Quality evaluation of Sino-implant (II)

KEY FACTS

FHI 360 has over 20 years of experience testing products to ensure the distribution of high-quality public health commodities.

A baseline quality profile has been established for Sino-implant (II), which will serve as the backbone for continued evaluation of the product through 2014.

To date, Sino-implant (II) quality-testing activities have shown that the product manufacturer, Shanghai Dahua Pharmaceutical Co., Ltd., is capable of producing an implant that meets international quality standards.

Sino-implant (II), a subdermal two-rod implant, has been available in China for more than 15 years and is also available in a growing number of African, Asian and Latin American countries. With support from the Bill & Melinda Gates Foundation, FHI 360 has developed and implemented an independent quality testing program for Sino-implant (II) to provide additional evidence of product quality. One cornerstone of this effort is an extensive annual evaluation of Sino-implant (II) to assess product quality and verify that it meets international quality standards.

Ongoing product quality evaluation

To assess the quality of Sino-implant (II), a quality evaluation and monitoring program was designed and implemented starting in 2008. The evaluation program includes an annual battery of tests to assess

- Aspects of the active ingredient, levonorgestrel
- The quality of the final product (to detect the level of elements/substances that are part of the implant and to predict how the body will react to product contact)
- Packaging components

This in-depth testing is based on standards set forth in the United States and British Pharmacopeias and by the ASTM and the International Organization for Standardization (ISO).

Monitoring activities also include independent lot-release testing of commercial lots. Based on standards approved by the China State Food and Drug Administration (SFDA), these tests address identification, content level and release rates of the active ingredient, as well as product sterility.

Manufacturer information

Shanghai Dahua Pharmaceutical Co., Ltd. (commonly known as Dahua) is registered by the SFDA and designated by the National Population and Family Planning Commission of China for the manufacture of contraceptive products. The current manufacturing facility opened in 2004 and was specifically designed and built to meet Good Manufacturing Practice (GMP) standards. In addition, the manufacturing facility was

- Built specifically for the manufacture of contraceptive implants
- GMP certified by the People's Republic of China
- ISO 9001 and ISO 13485 certified by NQA, an international certification organization in the United Kingdom

Over eight million units of Sino-implant (II) have been distributed since 1994.

Good Manufacturing Practices

The Dahua facility is deemed to be in compliance with the World Health Organization's GMP standards. This determination and other independent audits, in combination with successful inspections by national drug regulatory authorities prior to approval, are evidence of Dahua's commitment to maintaining a high-quality manufacturing facility.

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Summary of product quality evaluation activities 2008–2013

The results from the first six years of the laboratory testing program (2008–2013) showed that Dahua demonstrates the ability to produce a contraceptive implant that meets international quality standards.[1]

Test	Number of Lots						Results
	2008	2009	2010	2011	2012	2013	
Quality Monitoring Activities							
Verification that each lot of Sino-implant (II) meets the requirements specified by the regulatory authority.	10	3	4	9	8	6	Met requirements
Annual Quality Evaluation							
Specifications for levonorgestrel content	3	3	3	3	3	3	Met requirements with 1 exception in 2013[1]
Evaluation of residuals remaining after the sterilization process	3	3	3	3	3	3	Met requirements
Evaluation of levels of metal elements	3	3	3	3	3	3	Met requirements
Evaluation of residual levels of solvents utilized during the manufacturing process	3	3	3	3	3	3	Met requirements
Tests to identify the presence of possible bacterial components	3	3	3	3	3	3	Met requirements
Tests to predict how the body will react to product contact	3	3	3	3	3	3	Met requirements
Tests to ensure that the package is sealed appropriately	3	3	3	3	3	3	Met requirements
Tests to show that the package can be used in contact with the product	1	1	2	3	3	2	Met requirements

Source: FHI 360. Sino-implant (II) Initiative: quality assurance evaluation. Durham, NC: Unpublished final reports; 2008–2013.

For more information, please email: sino_implant@fhi360.org.

[1] The battery of tests used 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). Prior to 2013, all requirements were met for Sino-implant (II) for all tests conducted. In 2013, the BP standard was changed to include more strict specifications. With the exception of a related substance test for the newly refined 2013 BP standard, the Sino-implant (II) samples met the quality requirements for the tests conducted in 2013.