

MEDTRUE ENTERPRISE CO., LTD

Certificate of Analysis

Commodity	three-way stopcock with extension tube	Sterile Date	24.03.30
Lot No.	231130	Lot QTY.	100000pcs
Mfg. date	2023.11.30	Exp. date	2028.11.29
Test Basis	ISO8536-9:2004	Report Date	2024.04.10
Test Items	Requirements		Result
Sterility	It should be sterile.		conformity
Pyrogen	There should be no pyrogen.		conformity
Reducing(oxidizable)matter	The total amount of potassium permanganate solution used[c(KMnO ₄ =0.002mol/L)] shall not exceed 2.0ml		---
Titration acidity or alkalinity	Not more than 1ml of either standard volumetric solution shall be required for the indicator to change to the colour grey		--
UV absorbency of extract solution	Absorbency of inspection solution should not exceed 0.1.		--
EO residua	EO residua of each set of Transfusion system should not be more than 4mg/pcs.		conformity
Transparency	Fill the fluid line with distilled water.Inspect visually whether the air-water interface is detectable.		conformity
Adapters with female/male conical fittings	The conical connection is tested for 15 min,using distilled water under internal excess pressure of 200KPa at (23 ± 1) °C and (40 ± 1) °C.Inspect it for any leakage of water		conformity
Leakage	Connect the accessory with its openings closed to a compressed air supply.Apply air with an internal excess pttessure of 20KPa at (23 ± 1) °C and(40 ± 1) °C to the accessory for 15min. Inspect the accessory for any leakage of air.		conformity
	Fill the set with degassed,distilled water,connect it with its openings sealed to a vacuum device and subiect it to an internal excess pressure of -20KPa at (23 ± 1) °C and(40 ± 1) °C for 15s.Inspect whether air enters the set.		conformity
	Fill the accessory with distilled water and apply an internal excess pressure of 200KPa at (23 ± 1) °C and(40 ± 1) °C for 15min .there shall be no leakage of air or water.		conformity
Breaking strength	All parts of a fluid line shall withstand a static tensile fore of at least 15N for 15s		conformity
Manipulation of stopcocks	Flow channsls can be opened and closed without any adverse effect on the functionality of adjacent components.		conformity
tubing	Length ≥ 500mm		505-511mm
Conclusion	conformity		

Examiner:

Checker:

