

***** **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:	41XA31FA00	Quantity:	23 472
Manufacturing date:	31 January 2025	Expiry date:	2026-12

Test results

1. CPD Anticoagulant solution

	Method ¹	Nominal value	Limits	Results
Sodium citrate.2H ₂ O	HPLC	26,3 g/l	25,0 — 27,6 g/l	25,2 g/l
Citric acid.1H ₂ O	HPLC	3,27 g/l	2,94 — 3,60 g/l	3,23 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr.Ph.	2,51 g/l	2,38 — 2,64 g/l	2,43 g/l
Glucose.1H ₂ O ²	HPLC	25,5 g/l	24,2 — 26,8 g/l	25,0 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5,6	5,3 — 5,9	5,8
Volume	Volumetr.	63 ml	57 — 69 ml	66 ml

2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 — 9,21 g/l	8,59 g/l
Adenine	HPLC	0,169 g/l	0,161 — 0,177 g/l	0,167 g/l
Glucose.1H ₂ O ²	HPLC	9,00 g/l	8,55 — 9,45 g/l	8,77 g/l
Mannitol	HPLC	5,25 g/l	4,99 — 5,51 g/l	5,15 g/l
5-HMF	HPLC		< 5 ppm	0,3 ppm
pH	Potent.	5	3,5 — 6,0	5,2
Volume	Volumetr.	100 ml	90 — 110 ml	106 ml

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

²⁾ As total reducing sugars

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| 3. Characteristics: clear, colourless to faintly yellow solution practically free from visible particles | conform |
| 4. Physical control: in accordance with specifications | conform |
| 5. Sterility (Eur. Pharm.): sterile | conform |
| 6. Bacterial Endotoxines (Eur. Pharm.): | CPD: < 5,56 EU/ml
SAGM: < 5,56 EU/ml |
| 7. Used Filterbatch | conform
24RF038 |

<u>Batch released by Quality Assurance.</u>	<u>Manufactured by:</u>
Date: 11.03.2025	Fresenius Kabi AG
Name: Tykva František	Plant:
Signature: 	Fresenius Kabi Horátev CZ s.r.o.
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