



**FRESENIUS
KABI**

**** **CERTIFICATE OF ANALYSIS** ****

Article: CompoFlow®4F T&B-66,5ml CPD/105ml SAG-M-RCC-PDS-V

Article number: CQ32R60

Anticoagulant solution: 66.5 ml CPD

Preservation solution: 105 ml SAG-Mannitol

Batch Number: 41YF04FA00

Manufacturing Date: 01-Jun-2026

Quantity: 7080 pieces
Expiration Date: May-2028

CPD Anticoagulant solution

	Method ¹	Nominal Value	Limits	Results
Volume	Volumetr.	67	61 - 72 ml	71 ml
Sodium citrate.2H ₂ O	HPLC	26.3	25.0 – 27.6 g/l	25.7 g/l
Citric acid.1H ₂ O	HPLC	3.27	2.94 – 3.60 g/l	3.19 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr. Ph.	2.51	2.38 – 2.64 g/l	2.45 g/l
Glucose.1H ₂ O ²	HPLC	25.5	24.2 - 26.8 g/l	24.5 g/l
5-HMF	HPLC		≤ 5 ppm	0.5 ppm
pH	Potent.	5.6	5.3 – 5.9	5.7

SAG-Mannitol Preservation solution

	Method ¹	Nominal Value	Limits	Results
Volume	Volumetr.	105	95 - 115 ml	108 ml
Sodium chloride	Argent.	8.77	8.33 – 9.21 g/l	8.63 g/l
Adenine	HPLC	0.169	0.161 – 0.177 g/l	0.165 g/l
Sugars	HPLC			
Glucose.1H ₂ O ²		9.00	8.55 – 9.45 g/l	8.77 g/l
Mannitol		5.25	4.99 – 5.51 g/l	5.11 g/l
5-HMF	HPLC		≤ 5 ppm	0.4 ppm
pH	Potent.	5.0	3.5 - 6.0	5.2

1) The used test methods are equivalent or more accurate than the corresponding methods described in the Eur. Pharm.

2) As total reducing sugars

Characteristics	clear, colourless to faintly yellow solution practically free from visible particles	conform
Physical control	in accordance with specifications	conform
Sterility (Eur. Pharm.)	sterile	conform
Bacterial Endotoxines (Eur. Pharm.)	CPD < 5.56 EU/ml SAGM < 5.56 EU/ml	conform conform
Used Filter batch		26RK028

Batch released by Quality Assurance.		Manufactured by: Fresenius Kabi Plant: Fresenius Kabi Horátev CZ s.r.o. Hořátev 104 289 13 Czech Republic
Date:	19-Jun-2026	
Name:	František Tykva	
Signature:		

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