



FINAL REPORT

**Sino-implant (II) Initiative: 2011 Quality Assurance Evaluation**

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FHI 360

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# Final Report

## Sino-implant (II): 2011 Quality Assurance Evaluation

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## **Executive Summary**

A quality assurance evaluation and monitoring program was implemented by FHI to verify that Sino-implant (II) meets lot release specifications for the product. This report expands on the results obtained after the quality assurance evaluation and monitoring program conducted in 2008, 2009 and 2010.

Commercial lot release testing verification was conducted for all nine lots of Sino-implant (II) that were shipped to countries as part of the Sino-implant (II) introduction in developing countries. In all instances results were in compliance with Sino-implant (II) lot release specifications (Table 1).

A more extensive battery of tests was conducted to evaluate if Sino-implant (II) meets international quality standards. The battery of tests selected was based on standards from the United States Pharmacopeia (USP), British Pharmacopeia (BP), International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM). Sino-implant (II) samples tested met the quality requirements for all tests conducted (Table 1).

We conclude that Shanghai Dahua Pharmaceutical Co., Ltd continues to demonstrate the ability to consistently produce a contraceptive implant that meets international quality standards.

**Table 1. Summary of the quality assurance evaluation of Sino-implant (II)**

Test	Lot #	Results	
<b>Quality Assurance Monitoring of Sino-implant (II)</b>			
Sino-implant (II): Commercial Lot Release Testing Verification <sup>a</sup>	11092010	Met requirements	
	02102011		
	03252011		
	04122011		
	05092011		
	05262011		
	06132011		
08092011			
10262011			
<b>Annual Quality Assurance Evaluation of Sino-implant (II)</b>			
Levonorgestrel: Active Ingredient Quality Assurance Evaluation	Levonorgestrel: China Pharmacopeia Evaluation <sup>a</sup>	ZQ201101014 ZQ201101015 ZQ20100018-3	Met requirements
	Levonorgestrel: British Pharmacopeia Evaluation <sup>c</sup>		Met requirements
Sino-implant(II) : Final Product Quality Assurance Evaluation	Sample Lot Release Verification <sup>a</sup>	01122010 11092010 16122010	Met requirements
	Ethylene Oxide Residuals Evaluation <sup>b</sup>		Met requirements
	Inorganic Impurities Evaluation <sup>c</sup>		Met requirements
	Residual Solvents Evaluation <sup>d</sup>		Met requirements
	Bacterial Endotoxin Evaluation <sup>b</sup>		Met requirements
	Cytotoxicity Evaluation <sup>b</sup>		Met requirements
Sino-implant(II) : Packaging Material Evaluation	Packaging Physicochemical Evaluation <sup>b</sup>	(09-1143)-10-22-1 (11-0719A)-11-9-22-1 (11-0719)-11-8-21-1	Met requirements
	Sino-implant (II): Package Integrity Evaluation <sup>b</sup>	01122010 11092010 16122010	Met requirements

<sup>a</sup> Conducted by SGS Life Sciences Division, Shanghai, China

<sup>b</sup> Conducted by Nelson Laboratories, Inc., Salt Lake City, UT

<sup>c</sup> Conducted by EAG-Life Sciences, Maryland Heights, MO

<sup>d</sup> Conducted by Irvine Pharmaceutical Sciences, Irvine, CA

<sup>e</sup> Conducted by Lancaster Laboratories, Lancaster, PA