ACILA AG

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Typ	**PYROVAC 10**	**PYROVAC 20**	**PYROVAC 25**
Article-Number	1960500	1960495	1960490
Named volume	10 ml	20 ml	25 ml
Content	100 µl water for injections in accordance with EP and USP		
Components			
Vial:			
Material:	Tubular glass (borosilicate)		
Glas color	colorless		
Glas type	Ph. Eur., 3.2.1 Glass containers for pharmaceutical use USP <660> Glass Containers for Pharmaceutical Use		
size	in accordance with DIN EN ISO 8362 part 1		
Stopper	Rubber stopper 20 mm grey for multiple piercing type I in accordance with EP 3.2.9 , USP <381> and DIN EN ISO 8362 part 5 - Basic polymer: brombutyl - Filler: silicate - Colour: anorganic pigment - Vulcanisation: unconventional - Hardness: 50 ± 5(Shore A) - Specific gravity: 1,37 ± 0,04[g/cm^3] - Ash: 46,4 ± 2,0[%] - Gas- and vapour permeability: very low		
Cap	metal cap in accordance with DIN EN ISO 8362 part 6		
Specification			
Pressure	ca. 10 mbar		
Sterility			
method	steam sterilisation 121° C, 20 min in accordance with EP 5.1.1 and USP <1211>		
specification	sterile		
Endotoxin			
test method	- 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		
specification	- < 0,01 I.E./ vial		
Particles			
test method	light scattering in accordance with EP 2.9.19 and USP <788>		
specification	< 60 / vial (particles ≥ 25 µm) < 600 / vial (particles ≥ 10 µm)		

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Typ	**PYROVAC 15S**
Article-Number	1960497
Named volume	15 ml
Content	100 µl water for injections in accordance with EP and USP
Components	
Vial:	
Material:	Tubular glass (borosilicate)
Glas color	colorless
Glas type	Ph. Eur., 3.2.1 Glass containers for pharmaceutical use USP <660> Glass Containers for Pharmaceutical Use
size	53,5±0,5 X 25,5±0,25mm
Stopper	Rubber stopper 20 mm grey for multiple piercing type I in accordance with EP 3.2.9 , USP <381> and DIN EN ISO 8362 part 5 - Basic polymer: brombutyl - Filler: silicate - Colour: anorganic pigment - Vulcanisation: unconventional - Hardness: 50 ± 5(Shore A) - Specific gravity: 1,37 ± 0,04[g/cm^3] - Ash: 46,4 ± 2,0[%] - Gas- and vapour permeability: very low
Cap	metal cap in accordance with DIN EN ISO 8362 part 6
Specification	
Pressure	ca. 10 mbar
Sterility	
method	steam sterilisation 121° C, 20 min in accordance with EP 5.1.1 and USP <1211>
specification	sterile
Endotoxin	
test method	- 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)
specification	- < 0,01 I.E./ vial
Particles	
test method	light scattering in accordance with EP 2.9.19 and USP <788>
specification	< 60 / vial (particles ≥ 25 µm) < 600 / vial (particles ≥ 10 µm)

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Typ	**PYROVAC 30**	**PYROVAC 50**	**PYROVAC 100**
Article-Number	1960489	1960492	1960491
Named volume	30 ml	50 ml	100 ml
Content water for injections in accordance with EP and USP	300 µl	300 µl	1,0 ml

Components	
Vial:	
Material:	Moulded glass (borosilicate)
Glas color	colorless
Glas type	Ph. Eur., 3.2.1 Glass containers for pharmaceutical use USP <660> Glass Containers for Pharmaceutical use
size	in accordance with DIN EN ISO 8362 part 4
Stopper	Rubber stopper 20 mm grey for multiple piercing type I in accordance with EP 3.2.9 ,USP <381> and DIN EN ISO 8362 part 5 - Basic polymer: brombutyl - Filler: silicate - Colour: anorganic pigment - Vulcanisation: unconventional - Hardness: 50 ± 5(Shore A) - Specific gravity: 1,37 ± 0,04[g/cm^3] - Ash: 46,4 ± 2,0[%] - Gas- and vapour permeability: very low
Cap	metal cap in accordance with DIN ISO EN ISO 8362 part 6
Specification	
Preassure	ca. 10 mbar
Sterility	
method	steam sterilisation 121° C, 20 min in accordance with EP 5.1.1 and USP <1211>
specification	sterile
Endotoxin	
test method	- 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)
specification	- < 0,01 I.E./ vial
Particles	
test method	light scattering in accordance with EP 2.9.19 and USP <788>
specification	< 60 / vial (particles ≥ 25 µm) < 600 / vial (particles ≥ 10 µm)

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