

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

**Title :** Liquorice Extract in Block (Item No. 41021980)

**Spec. No. :** SP-AK30-L2

**Reference(s) :** GPO specification

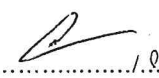
**Rev. No. :** 04

**Other Requirements :** GPO specification

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### GPO specification

Test Items	Specification
Description	Black, solid mass, characteristic odour.
Identification (HPLC)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Glycyrrhizic acid.
Loss on drying	Not more than 11.0% w/w.
18 $\beta$ -Glycyrrhizic acid	Not less than 2.0% w/w of 18 $\beta$ -glycyrrhizic acid, calculated on the dried basis.
Colour of aqueous extract	Dark brown to black viscous liquid; homogeneous mass.
Ochratoxin A	Not more than 80 $\mu$ g per kilogram of extract.

Prepared by : Benjawan Ubonklee / 06/05/21 Head of Raw Material Standard Section 2	Reviewed by : (Acting) Sundanee / 06/05/21 Director of Raw Material Standard Division	 / 07/05/21 Director of Regulatory Strategy Division	Approved by : (Acting) Tawee Lumbant / 19/05/21 Director of Quality Assurance Department	Eff. Date 31/05/21
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### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Liquorice Extract in Block (Item No. 41021980).
Sampling plan	1. N Plan ( $\sqrt{N} + 1$ ) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-L2.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers. Protect from direct sunlight.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective date
01	จัดทำเอกสาร โดยอ้างอิงตาม GPO specification และ BP 1993	21/05/1998
02	Update โดยอ้างอิงตาม GPO specification และ BP 2009	19/10/2009
03	Update โดยอ้างอิงตาม GPO specification	25/10/2018
04	1) Update โดยอ้างอิงตาม GPO specification และ BP 2020 ( Monograph Liquorice และ Liquorice Dry Extract for Flavouring Purpose) โดยมีการเพิ่มหัวข้อ Ochratoxin A และยกเลิกหัวข้อ Alcohol content และ Total solid 2) เปลี่ยนชื่อหัวข้อจาก Glycyrrhizic acid เป็น 18 $\beta$ -Glycyrrhizic acid เพื่อให้เกิดความชัดเจน	31/05/2021

Prepared by : Benjawan Ubonklee, 06/05/21 Head of Raw Material Standard Section 2	Reviewed by : Sunwannee (Acting) Sunwannee, 06/05/21 Director of Raw Material Standard Division	Approved by : (Acting) Tinnakorn Luvitwong, 07/05/21 Director of Quality Assurance Department	Eff. Date 31/05/21
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