

		KANSUK LABORATUARI	
SUBJECT LEUKOCYTE FILTER CERTIFICATE OF ANALYSIS		Document No IL_KT_F_1.16.2.2	
Issue Date: 08.10.2018	PROCESS NAME BLOOD BAG AND SERUM PRODUCTION PROCESS, PHARMACEUTICAL PRODUCTION PROCESS	Revision No: 3	
Validity Date: 15.10.2018			

CE1984

CERTIFICATE OF ANALYSIS

PRODUCT NAME : KAN. BC POOLING PLT- FILT 5D STR
 CODE NO : 20004146520
 LOT NUMBER : 1911075
 QUANTITY RELEASED : 120
 RELEASE DATE : 25.11.2019
 PRODUCTION DATE (Y-M) : 2019-11
 EXPIRY DATE (Y-M) : 2022-11
 TYPE OF STERILIZATION : GAMA IRRADIATION
 STERILIZATION DATE : 15.11.2019

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 RESPONSIBLE (Name, Signature) : A.FİDAN

