



**FRESENIUS  
KABI**

\*\*\*\*\* **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: 41XH27FA00  
Manufacturing date: 27 August 2025  
Quantity: 23 160  
Expiry date: 2027-07

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 g/l | 25,3 g/l |
| Citric acid.1H <sub>2</sub> O                       | HPLC                | 3,27 g/l      | 2,94 – 3,60 g/l | 3,18 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 | 2,39 g/l |
| Glucose.1H <sub>2</sub> O <sup>2</sup>              | HPLC                | 25,5 g/l      | 24,2 – 26,8 g/l | 24,5 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      | 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   | 8,61 g/l  |
| Adenine                                | HPLC      | 0,169 g/l     | 0,161 – 0,177 g/l | 0,164 g/l |
| Glucose.1H <sub>2</sub> O <sup>2</sup> | HPLC      | 9,00 g/l      | 8,55 – 9,45 g/l   | 8,77 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         | 5,1       |
| 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

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 25RF024,25RF025,25RF027

|                                                                                                |                                  |
|------------------------------------------------------------------------------------------------|----------------------------------|
| Batch released by Quality Assurance.                                                           | Manufactured by:                 |
| Date: 19.09.2025                                                                               | Fresenius Kabi AG                |
| Name: Tykva František                                                                          | Plant:                           |
| Signature:  | Fresenius Kabi Horatev CZ s.r.o. |
|                                                                                                | Hořátev 104, 289 13              |
|                                                                                                | Czech Republic                   |