



U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

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Notice to Purchasers of USP Prednisone Tablets Lot P11300 Concerning Relabeling

On March 1, 2010, USP released Prednisone Tablets Lot P11300 replacing the previous Lot numbered P0E203.

USP's Prednisone Tablets are similar to other USP reference materials in that they have an assigned value. Other reference materials typically have an assigned value that reflects content. In contrast, the assigned value for Prednisone Tablets is the acceptance range that is derived from a collaborative study.

USP conducted the collaborative study for Lot P11300 in 2009. The study not only resulted in a new acceptance range but also assessed a new approach for the evaluation of performance verification test results. For these reasons, USP made Lot P11300 a continuation lot. Following customary practice, USP renumbered the continuation lot from P0E203 to P11300 but kept the letter P to indicate that it was from the same manufactured batch. Again in accordance with customary practice, the continuation lot should fully replace the prior lot. To assist customers in avoiding excess stocks of Lot P0E203, USP provided two early announcements of its plans, on January 18, 2010, and February 9, 2010.

USP relabeled continuation Lot P11300 prior to its release into commerce. USP did this by removing the existing label with as little handling as possible. Some customers have reported seeing remnants of adhesive and paper from the prior label on some bottles of the continuation lot. USP assures customers that this does not mean that the new continuation lot is damaged or defective in any way.

Prior announcements regarding USP Dissolution Performance Verification Testing appear on USP's Web site at: <http://www.usp.org/goto/pvt>

**Headquarters**

12601 Twinbrook Parkway  
Rockville, Maryland 20852  
+1-301-881-0666

**Europe/Middle East/Africa**

Münchensteinerstrasse 41  
CH-4052 Basel, Switzerland  
+41 (0)61 316 30 10

**USP-India Private Limited**

ICICI Knowledge Park  
Genome Valley  
Labs 7-10, Phase III  
Turkapally, Shameerpet  
Ranga Reddy District  
Hyderabad 500 078, A.P., India  
+91-40-2348-0088

**USP-China**

Building 11  
Lane 67 Libing Road  
Zhangjiang Hi-Tech Park  
Shanghai, 201203, China  
+86-21-51370600

**USP-Brazil**

Avenida Ceci, 1600 - Tamboré  
Barueri/SP, Brazil  
06460-120  
+55-11-3245-6400

Richard Wailes  
Vice President, Sales and Marketing

William F. Koch, Ph.D.  
Chief Standards Acquisition and Metrology Officer