MOLDOVA EUROPEANĂ

ALDARMED
Medical Supplies Factory

TECHNICAL DATA SHEET

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ITEM : 3 PARTS 10 ML SYRINGE with 21G x 1 ½" NEEDLE

DESCRIPTION : Sterile hypodermic syringe for single use that is made of plastic material, pyrogen free, non-toxic, sterilized with ethylene oxide and used for aspiration of liquids or used for injection of liquid after filled

PROPERTIES

PHYSICAL PROPERTIES	STANDARD (TEST METHOD)	UNITE	RESULT
Material	TS EN ISO 7886-1	–	Medical
Capacity	TS EN ISO 7886-1	ml	10 (± % 5)
Death Space	TS EN ISO 7886-1	ml	Max.0,1
Total graduated capacity	TS EN ISO 7886-1	ml	10 ml
Dimensions	TS EN ISO 7886-1	mm	Ø inside = 15,90 Ø outside = 16,70 └ barrel = 84,51 └ plunger = 75,55 └ plunger + gasket = 77,80
Air Leakage during aspiration	TS EN ISO 7886-1	kPa/sn	No leakage at 88 kPa vacuum at 60 second
Liquid leakage under compression	TS EN ISO 7886-1	kPa/sn	No leakage at 300 kPa pressure at 30 second
Conic fittings (centric)	TS 3521-1 EN 20594-1	%	6% (Luer)
Needle size	TS 4002 EN ISO 7864	mm	0.80 x 40
Needle penetration force	TS 4002 EN ISO 7864	N	0.58-0.68
Bond between needle and tube	TS 4002 EN ISO 7864	N	Does not broken by 44N
Cylinder-piston difference	TS EN ISO 7886-1 (Article 12)	mm	11 mm
Scale length	TS EN ISO 7886-1 (Article 10.3)	mm	50,50 mm
Scale interval	TS EN ISO 7886-1 (Article 10.2)	ml	0,5 ml
Increment between graduation lines to be numbered	TS EN ISO 7886-1 (Article 10.2)	ml	1 ml
Lubricant	TS EN ISO 7886-1	gr/cm^2	0,25 polydimethyl siloxane
Weight	AldarMed	gr	7,60-7,70
CHEMICAL PROPERTIES			
Neutrality	TS EN ISO 7886-1	pH	Difference less than 1
Pb, Zn, Sn, Fe	TS EN ISO 7886-1	mg/lt	Totally less than 5
Cd	TS EN ISO 7886-1	mg/lt	Less than 0,1
Ethylene oxide residue	TS 9897	mg/lt	Less than 5
BIOLOGICAL PROPERTIES			
Cytotoxicity	EN ISO 10993		Not cytotoxic
Toxicity	EN ISO 10993		Does not cause acute systemic toxicity
Pyrogenity	EN ISO 10993-11. European Pharmacopoeia 7th		Apyrogen
Sterility	EN ISO 556, TS 10409/October 1992		Sterile
Hemolytic effect	EN ISO 10993-11, TS 6459/January		Not hemolytical
Sensitization	EN ISO 10993-10/March 1998		No sensitivity
Irritation	EN ISO 10993-10/March 1998		No irritation effect
PACKAGING PROPERTIES AND HANDLING			
Primary Packing	TS EN ISO 7886-1	–	Transparent film + Blister Packing from medical grade paper and statements expressed in the standards
Secondary Packing	TS EN ISO 7886-1	–	innerand out surface testliner, flutting wave, offset printed box and statements expressed in the standards
Transport-Storage-Packing	AldarMed	–	8 inner boxes are put in outer boxes or wrapped container
Storage Condition	AldarMed	–	Kept out of direct sun light and stored in clean and dry storage areas at max. 45 °C

	PREPARED BY	APPROVED BY
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