

**SPECIFICATION**

**Product** : Plasmasubstrate, lyophilized **Page** : 1 / 1  
**Product no.** : 0463010003 30 mL **Version** : 1  
**valid from** : 01/03

**Synonym** : EP-Plasma, lyophilized  
Plasmasubstrate R1, lyophilized

**Origin** : Germany

Tests	Methods		Specification
pH	acc. to Ph. Eur	2.2.3	7,0 – 9,0
Recalcification time	acc. to Ph. Eur.	2.7.5	sec
Clotting time blank	acc. to Ph. Eur.	2.7.5	< 60 sec
Clotting time for 1 IU Heparin/mL	acc. to Ph. Eur.	2.7.5	sec

Reconstituted Plasmasubstrate corresponds to Plasmasubstrate R1 according to Ph. Eur..

**Reconstitution**

1. Add 30 mL of purified water
2. Gently swirl, do not shake the solution
3. Let set for 30 minutes at a temperature between 20°C – 25°C
4. Gently swirl again and let set for a few minutes
5. Repeat step 4 until the lyophilisate is completely dissolved
6. Use immediately after reconstitution according to Ph. Eur.

<b>Primary packing</b>	<b>: certified injection-bottles, glas type 1 (Ph.Eur. 3.2.1)</b>
<b>Storage</b>	<b>: 2°C -8°C</b>
<b>Durability</b>	<b>: 3 years</b>