

M14-4

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Pfizer Asia Manufacturing Pte Ltd
Clean Tech One
1 Clean Tech Loop, #04-07
Singapore 637141



Pfizer Global Supply

CERTIFICATE OF ANALYSIS REFERENCE STANDARD

Medroxyprogesterone Acetate
LOT 110406-QCS

Purity: 99.7% Medroxyprogesterone Acetate when used as is

Re-certification Date: Jun 2018

Storage Conditions: 15°C-30°C (CRT)

PARAMETER	RESULT	VALUE USED IN ASSIGNMENT BASIS
Appearance	White to off-white powder	N/A
Loss on Drying	0.1%	0.1%
Identification – IR	Meets test	N/A
Related Compounds - HPLC	0.2%	0.2%
Identification – HPLC	Meets test	N/A

Assignment Basis: CMB: 100% - %LOD - %HPLC impurities

Compendial Comparison: Compares to Medroxyprogesterone Acetate USP lot I1K073


Notes: Bottles are labeled 110406-QCS-XX, where XX represents the subdivision.
Source lot for this material is Kalamazoo, MPY11001K.

Manufacture Date: June 2011

Prepared by:


Global Reference Standards
12-Mar-2015
Date

Approved by:


Quality Assurance
13-MAR-2015
Date



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Next Page Contains Certificate of Compliance
A Certificate of Compliance demonstrates that
Pfizer Quality Control Reference Standard
Meets Japanese Reference Standard Specifications

Signature



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Pfizer Inc
Eastern Point Road
Groton, Connecticut 06340-8257



Pfizer Global Manufacturing

CERTIFICATE OF COMPLIANCE

REFERENCE STANDARD

Medroxyprogesterone Acetate
LOT 110406-QCS

Japanese registration specifications for the reference standard of Medroxyprogesterone Acetate.

TEST OR ASSAY	SPECIFICATION	RESULT
Assay (HPLC)	NLT 99.0%	meets test
Identification – IR	Confirm	meets test

Prepared by:

12-Mar-2015

Global Reference Standards

Date

Approved by:

13-MAR-2015

Quality Assurance

Date

