



FINAL REPORT

Sino-implant (II) Initiative: 2013 Quality Assurance Evaluation

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Submitted by:

FHI 360

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Table of Contents

Final Report	ii
Executive Summary	iv
Introduction.....	1
Section I: Quality Assurance Monitoring of Sino-implant (II).....	2
Brief Description of Sino-implant (II) Commercial Lot Release Testing	2
Results of Sino-implant (II) Commercial Lot Release Verification	3
Conclusion of 2013 Quality Assurance Monitoring of Commercial Lots of Sino-implant (II)	3
Section II: Annual Quality Assurance Evaluation of Sino-implant (II)	4
Levonorgestrel: Active Pharmaceutical Ingredient (API) Quality Assurance Evaluation	4
Levonorgestrel CP Evaluation	4
Levonorgestrel BP Evaluation	5
Conclusion of Levonorgestrel: Active Ingredient Quality Assurance Evaluation.....	7
Sino-implant (II): Final Product Quality Assurance Evaluation.....	8
Sino-implant (II) Sample Lot Release Verification	8
Ethylene Oxide Residuals Evaluation.....	9
Inorganic Impurities Evaluation	10
Residual Solvents Evaluation	14
Bacterial Endotoxin Evaluation	15
Cytotoxicity Evaluation	16
Sino-implant (II): Packaging Material Evaluation.....	17
Packaging Physicochemical Evaluation	17
Package Integrity Evaluation	18
Section III: Summary of Results of the 2013 Comprehensive Quality Assurance Evaluation	19

Tables

Table 1. Summary of the quality assurance evaluation of Sino-implant (II).....	v
Table 2. Sino-implant (II) commercial lot release verification test results.....	3
Table 3. Levonorgestrel: lot release verification test results analyzed using the Chinese Pharmacopeia monograph.....	5
Table 4. Levonorgestrel: lot release verification test results analyzed using the BP monograph by Lancaster Laboratories.....	6
Table 5. Sino-implant (II) sample lot release verification results.....	8
Table 6. Ethylene oxide residuals test results of Sino-implant (II).....	9
Table 7. ICP-MS test results of Sino-implant (II) and Jadelle™: USP inorganic impurities (Heavy Metals).....	12
Table 8. ICP-MS test results of Sino-implant (II) and Jadelle™: additional inorganic impurities.	13
Table 9. Residual solvents test results of Sino-implant (II).....	14
Table 10. Limulus Amebocyte Lysate (LAL) Test (Kinetic Turbidimetric Technique) test results of Sino-implant (II).....	15
Table 11. MEM elution test results of Sino-implant (II).	16
Table 12. Physicochemical test results of Sino-implant (II) packaging film.....	17
Table 13. Bubble emission test results of Sino-implant (II).	18
Table 14. Comprehensive tabulated summary of the quality assurance results of Sino-implant (II) tests conducted.....	19

Executive Summary

A quality assurance evaluation and monitoring program was implemented by FHI 360 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 from 2008 to 2012.

Commercial lot release testing verification was conducted for all six 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). With exception to one (1) newly refined 2013 BP standard, the Sino-implant (II) samples tested met the quality requirements for all tests conducted (Table 1).

In working to meet all international quality standards, we are currently undergoing the qualification of a new API supplier to ensure the more stringent 2013 BP specification can be met.

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

Test	Lot #	Result	
Quality Assurance Monitoring of Sino-implant (II)			
Sino-implant (II): Commercial Lot Release Testing Verification ^a	01082013 01212013 05072013 05282013 06302013 09152013	Met requirements	
Annual Quality Assurance Evaluation of Sino-implant (II)			
Levonorgestrel: Active Pharmaceutical Ingredient Quality Assurance Evaluation	Levonorgestrel: China Pharmacopeia Evaluation ^a	ZQ20120012 ZQ20130002 ZQ20130003	Met requirements
	Levonorgestrel: 2011 British Pharmacopeia Evaluation ^c		Met requirements
	Levonorgestrel: 2013 British Pharmacopeia Evaluation ^c		Met requirements with exception of related substances
Sino-implant(II) : Final Product Quality Assurance Evaluation	Sample Lot Release Verification ^a	10112012 07102012 20102012	Met requirements
	Ethylene Oxide Residuals Evaluation ^b		Met requirements
	Inorganic Impurities Evaluation ^c		Met requirements
	Residual Solvents Evaluation ^d		Met requirements
	Bacterial Endotoxin Evaluation ^b		Met requirements
	Cytotoxicity Evaluation ^b		Met requirements
Sino-implant(II) : Packaging Material Evaluation	Packaging Physicochemical Evaluation ^b	11-0719A-1-11-9-22-1 11-0719-11-8-23-1	Met requirements
	Sino-implant (II): Package Integrity Evaluation ^b	10112012 07102012 20102012	Met requirements

^a Conducted by SGS Life Sciences Division, Shanghai, China

^b Conducted by Nelson Laboratories, Inc., Salt Lake City, UT

^c Conducted by SGS Life Sciences Division, Lincolnshire, IL

^d Conducted by Irvine Pharmaceutical Sciences, Irvine, CA

^e Conducted by Lancaster Laboratories, Lancaster, PA