°C temperature < 80% RH)
Disposal	The user must follow the legal regulations regarding disposal of hospital waste.
Manufacturer	Medicina ltd Units 1-4 Rivington View Business park Station Road, Blackrod Bolton BL6 5BN UK
Classification	Class IIa Annex V & VII
Conformity Assessment Route:	MDD 93/42/EEC