

Seite 1 von 1	PRODUCT SPECIFICATION STERICERT® Glass Sample Vials - 30 ml, 50 ml, 100 ml	Revision: 0
		Date: 2026-04-07

Article Number	1960300 / 1960301	1960410 / 1960304	1960305 / 1960306
Nominal Volume	30 ml	50 ml	100 ml
Content: Water for Injections in accordance with EP and USP	300 µl	500 µl	1.0 ml

Components	
Vial:	
Material:	Borosilicate glass
Glass color	colorless
Glass type	Injection vials made of moulded glass in accordance with DIN EN ISO 8362 Part 4
Stopper	Rubber stopper 20 mm, teflon-coated, grey suitable for multiple piercing, Typ I in accordance with EP 3.2.9, USP <381> and DIN EN ISO 8362 Part 2 <ul style="list-style-type: none"> - Basic polymer: Chlorobutyl - Reinforcement: Inert Mineral - Curing system: unconventional - Durometer (Shore A): 40 - Gas- and vapour permeability: very low
Cap	Caps made of aluminium-plastics combinations for injection vials in accordance with DIN EN ISO 8362 Part 6

Specification	
Sterility method specification	steam sterilisation 121° C, 20 min in accordance with EP 5.1.1 and USP <1211> sterile
Endotoxin test method Spezifikation	<ul style="list-style-type: none"> - Ph. Eur. 2.6.14, Method C - USP <85> - ANSI/AAMI ST72:2019 (Bacterial endotoxins- test methods, routine monitoring and alternatives to batch testing) - USP <1225> (Validation of Compendial Procedures) - USP <1226> (Verification of Compendial Procedures) - < 0.01 I.E. / vial
Particles test method specification	light scattering in accordance with EP 2.9.19 and USP <788> < 60 / vial (particles ≥ 25 µm) < 600 / vial (particles ≥ 10 µm)

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