



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

Article: CompoFlow® 4F T&B 63 ml CPD/100 ml SAGM - RCC - PDS-V  
 Article number: CQ32250  
 Anticoagulant solution: 63 ml CPD  
 Preservation solution: 100 ml SAG-Mannitol  
 Batch number: 85UM21FA00  
 Manufacturing date: 2023.12  
 Quantity: 19389  
 Expiry date: 2025.11

Test results

1. CPD Anticoagulant solution

|   | Method <sup>1</sup> | Nominal value | Limits      | Results  |
|---|---------------------|---------------|-------------|----------|
| Sodium citrate.2H <sub>2</sub> O                    | Titration           | 26.3 g/l      | 25.0 - 27.6 | 25.8 g/l |
| Citric acid.1H <sub>2</sub> O                       | Titration           | 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 | UV                  | 2.51 g/l      | 2.38 - 2.64 | 2.44 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     | 0.4 ppm  |
| pH  | Potent              | 5.6           | 5.3 - 5.9   | 5.7      |
| Volume  | Volumetr.           | 63 ml         | 57 - 69     | 67 ml    |

2. SAG-Mannitol Preservation solution

|  | Method    | Nominal value | Limits      | Results   |
|--|-----------|---------------|-------------|-----------|
| Sodium chloride                        | Argent.   | 8.77 g/l      | 8.33 - 9.21 | 8.65 g/l  |
| Adenine                                | UV        | 0.169 g/l     | 0.161-0.177 | 0.167 g/l |
| Glucose.1H <sub>2</sub> O <sup>2</sup> | HPLC      | 9.00 g/l      | 8.55 - 9.45 | 8.87 g/l  |
| Mannitol                               | HPLC      | 5.25 g/l      | 4.99 - 5.51 | 5.11 g/l  |
| 5-HMF                                  | HPLC      |               | < 5 ppm     | 0.4 ppm   |
| pH                                     | Potent.   | 5             | 3.5 - 6.0   | 5.2       |
| Volume                                 | Volumetr. | 100 ml        | 90 - 110    | 106 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 23113014

|   |   |
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| <u>Batch released by Quality Assurance.</u><br>Date: 05 Mar 2024<br>Name: Xu Xiaoying<br>Signature: | <u>Manufactured by:</u><br>Fresenius Kabi AG<br>Plant: FKGZ |
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