COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Butylated Hydroxyanisole USP (Item No. 41010175)	**Spec. No.**	: SP-AK30-B27
Reference(s) : USP 43/NF 38 p. 5651-5652	**Rev. No.**	: 04
Other Requirements : GPO specification	**Page**	: 1/2

USP 43/NF 38

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. Spectroscopic Identification Tests <197A> B. HPLC	Conforms to IR standard spectrum. The retention times of the main peak of the Sample solution corresponds to that of the Standard solution. The chromatographic profile of the Sample solution should be similar to that of the Standard solution and exhibit only 1 major peak corresponding to butylated hydroxyanisole.
Residue on ignition	Not more than 0.01%, determined on a 10-g specimen.
Assay	Not less than 98.5% of $C_{11}H_{16}O_2$, as a sum of the two isomer.

GPO specification

Test Items	Specification
Heavy metals	Not more than 10 ppm, Method II.

Prepared by :	Reviewed by :		Approved by :	Eff. Date
(Acting) 07/06/21	(Acting) 07/06/21	08/06/21	(Acting) 09/06/21	01/08/21
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	

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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	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-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 ปี จำเป็นต้องทบทวน โดยยังคง spec USP 37 เหมือนเดิม	30/06/17
04	Update spec. เป็น USP 43 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรายา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป นอกจากนี้เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน	01/08/21

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