

Bureau of Laboratory Quality Standards Ministry of Public Health

This is to certify that

The Reference Material Producer of
Reference Standard Center, Bureau of Drug
and Narcotic, Department of Medical Sciences
88/7 Moo 4 Tiwanon Road, Talat Khwan,
Mueang Nonthaburi, Nonthaburi 11000, Thailand

has been accepted as an accredited reference material producer
complying with the ISO 17034:2016
and the requirement of the Bureau of Laboratory Quality Standards.

The reference material producer has been accredited for reference material listed in the scope within the field of

Pharmaceutical Reference Material Producer

(Mr.Surasak Muenphon)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation: 21 September 2023

Valid Until : 20 September 2027 Accreditation Number 7003/66

The reference material producer of Reference Standard Center, Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited reference material producer in the field of pharmaceutical reference material for the following scopes.

No.	Type * (CRM / RM)	Matrix / Artefact	Property / Value(s) / Identity / Characterization range	Approach ** used to assign property values
1.	CRM	Amlodipine besylate: Pure organic compound, - Solid form (white, crystalline powder), - Pharmaceutical material	$> 990 \pm 5 \mu g/mg$ of amlodipine besylate (as is basis) Measurement uncertainty (MU) at 95% confidence level (coverage factor, $k=2$)	Characterization of a non-operationally defined measurand using competent laboratories.

* Type

CRM = Certified Reference Material(s)

RM = Reference Material(s)

Reference to ISO 17034:2016 clause 3.2 and 3.3 for full definitions.

** Approach used to assign property values

Reference to ISO 17034:2016 clause 7.12.3 Note 1 (b).

Bureau of Laboratory Quality Standards

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Reviewed by Head of Laboratory Accreditation Section.....

Savonse Aromsook)