



Certificate of Analysis

Plant:	STOELZLE UNION s.r.o., U Sklárný 300, CZ-330 24 Heřmanova Hut		
Part No.:	72722201890	Item Description:	50 ml Dropper bottle
Drawing N°:	E-018-00-18	Glass Color:	Amber
Lot N°:	C40002201	Produced Quantity:	4,885,650
Production period from: 30.04.2025		until 14.05.2025	Minimum Shelf Life: 14.05.2030
Confirmation:			
It is confirmed, that the above container conforms to the internal requirements, based on ISO 9001/15378. Inspection and testing were done according to the technical drawing, valid standards and valid "Defect Evaluation list for containers made from moulded glass", Vol. 14. The results do not exceed the permissible limits. Where alternative agreements exist between the supplier and customer, the relevant values have been based on these.			

Glass Quality

Material type: Moulded Glass **Class 3**

Arsenic Release Pharm. Eur., USP*:	Result: < 0,1 ppm	Limit: 0,1 ppm
Heavy Metal Content*:	Result: <100 ppm	Limit: 100 ppm
Light transmission Ph.Eur., USP	Result: 0.2 %	Limit: 10 %
Hydrolytic class (powdered glass) Ph.Eur., USP	Result: 0.38 ml 0,02 N HCl	Limit: 0.85 ml 0,02 N HCl
Hydrolytic resistance inner surface Ph.Eur., USP	Result: 4.1 ml 0,01 N HCl	Limit: 4.8 ml 0,01 N HCl

Surface Treatment

Description	Unit	LSL	USL	Result
CE-Coating: T5				Conforming

Attributive and Variable Characteristics

Results

Characteristic	Unit	LSL	Nominal	USL	AVG	S-Dev
Bottle marks					Conforming	
Through Bore Diameter	mm	10.00	10.00		11,57	0.27
Bore Diameter	mm	10.50	10.65	10.80	10.63	0.09
Thread	mm	17.50	17.75	18.00	17.77	0.05
Ring	mm	19.80	20.00	20.20	20.01	0.09
Body Diameter mid	mm	37.40	38.00	38.60	38.06	0.13
Height	mm	90.70	91.70	92.70	92,16	0.21
Weight	g				61,28	0.81
Brimful capacity	ml	56.50	58.00	59.50	57,96	0.39

Visual Examinations

Specification	Result
Appearance: Acc. to Defect List	Conforming

Release

Release: Yes Comment:

Quality Department

Date: _____

Signature: _____

