

		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 : K002109075
QUANTITY RELEASED : 100
RELEASE DATE : 15.09.20210
PRODUCTION DATE (Y-M) : 2021-09
EXPIRY DATE (Y-M) : 2024-09
TYPE OF STERILIZATION : GAMA IRRADIATION
STERILIZATION DATE : 10.09.2021

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) :

A.FİDAN

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.