FRESENIUS KABI

**** CERTIFICATE OF ANALYSIS ****

Article: COMPOFLOW®4F T&B-63 ML CPD/100 ML SAG-M-RCC+PDS-V
Article number: CQ32250
Anticoagulant solution: 63 ml CPD
Preservation solution: 100 ml SAG-Mannitol
Batch Number: 41YF28FA00 Quantity: 10344 pieces
Manufacturing Date: 24-Jul-2026 Expiration Date: May-2028

CPD Anticoagulant solution

	Method [1]	Nominal Value	Limits	Results
Volume	Volumetr.	63	57 - 69 ml	66 ml
Sodium citrate.2H20	HPLC	26.3	25.0 – 27.6 g/l	25.2 g/l
Citric acid.1H2O	HPLC	3.27	2.94 – 3.60 g/l	3.19 g/l
NaH2PO4.2H2O	HPLC or Spectr. Ph.	2.51	2.38 – 2.64 g/l	2.42 g/l
Glucose.1H2O[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.	100	90 - 110 ml	104 ml
Sodium chloride	Argent.	8.77	8.33 – 9.21 g/l	8.62 g/l
Adenine	HPLC	0.169	0.161 – 0.177 g/l	0.165 g/l
Sugars	HPLC			
Glucose.1H2O[2]		9.00	8.55 – 9.45 g/l	8.74 g/l
Mannitol		5.25	4.99 – 5.51 g/l	5.09 g/l
5-HMF	HPLC		≤ 5 ppm	0.5 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	conform
	SAGM < 5.56 EU/ml	conform
Used Filter batch		26RY007, 26RK031, 26RK033

Batch released by Quality Assurance.

Date: 28-Aug-2026
Name: František Tykva
Signature:

Manufactured by:
Fresenius Kabi
Plant: Fresenius Kabi Horatev CZ s.r.o.
Hořátev 104
289 13
Czech Republic

Form.no. 17-4224/5

Secure Report ID: 2506
LIMS Lot Nums: 2806,2778,2848
COA ID: 2,148

CoA Setup: Finished Product_EN v2
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