

**SUNAR
MISIR**

ANALYSIS RESULT REPORT

QUALITY MANAGEMENT

DATE 29.05.2025
CUSTOMER NAME BDV BEHRENS GMBH
PRODUCT NAME PHARMA GRADE SUNSORB 70/70 SORBITOL SYRUP
PACKAGING TYPE DRUM OF 300KGS
QUANTITY 24.000KGS
LOT NUMBER 10263/EXP
PRODUCTION DATE 26.04.2025
SHELF LIFE 26.04.2027
EXP.DATE
CONTAINER NUMBERS ARE ON THE PACKING LIST

PRODUCT PROPERTIES

PHYSICAL AND CHEMICAL ANALYSIS

PARAMETERS	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	70,21	SUNAR INTERNAL METHOD
REFRACTIVE INDEX (20°C)	1,4580	1,4616	1,4597	EUR. PHARMACOPOEIA
DENSITY	1,28	1,30	1,30	SUNAR INTERNAL METHOD
WATER(%)	29,0	30,5	29,80	SUNAR INTERNAL METHOD
PH	5,0	7,5	6,7	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 (anhydrous substance)	72,00	92,0	79,50	EUR. PHARMACOPOEIA
REDUCING SUGAR (as glucose in dry basis) (%)	—	0,2	<0,2	EUR. PHARMACOPOEIA
REDUCING SUGAR AFTER HYDROLYSIS (TOTAL SUGAR) as glucose in dry basis (%)	—	9,3	<9,3	USP-NF
ANGLE OF OPTICAL ROTATION (DEG.)	+1,5	+3,5	3,1	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	—
HEAVY METAL ANALYSIS	MIN	MAX	RESULT	
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 Pb) (ppm)	—	10	<10	EXTERNAL ANALYSIS
MICROBIOLOGICAL ANALYSIS	MIN	MAX	RESULT	
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 AERUGINOSA (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
Laboratory Assistant

VOLKAN SERTKAYA

SUNAR MISIR
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5 OCAK Y.D. : 782 007 1099
Yolcucağı Mah. M. K. KARATASNo: 565 Seyhan Mah. Çiğdemli Bulv.
/ TÜRKİYEAPPROVED BY
Quality Management Director

HATİCE TOKAT