

***** **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:	41XD28FA00	Quantity:	23 472
Manufacturing date:	30 April 2025	Expiry date:	2027-03

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	25,3 g/l
Citric acid.1H ₂ O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,22 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr.Ph.	2,51 g/l	2,38 – 2,64 g/l	2,41 g/l
Glucose.1H ₂ O ²	HPLC	25,5 g/l	24,2 – 26,8 g/l	24,2 g/l
5-HMF	HPLC		< 5 ppm	0,5 ppm
pH	Potent.	5,6	5,3 – 5,9	5,8
Volume	Volumetr.	63 ml	57 – 69 ml	67 ml

2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,62 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,164 g/l
Glucose.1H ₂ O ²	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,82 g/l
Mannitol	HPLC	5,25 g/l	4,99 – 5,51 g/l	5,07 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5	3,5 – 6,0	5,1
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 conform
SAGM: < 5,56 EU/ml conform |
| 7. Used Filterbatch | 25GY001,25RF009 |

<u>Batch released by Quality Assurance.</u>	<u>Manufactured by:</u>
Date: 28.05.2025	Fresenius Kabi AG
Name: Tykva František	Plant: Fresenius Kabi Horátev CZ s.r.o.
Signature: 	Hořátev 104, 289 13
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