

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

Article: CompoFlow® 4F T&B CPD SAG-M RCC - PDS-V  
Article number: CQ32250  
Anticoagulant solution: 63 ml CPD  
Preservation solution: 100 ml SAG-Mannitol  
Batch number: 71XF24FA00 Quantity: 6528  
Manufacturing date: 2025-06 Expiry date: 2027-05

Test results

1. CPD Anticoagulant solution

|                                                     | Method <sup>1</sup> | Nominal value | Limits      | Results   |
|-----------------------------------------------------|---------------------|---------------|-------------|-----------|
| Sodium citrate.2H <sub>2</sub> O                    | HPLC                | 26.3 g/l      | 25.0 - 27.6 | 25.4 g/l  |
| Citric acid.1H <sub>2</sub> O                       | HPLC                | 3.27 g/l      | 2.94 - 3.60 | 3.22 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 | 2.43 g/l  |
| Glucose.1H <sub>2</sub> O <sup>2</sup>              | HPLC                | 25.5 g/l      | 24.2 - 26.8 | 25.0 g/l  |
| 5-HMF                                               | HPLC                |               | < 5 ppm     | 0.353 ppm |
| pH                                                  | Potent              | 5.6           | 5.3 - 5.9   | 5.7       |
| Volume                                              | Volumetr.           | 63 ml         | 57 - 69     | 65 ml     |

2. SAG-Mannitol Preservation solution

|                                        | Method    | Nominal value | Limits      | Results   |
|----------------------------------------|-----------|---------------|-------------|-----------|
| Sodium chloride                        | Argent.   | 8.77 g/l      | 8.33 - 9.21 | 8.54 g/l  |
| Adenine                                | HPLC      | 0.169 g/l     | 0.161-0.177 | 0.166 g/l |
| Glucose.1H <sub>2</sub> O <sup>2</sup> | HPLC      | 9.00 g/l      | 8.55 - 9.45 | 8.89 g/l  |
| Mannitol                               | HPLC      | 5.25 g/l      | 4.99 - 5.51 | 5.12 g/l  |
| 5-HMF                                  | HPLC      |               | < 5 ppm     | 0.260 ppm |
| pH                                     | Potent.   | 5             | 3.5 - 6.0   | 5.4       |
| Volume                                 | Volumetr. | 100 ml        | 90 - 110    | 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

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 90832/25

|                                                                                                                                                                       |                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <u>Batch released by Quality Assurance.</u><br><br>Date: 14.04.2025<br>Name: Vanessa Barboza Siqueira<br>Signature: Responsável Técnica Substituto<br>CRF-SP. 111.974 | <u>Manufactured by:</u><br><br>Fresenius Kabi AG<br>Plant: Fresenius Hemocare Brasil Ltda. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|