

AYSET

TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL
ELEKTRONİK GIDA TEMİZLİK MADDELERİ SAN. A.Ş.
SARİHAMZALI YOLU ÜZERİ NO:54 ADANA-TURKEY
TEL : +90-322-441 12 99 FAX : +90-322-441 12 98

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Document No : R.KK.10
Validity : 03.12.2001
Revision No : 01
Revision Date : 01.11.2002
Revision reason : DRF.KK02/051
Page No : 1/1

REPORT NO : R10030
LOT NO : 10030
PRODUCT NAME : VACUUM BLOOD COLLECTION TUBE
PRODUCT TYPE : 16X100 - EDTA 3KE 9ML
REFERENCE NO : 70699
REPORT DATE : 20.02.2023
STERILIZATION DATE : 2023-02
STERILIZATION DATE : 2024-08
LOT SIZE (N) : 30.000 Pcs.
SAMPLES : 100 Pcs.

PHYSICAL TESTS	STANDARDS	TEST METHOD	LIMITS	RESULTS
Material	EN 6710	EN 6710	Medical PET, gasket and (PE) tube cap	PET - PE
Cleanliness	EN 6710	EN 6710	Free from particles and extraneous matter	Free from particles and extraneous matter
Appearance	EN 6710	EN 6710	No sharp edge bulge and burr	Complied
Transparency	EN 6710	EN 6710	Transparent under UV light or daylight	Transparent
Nominal Liquid Capacity	EN 6710	T.KK. 95	Between 90% - 110% of nominal capacity	Complied
Scale and Filling Line	EN 6710	T.KK. 95	+/-%10 of filling line	Complied
Diameter and Length of Tube	AYSET	T.KK. 87	15,50(+/-0,3)X99,80(+/-0,3)mm	15,50 X 99,89mm
Diameter and Length of Cap	AYSET	T.KK. 87	18,50(+/-0,1)X19,75(+/-0,1)mm	18,52 X 19,72mm
Cap	EN 6710	T.KK. 96	No cap loose	No loose
Leakage	EN 6710	T.KK. 96	No leakage	No leakage
Resistance	EN 6710	T.KK. 84, T.KK. 95 VE T.KK. 96	No visual defect	No visual defect
Crack Test	AYSET	T.KK.111	No Crack	No Crack
Centrifuge	EN 6710	T.KK. 84	No error at 3000 rpm	No error
Additive Quantity	EN 6710	T.KK. 104	From 90% to 100%	Complied
Harmony Between Parts	EN 6710, AYSET	T.KK. 97	Compatible	Compatible
Label Information and Additive Letter Coding	EN 6710, AYSET	T.KK. 102	Complied with Table-1	Complied
Label Stickiness	EN 6710, AYSET	T.KK. 102	Label should stick fully and no peeling off	Complied
Vacuum Control	EN 6710, AYSET	T.KK. 103	Available vacuum according to the product type	Complied
BIOLOGICAL TESTS	STANDARDS	TEST METHOD	LIMITS	RESULTS
Sterility Test	EN ISO 11137-2	EN ISO 11137-2	Sterile (with radiation)	Sterile

REMARKS : Validation check before test is acceptable and results are within limits.

RESULT : Products are appropriate for delivery.

PHYSICAL - CHEMICAL TEST PREPARED BY	BIOLOGICAL TEST PREPARED BY	QUALITY CONTROL MANAGER	RESPONSIBLE MANAGER
Hasan KURTULUŞ Mine Technician	Hacer TEKGÖZ Chemical Engineer	Ömer DEĞİRMENCİOĞLU Chemist	ÖZGÜL UYAN Chemist
			