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| <h1 style="margin:0;">AYSET</h1> <p style="font-size: small; margin: 0;">TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL<br/>ELEKTRONİK GIDA TEMİZLİK MADDELERİ SAN. A.Ş.<br/>SARIHAMZALI YOLU ÜZERİ NO:54 ADANA-TURKEY<br/>TEL : +90-322-441 12 99 FAX : +90-322-441 12 98</p> | <b>QUALITY CONTROL DEPARTMENT</b> | Document No : R.KK.10<br>Validity : 03.12.2001<br>Revision No : 01<br>Revision Date : 01.11.2002<br>Revision reason : DRF.KK02/051<br>Page No : 1/1 |
|  | <b>CERTIFICATE OF ANALYSIS</b>    |   |

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| REPORT NO : R10019<br>LOT NO - EXPIRY : 10019<br>PRODUCT NAME : VACUUM BLOOD COLLECTION TUBE<br>PRODUCT TYPE : 13X100 - 9NC SODIUM CITRATE 4,5ML-3,8%<br>REFERENCE NO : 81282 | REPORT DATE : 04.12.2023<br>STERILIZATION DATE : 2023-12<br>EXPIRY DATE : 2024-12<br>LOT SIZE (N) : 20.000 Pcs.<br># SAMPLES : 100 Pcs. |
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| PHYSICAL TESTS                               | STANDARDS      | TEST METHOD                       | LIMITS   | RESULTS                                   |
|--|----------------|-----------------------------------|--|---|
| Material                                     | EN 6710        | EN 6710                           | Medical PET, gasket and (PE) tup 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                          | 12,40(+/-0,1)X100,10(+/-0,1)mm                 | 12,80 X 100,06mm                          |
| Diameter and Length of Cap                   | AYSET          | T.KK. 87                          | 16,00(+/-0,1)X18,60 (+/-0,1)mm                 | 16,04 X 18,60mm                           |
| 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<br>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.

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