

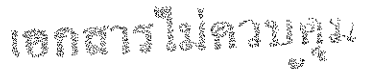
THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Butylated Hydroxyanisole USP (Item No. 41010175)	Spec. No. : SP-AK30-B27
Reference(s) : USP 37 p. 5881-5882	Rev. No. : 03
Other Requirements : -	Page : 1/2

USP 37

Test Items	Specification
Description	White or slightly yellow, waxy solid, having a faint, characteristic odor.
Solubility	Freely soluble in alcohol, in propylene glycol, in chloroform and in ether; insoluble in water.
Identification	
A. Chemical test	A blue color is produced.
B. HPLC	The retention times of 3-ter-butyl-4-hydroxyanisole and 2-ter-butyl-4-hydroxyanisole from the Sample solution correspond to those from the Standard solution, as obtained in the Assay.
Residue on ignition	Not more than 0.01%, determined on a 10-g specimen.
Heavy metals	Not more than 10 ppm, Method II.
Assay	Not less than 98.5% of $C_{11}H_{16}O_2$.


 30/06/17

Prepared by : Suriyanee, 01/02/17 Head of Raw Material Standard Section 1	Reviewed by : Yunaporn, 06/02/17 Director of Raw Material Standard Division	Reviewed by : Vichien Rungwong, 06/02/17 Director of Regulatory Compliance and Documentation Division	Approved by : B. Cee, 07/02/17 Director of Quality Assurance Department	Eff. Date 30/06/17
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Butylated Hydroxyanisole USP (Item No. 41010175).
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-B27.
Storage condition	Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	Up spec เป็น USP 37	31/07/14
03	เนื่องจากเอกสารมีอายุ 3 ปีจำเป็นต้องทบทวน โดยยังคง spec USP 37 เหมือนเดิม	30/06/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sungmee., 01/02/17 Head of Raw Material Standard Section 1	Reviewed by : Yunaporn., 06/02/17 Director of Raw Material Standard Division	Vichien Rungwongroj., 06/02/17 Director of Regulatory Compliance and Documentation Division	Approved by : B. Cee 07/02/17 Director of Quality Assurance Department	Eff. Date 30/06/17
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