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 : 9398/BDV
PRODUCTION DATE : 26.10.2024
SHELF LIFE : 26.10.2026
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
IDENTIFICCATION 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	70,90	SUNAR INTERNAL METHOD
REFRACTIVE INDEX (20°C)	1,4580	1,4616	1,4613	EUR. PHARMACOPOEIA
DENSITY	1,28	1,30	1,30	SUNAR INTERNAL METHOD
WATER(%)	29,0	30,5	29,10	SUNAR INTERNAL METHOD
PH	5,0	7,5	6,0	USP-NF
CONDUCTIVITY (µs/cm)	—	10	3,00	EUR. PHARMACOPOEIA
SULPHATED ASH(IN DRY BASIS) (%)	—	0,1	<0,1	SUNAR INTERNAL METHOD
CHOLRIDE(mg/kg)	—	50	<50	SUNAR INTERNAL METHOD
SULPHATES(mg/kg)	—	100	<100	SUNAR INTERNAL METHOD
D-SORBITOL(anydrous substance)	72,00	92,0	76,20	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
SOLUBITILY		Totally Soluble	Confirms	—
HEAVY METAL ANAYSIS	**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 ph)(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 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
GÜNAY TULUK	MİKAİL KARATAŞ	HATİCE TOKAT

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
IDENTIFICCATION 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
CHOLRIDE(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
SOLUBITILY		Totally Soluble	Confirms	—
HEAVY METAL ANAYSIS	**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 ph)(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 AERUGINOSE (cfu/10 gram)	—	**NEGATIVE**	NEGATIVE	EXTERNAL ANALYSIS

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ANALYSED BY	**RECORDED BY**	**APPROVED BY**
Laboratory Assistant	Laboratory Assistant	Quality Management Director
AHMET ESMER	MİKAİL KARATAŞ	HATİCE TOKAT