



Certificate of Analysis

Process Quality Assurance
Form 13.05.01.01 Version 03

Plant:	Stözlze-Union s.r.o, U Sklářny 300, CZ-330 24 Heřmanova Hut		
Part No.:	35053200190	Item Description:	50 ml Injection Vial
Drawing N°:	CO-076.1	Glass Color:	Amber
Lot N°:	240004921	Produced Quantity:	359,640
Production period from:	03.06.2019	until	05.06.2019
		Minimum Shelf Life:	05.06.2024

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 Content*:	Result:	< 0,1 ppm	Limit:	0,1 ppm
Heavy Metal Content*:	Result:	< 100 ppm	Limit:	100 ppm
Light transmission Ph.Eur.,USP	Result:	3,63 %	Limit:	10 %
Hydrolytic class (powdered glass) Ph.Eur., USP	Result:	0,43 ml 0,02 N HCl	Limit:	0,85 ml 0,02 N HCl
Hydrolytic resistance inner surface Ph.Eur., USP	Result:	3,75 ml 0,01 N HCl	Limit:	4,8 ml 0,01 N HCl

Surface Treatment

Description	Unit	LSL	USL	Result
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Attributive and Variable Characteristics

Results

Characteristic	Unit	LSL	Nominal	USL	AVG	S-Dev
Bottle marks					Conforming	
Through Bore Diameter	mm	11.50	11.50		12,86	0.12
Bore Diameter	mm	12.40	12.60	12.80	12.78	0.05
Ring	mm	19.60	19.80	20.00	19.87	0.04
Body Diameter mid	mm	41.50	42.00	42.50	41.93	0.09
Height	mm	72.20	73.00	73.80	72.74	0.17
Weight	g				50,13	0.31
Brimful capacity	ml	57.00	60.00	63.00	59,08	0.22

Visual Examinations

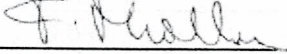
Appearance:	Specification	Result
	Acc. to Defect List	Conforming

Release

Release: Yes Comment:

Quality Department

Date: 6.6.2019

Signature: 
QA Manager STU