



IQPP Donor Fluid Administration Standard

Version 1.0



Background

The IQPP Donor Fluid Administration Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Committee, and was approved by the PPTA Source Board of Directors on April 14, 2016.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.

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1. Introduction

The ability to manufacture and provide life-saving plasma protein therapies is dependent on the generous donations of quality plasma from committed, healthy plasma donors. The health and safety of donors is of the highest importance.

IQPP-certified plasma centers have in place a program to administer fluids as part of the donation process. This voluntary standard was developed to enhance donor safety by assisting donors in sustaining hydration on the day of donation.

This IQPP Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

2. Scope

This standard applies to facilities that collect Source Plasma.

3. Purpose

Plasma donation is a safe procedure which is enhanced by administration of fluids to the donor as part of the donation process. This standard establishes a requirement for centers to have a policy to assist the plasma donor in expediting the return of fluid balance.

4. Requirements

4.1. Fluid Administration

4.1.1 Administer a minimum of 250 mL of 0.9% sodium chloride solution (NaCl; saline) intravenously to donors as part of the automated plasmapheresis process.

NOTE: In the United States, industry practice is to use 500 mL of 0.9% NaCl when available.

4.1.2 When administration of intravenous NaCl 0.9% is not possible (including but not limited to examples of donors with limited venous access, donor reported complications with NaCl 0.9%, shortage of available NaCl 0.9% solution in the market), administer either:

- a minimum of 250 mL of an oral electrolyte solution that contains sodium, or
- a combination of intravenous NaCl 0.9% and an oral electrolyte solution that contains sodium. The total quantity administered shall be, at minimum, 250 mL.



4.1.3 If oral fluids are administered, the facility shall take measures to facilitate the successful consumption of the fluids by the donor within the center premises, in accordance with a method documented in the facility's SOPs.

4.2. Education

Centers shall educate donors on the importance of fluid administration and maintaining appropriate hydration pre- and post- donation.

NOTE: See also the IQPP Donor Education Standard for requirements in general related to donor education.

5. Audit and Compliance Verification

5.1. During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Standard. They shall then review the procedures for compliance with the Standard.

5.2. During the IQPP Plasma Center Audit, the auditor shall observe that the company's SOPs are followed.