

**SUNAR  
MISIR****ANALYSIS RESULT REPORT****QUALITY MANAGEMENT**

DATE : 31.10.2024  
 CUSTOMER NAME : BDV BEHRENS GMBH  
 PRODUCT NAME : PHARMA GRADE SUNSORB 70/70 SORBITOL SYRUP  
 PACKAGING TYPE : DRUM OF 300KGS  
 QUANTITY : 24.000KGS  
 LOT NUMBER : 9386  
 PRODUCTION DATE : 23.10.2024  
 SHELF LIFE : 23.10.2026  
 EXP.DATE : CONTAINER NUMBERS ARE ON THE PACKING LIST

**PRODUCT PROPERTIES****PHYSICAL AND CHEMICAL ANALYSIS**

PAREMETERS	MIN	MAX	RESULT	REFERENCE METHOD
PHYSICAL FORM		Clear, colorless, viscous water-miscible liquid	Confirms	EUR. PHARMACOPOEIA
APPEARANCE		Clear, colorless solution	Confirms	EUR. PHARMACOPOEIA
TASTE		Unique Taste	Confirms	EUR. PHARMACOPOEIA
ODOR		Unique Odor	Confirms	EUR. PHARMACOPOEIA
IDENTIFICATION TESTS A.B.C	—	—	Confirms	A:Principle peak in chromatogram(HPLC) B:Angle of rotation C:Clear,syrupy liquid at 25°C
DRY SUBSTANCE	69,5	71,0	69,81	SUNAR INTERNAL METHOD
REFRACTIVE INDEX (20°C)	1,4580	1,4616	1,4587	EUR. PHARMACOPOEIA
DENSITY	1,28	1,30	1,30	SUNAR INTERNAL METHOD
WATER(%)	29,0	30,5	30,20	SUNAR INTERNAL METHOD
PH	5,0	7,5	6,0	USP-NF
CONDUCTIVITY (µs/cm)	—	10	2,00	EUR. PHARMACOPOEIA
SULPHATED ASH(IN DRY BASIS) (%)	—	0,1	<0,1	SUNAR INTERNAL METHOD
CHLORIDE(mg/kg)	—	50	<50	SUNAR INTERNAL METHOD
SULPHATES(mg/kg)	—	100	<100	SUNAR INTERNAL METHOD
D-SORBITOL(anydrous substance)	72,00	92,0	79,90	EUR. PHARMACOPOEIA
REDUCING SUGAR(as glucose in dry basix) (%)	—	0,2	<0,2	EUR. PHARMACOPOEIA
REDUCING SUGAR AFTER HYDROLISIS(TOTAL SUGAR)As glucose in dry basis(%)	—	9,3	<9,3	USP-NF
ANGLE OF OPTICAL BOTATION(DEG.)	+1,5	+3,5	3,0	EUR. PHARMACOPOEIA
RESIDUE ON IGNITION %	—	0,1	<0,1	USP-NF
ACIDITY (0,01 N NaOH)(ml)	—	0,2 ml	<0,2	SUNAR INTERNAL METHOD
ETHYLENGLYCOL(mg/kg)	—	1000	<1000	USP-NF
DIETHYLENGLYCOL(mg/kg)	—	1000	<1000	USP-NF
SOLUBILITY		Totally Soluble	Confirms	—
<b>HEAVY METAL ANALYSIS</b>	<b>MIN</b>	<b>MAX</b>	<b>RESULT</b>	<b>REFERENCE METHOD</b>
NICKEL(ppm)	—	1,0	<1,0	EXTERNAL ANALYSIS
LEAD (ppm)	—	0,5	<0,5	EXTERNAL ANALYSIS
ARSENIC (ppm)	—	1,0	<1,0	EXTERNAL ANALYSIS
HEAVY METALS(in terms of ph)(ppm)	—	10	<10	EXTERNAL ANALYSIS
<b>MICROBIOLOGICAL ANALYSIS</b>	<b>MIN</b>	<b>MAX</b>	<b>RESULT</b>	<b>REFERENCE METHOD</b>
MOULD(cfu/gr)	—	10	<10	TS ISO 21527-2
OSMOPHILIC YEAST (cfu/gr)	—	10	<10	TS ISO 21527-2
ESCHERIA COLI(ABSENT IN 1 Gram)	—	NEGATIVE	NEGATIVE	TS ISO 16649-1 AND-2
SALMONELLAE (ABS IN 25 G)	—	NEGATIVE	NEGATIVE	EXTERNAL ANALYSIS
ENTEROBACTERIA (cfu/gram)	—	NEGATIVE	NEGATIVE	ISO 21528-2
STAPHYLOCOCCUS AEREUS (cfu/10 gram)	—	NEGATIVE	NEGATIVE	ISO 6888-1
PSEUDOMONAS AERUGINOSE (cfu/10 gram)	—	NEGATIVE	NEGATIVE	EXTERNAL ANALYSIS

\* ENTERPRISE REGISTRATION NUMBER TR-01-K-000192

**\*GMO DECLARATION;**

We declare that our product meets Turkish Republic Regulations number 5977 "Biosafety Law" and number 27671 "Regulation on Genetically Modified Organisms and Products" by periodical control and analysis below.

Our company gets information from all suppliers about the seed, origin, storage conditions and transportation circumstances; ask for the transportation records and ask for the guarantee to meet "Biosafety Law".

To check the suppliers commitment, our company collects samples, makes related analyses and record them systematically.

**\*CONFORMITY WITH EUROPEAN PHARMACOPOEIA AND USP-NF DECLARATION:**

This product meets the requirements of European pharmacopeia - sorbitol , Liquid (Non Crystallising) and USP/NF Official Liquid sorbitol Non Crystallising Monographs.

ANALYSED BY	RECORDED BY	APPROVED BY
Laboratory Assistant	Laboratory Assistant	Quality Management Director
AHMET ESMER	MIKAIL KARATAŞ	HATICE TOKAT