COPY No. 1

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : S(-) Amlodipine besilate hemipentahydrate (Item No. 41010105)	**Spec. No.** : SP-AK30-A54/1
Reference(s) : In-house specification	**Rev. No.** : 01
Other Requirements : ——	**Page** : 1/2

GPO specification

Test Items	Specification	
Description	White to pale yellow powder.	
Solubility	Freely soluble in methanol, very slightly soluble in isopropyl alcohol.	
Identification A. Infrared absorption B. HPLC	Conforms to standard IR spectrum. The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the assay.	
Sulfated ash	Not more than 0.1%.	
Specific optical rotation	-24.0° to -28.0°, on anhydrous basis.	
Water	Not more than 8.0% w/w.	
Chiral Purity	S-isomer	: Not less than 98.0%.
	R-isomer	: Not more than 2.0%.
Related compounds	Impurity D	: Not more than 0.3%.
	Unspecified individual impurity	: Not more than 0.1%.
	Total impurities excluding impurity D	: Not more than 0.3%.
Assay	98.0% - 102.0% of $C_{26}H_{31}ClN_2O_8S$, calculated on the anhydrous basis.	
Dimethyl formamide content	Not more than 880 ppm.	
Residual solvents	Acetone	: Not more than 5000 ppm.
	Isopropyl alcohol	: Not more than 5000 ppm.
	Cyclohexane	: Not more than 3880 ppm.

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ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sunannee 05/10/17	09/10/17	09/10/17	17/10/17	28/10/17
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

COPY No. 2

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RAW MATERIAL SPECIFICATION

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of S(-) Amlodipine besilate hemipentahydrate (Item No. 41010105).
Sampling plan	P plan : for Identification $\sqrt{N}+1$: for other tests
Testing procedure	Tests to be performed as per current version of WI-AK30-A54/1.
Storage condition	Preserve in well-closed containers. Store at controlled room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	First issue, อ้างอิง GPO specification โดยเนื้อหาทางสถาบันวิจัยฯอ้างอิงข้อมูลบริษัท Emcure Pharmaceutical Co, Ltd/ India และเป็น spec ที่ใช้ยื่นขึ้นทะเบียน	28/10/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee 05/10/17 Head of Raw Material Standard Section 1	Yuwayon 09/10/17 Director of Raw Material Standard Division	VARIN 09/10/17 Director of Regulatory Compliance and Documentation Division	Vichien Kumpongsuj 17/10/17 (Acting) Director of Quality Assurance Department	28/10/17