

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

Article:

Article number:	CQ32250	Quantity:	23 376
Anticoagulant solution:	63 ml CPD	Expiry date:	2028-01
Preservation solution:	100 ml SAG-Mannitol		
Batch number:	41YB18FA00		
Manufacturing date:	17 February 2026		

Test results

1. CPD Anticoagulant solution

	<b>Method<sup>1</sup></b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
Sodium citrate.2H <sub>2</sub> O	HPLC	26,3 g/l	25,0 – 27,6 g/l	25,1 g/l
Citric acid.1H <sub>2</sub> O	HPLC	3,27 g/l	2,94 – 3,60 g/l	3,20 g/l
NaH <sub>2</sub> PO <sub>4</sub> .2H <sub>2</sub> O	HPLC or Spectr.Ph.	2,51 g/l	2,38 – 2,64 g/l	2,43 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	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	5,7
Volume	Volumetr.	63 ml	57 – 69 ml	67 ml


2. SAG-Mannitol Preservation solution

	<b>Method</b>	<b>Nominal value</b>	<b>Limits</b>	<b>Results</b>
Sodium chloride	Argent.	8,77 g/l	8,33 – 9,21 g/l	8,61 g/l
Adenine	HPLC	0,169 g/l	0,161 – 0,177 g/l	0,165 g/l
Glucose.1H <sub>2</sub> O <sup>2</sup>	HPLC	9,00 g/l	8,55 – 9,45 g/l	8,73 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	5,3
Volume	Volumetr.	100 ml	90 – 110 ml	104 ml

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

<sup>2)</sup> 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<br>SAGM: < 5,56 EU/ml | conform<br>conform |
| 7. Used Filterbatch  |   | 26RF003            |

<u>Batch released by Quality Assurance.</u>	<u>Manufactured by:</u>
Date: 09.03.2026	Fresenius Kabi AG
Name: Tykva František	Plant: Fresenius Kabi Horátev CZ s.r.o.
Signature: 	Hořátev 104, 289 13 Czech Republic