

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

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|---|--------------------------------|
| Title: Disodium Edetate BP (Item No. 41031780) | Spec. No : SP-AK30-D004 |
| Reference(s) : BP 2018 p. I-829 to I-830 | Rev. No : 03 |
| Other Requirements : GPO Specification | Page : 1/2 |

BP 2018

| Test Items | Specification |
|---|--|
| Description | White or almost white, crystalline powder, odourless. |
| Solubility | Soluble in water, practically insoluble in 96% ethanol. |
| Identification | |
| - Infrared absorption spectrophotometry | Conforms to FT-IR standard spectrum. |
| - Chemical Test | No precipitate is formed. |
| - Sodium Test | A dense white precipitate is formed. |
| Appearance of solution | Solution S is clear and colourless. |
| pH | 4.0 to 5.5 for solution S. |
| Impurity A | Not more than 0.1%. |
| Iron | Not more than 80 ppm. |
| Assay | 98.5% - 101.0% of $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$. |

GPO Spec

| Test Items | Specification |
|------------|---|
| Packaging | Well-closed containers, original packs from the manufacturer. |

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|---|--|---|-----------------------|
| Prepared by : Sumanee / 24/04/19 Head of Raw Material Standard Section I | Reviewed by : Tarnwan / 25/04/19 Director of Raw Material Standard Division | Approved by : Vichien Rungwongroj / 26/04/19 Director of Regulatory Compliance and Documentation Division | Eff. Date 15/06/19 |
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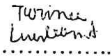

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Product Information

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|---------------------|---|
| Approved source (s) | Refer to current version of Approved Vendor List of Disodium Edetate BP (Item No. 41031780) |
| 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-D004. |
| Storage condition | Protected from light. |
| Retest period | 1 year after first testing date. |

History of changes

| Rev. No. | Description | Effective date |
|----------|---|----------------|
| 01 | อ้างอิง spec. เป็น BP 2012 | 17/01/12 |
| 02 | Update spec. เป็น BP2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2012 และ BP 2016 เหมือนกัน | 24/03/16 |
| 03 | เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2016 และ BP 2018 เหมือนกัน | 15/06/19 |

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| Prepared by :  Suwannee 24/04/19 Head of Raw Material Standard Section I | Reviewed by :  Thirine 25/04/19 Director of Raw Material Standard Division | Approved by :  Wichai 26/04/19 Director of Regulatory Compliance and Documentation Division | Eff. Date 15/06/19 |
|---|--|--|------------------------------|