

***** **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: 41WL25FA00
Manufacturing date: 27 November 2024
Quantity: 23 400
Expiry date: 2026-10

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	25,6 g/l
Citric acid.1H ₂ O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,20 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr.Ph.	2,51 g/l	2,38 – 2,64 g/l	2,40 g/l
Glucose.1H ₂ O ²	HPLC	25,5 g/l	24,2 – 26,8 g/l	24,8 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5,6	5,3 – 5,9	5,7
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	8,62 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,166 g/l
Glucose.1H ₂ O ²	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,81 g/l
Mannitol	HPLC	5,25 g/l	4,99 – 5,51 g/l	5,15 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	108 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

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 24RF034

<u>Batch released by Quality Assurance.</u>	<u>Manufactured by:</u>
Date: 23.01.2025	Fresenius Kabi AG
Name: Tykva František	Plant:
Signature: 	Fresenius Kabi Horatev CZ s.r.o.
	Hořátev 104, 289 13
	Czech Republic