

***** **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: 41WL12FA00
Manufacturing date: 8 November 2024

Quantity: 23 472
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	25,3 g/l
Citric acid.1H ₂ O	HPLC	3,27 g/l	2,94 — 3,60 g/l	3,17 g/l
NaH ₂ PO ₄ .2H ₂ O	HPLC or Spectr.Ph.	2,51 g/l	2,38 — 2,64 g/l	2,45 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	5,8
Volume	Volumetr.	63 ml	57 — 69 ml	67 ml

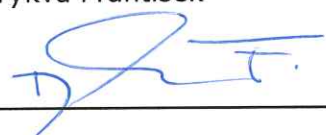
2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 — 9,21 g/l	8,64 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	8,84 g/l
Mannitol	HPLC	5,25 g/l	4,99 — 5,51 g/l	5,16 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

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 24GY009,24GY011

Batch released by Quality Assurance.	Manufactured by:
Date: 14.02.2025	Fresenius Kabi AG
Name: Tykva František	Plant:
Signature: 	Fresenius Kabi Horátev CZ s.r.o.
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