



P61-1

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

WRS P61-1

Pfizer Global Supply
CERTIFICATE OF ANALYSIS
REFERENCE STANDARD

Palbociclib
LOT 160041-QCS

Purity: 0.993 Palbociclib when used as is.

Re-certification Date: May 2018

Storage Condition: 15°C-30°C (CRT)

PARAMETER	RESULT
Appearance	Yellow powder
HPLC - Identification	RT consistent with structure
HPLC - Minor Substances (anisole)	0.27% w/w
HPLC - Minor Substances (indiv unspec imp)	NMT 0.05%
HPLC - Minor Substances (PF-00310864)	NMT 0.05%
HPLC - Minor Substances (PF-00447880)	0.14%
HPLC - Minor Substances (PF-00710042)	NMT 0.05%
HPLC - Minor Substances (PF-06651464)	0.07%
HPLC - Minor Substances (total imps)	0.21%
Minor Substances - GC (n-butanol)	0.21% w/w
Minor Substances - GC (n-heptane)	NMT 0.05% w/w
Residue on Ignition (<281>)	NMT 0.05%

Assignment Basis:

CMB: 100% - %HPLC impurities - %GC solvents - % Water - % ROI - % Anisole, supported by HPLC assay

Notes: Bottles are labeled 160041-QCS-XX, where XX represents the subdivision.
Source lot for this material is Pfizer, GR06533.

Manufacture Date: August 2012

Prepared By:

Mark P. ... 06 APR-2017

Global Reference Standards

Date

Released By:

Cellay Cla 11-APR-2017

Quality Assurance

Date



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



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CERTIFICATE OF COMPLIANCE REFERENCE STANDARD

Palbociclib
LOT 160041-QCS

Japanese registration specifications for the reference standard of Palbociclib:

TEST OR ASSAY	SPECIFICATION	RESULT
Appearance	Yellow to orange powder	Meets test
Identification - IR	Per compendial requirements	Meets test
Identification - H-NMR	Per compendial requirements	Meets test
Water - KF	NMT 0.5%	Meets test
HPLC - Minor Substances (Anisole)	NMT 0.5%	Meets test
HPLC - Minor Substances (PF-00310864)	NMT 0.15%	Meets test
HPLC - Minor Substances (PF-00447880)	NMT 0.5%	Meets test
HPLC - Minor Substances (PF-00710042)	NMT 0.4%	Meets test
HPLC - Minor Substances (PF-06651464)	NMT 0.15%	Meets test
HPLC - Minor Substances (Unspecified)	NMT 0.15% each	Meets test
HPLC - Minor Substances (Total Impurities)	NMT 1%	Meets test

Prepared by:

Mark Pittard 09 APR 2017
Global Reference Standards Date

Approved by:

Ailay Cla 11-APR-2017
Quality Assurance Date



