

**KANSUK LABORATUARI****SUBJECT** LEUKOCYTE FILTER CERTIFICATE OF ANALYSIS**Document No:** IL_KT_F_1.16.2.2**Issue Date:** 08.06.2021**PROCESS NAME** BLOOD BAG AND SERUM PRODUCTION PROCESS,
PHARMACEUTICAL PRODUCTION PROCESS**Revision No:** 4**Validity Date:** 15.06.2021**CE1984****LEUKOCYTE FILTER CERTIFICATE OF ANALYSIS**

PRODUCT NAME : KAN. BC POOLING PLT- FILT 5D STR
CODE NO : 20004146520
LOT NUMBER : K002205039
QUANTITY RELEASED : 80
RELEASE DATE : 03.06.2022
PRODUCTION DATE (Y-M) : 2022-05
EXPIRY DATE (Y-M) : 2025-05
TYPE OF STERILIZATION : GAMA IRRADIATION
STERILIZATION DATE : 02.06.2022

Filter information

Code	Description	Raw material	Filter type
58559	Sepacell filter PLX-5	PC+PET	Hard

Control and Tests	Reference	Acceptable Limits	Results
Physical Tests	ISO 3826-1:2013 + Internal Methods	Must be within the limits indicated for each test	PASS
Leakage controls	ISO 3826-1:2013 + Internal Methods	No leakage is allowed on visual inspection	PASS
Tensile strength of line connectors	ISO 3826-1:2013	Must resist a pull force of 15 N for 15 s.	PASS
Pyrogenicity test ⁽¹⁾	EP 2.6.14 2010:20614 Method A	Must be apyrogen	APYROGEN
Sterility test ⁽¹⁾	EP 2.6.1 04/2011:20601	Must be sterile	STERILE
Bioburden ⁽²⁾	ISO 11737-1	10 cfu / 40 mL	PASS

(1) Controls which are performed during stability studies

(2) Controls which are performed monthly

Quality Control Assistant Manager (Name, Signature) :

S.YAVUZ

We hereby declare that the above mentioned products meet all applicable provisions of Council Directive 93/42/EEC and all applicable harmonised and international standards for medical devices. All supporting documents are retained under the premises of the manufacturer.