

***** **CERTIFICATE OF ANALYSIS** *****

Article: CompoFlow®4F T&B-66,5ml CPD/105ml SAG-M-RCC-PDS-V
 Article number: CQ32R60
 Anticoagulant solution: 66,5 ml CPD
 Preservation solution: 105 ml SAG-Mannitol
 Batch number: 41WM04FA00
 Manufacturing date: 1 December 2024
 Quantity: 7 128
 Expiry date: 2026-11

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	25,4 g/l
Citric acid.1H ₂ O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,19 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	24,4 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5,6	5,3 – 5,9	5,7
Volume	Volumetr.	66,5 ml	61 – 72 ml	71 ml


2. SAG-Mannitol Preservation solution

	Method	Nominal value	Limits	Results
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,66 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,163 g/l
Glucose.1H ₂ O ²	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,80 g/l
Mannitol	HPLC	5,25 g/l	4,99 – 5,51 g/l	5,14 g/l
5-HMF	HPLC		< 5 ppm	0,4 ppm
pH	Potent.	5	3,5 – 6,0	5,0
Volume	Volumetr.	105 ml	95 – 115 ml	112 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 Horátev CZ s.r.o.
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