

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

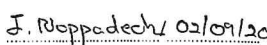
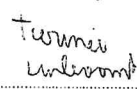

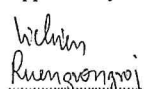
Title: Ammonium Carbonate NF (Item No. 41020100)	Spec. No. : SP-AK30-A12
Reference(s): USP 41/NF 36 page 5200 - 5201	Rev. No. : 09
Other Requirements: GPO Specification	Page : 1/2

USP 41/NF 36

Test Parameters	Requirement
Description	White powder, or hard, white or translucent masses, having a strong odor of ammonia, without empyreuma, and a sharp, ammoniacal taste.
Solubility	Freely soluble in water.
Identification	When heated, it is volatilized without charring, and the vapor is alkaline to moistened litmus paper. A solution (1 in 20) effervesces with acids.
Residue on ignition	Not more than 0.1%.
Chloride	Not more than 0.0035%.
Sulfate	Not more than 0.005%.
Assay	30.0% – 34.0% of ammonia (NH ₃).

GPO Specification

Test Parameter	Requirement
Heavy metals	Not more than 10 ppm.
Packaging	In an air tight and well-closed container.
GPO's receiving date	The receipt date of raw material at the GPO warehouse must be within 1 year 6 months after the raw material's manufacturing date.

Prepared by:  J. Ruppadech 02/09/20 Head of Raw Material Standard Section 2	Reviewed by: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">  Director of Raw Material Standard Division </div> <div style="width: 45%;">  Director of Drug Registration and Pharmacovigilance Division </div> </div>	Approved by:  Ruengrongroj 10/09/20 Director of Quality Assurance Department	Eff. Date 15/09/20
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Ammonium Carbonate NF (Item No. 41020100).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-A12.
Storage condition	Store at a condition stated on the label from the manufacturer or store at a temperature not above 30 °C. Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
07	Update ข้อกำหนดตาม USP 38/NF 33 และ GPO Specification	20/06/17
08	ทบทวนข้อกำหนด โดย GPO's receiving date เปลี่ยนจาก "The receipt date of raw material at the GPO warehouse must be within 1 year after the raw material's manufacturing date." เป็น "The receipt date of raw material at the GPO warehouse must be within 1 year 6 months after the raw material's manufacturing date."	28/02/18
09	Update ข้อกำหนดตาม USP 41/NF 36 และ GPO Specification ตามที่ได้รับแจ้งจากแผนกทะเบียนยา	15/09/20

Prepared by: J. Doppdech 02/09/20 Head of Raw Material Standard Section 2	Reviewed by: Tawee Limkham, 02/09/20 Director of Raw Material Standard Division	Approved by: Jichin Ruengvongroj 10/09/20 Director of Quality Assurance Department (Aching)	Eff. Date 15/09/20
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