

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Trifluoperazine Hydrochloride BP (Item No. 41011530) Spec. No. : SP-AK30-T14
 Reference(s) : BP 2016 p. II-1115 to II-1116 Rev. No. : 03
 Other Requirements : - Page : 1/2

BP 2016

| Test Items | Specification |
|------------------------------|--|
| Description | White, crystalline powder, odorless. |
| Solubility | Freely soluble in water, soluble in alcohol. |
| Identification | |
| A. UV Spectrophotometry | Examined between 280 nm and 350 nm, the solution shows an absorption maximum at 305 nm. Examined between 230 nm and 280 nm, the solution shows an absorption maximum at 255 nm. The specific absorbance at this maximum is about 650. |
| B. Thin layer chromatography | Examine under <i>ultraviolet light (365 nm)</i> and observe the fluorescence produced after a few minutes. The spot in the chromatogram obtained with solution (1) is similar in position, colour, fluorescence and size to that in the chromatogram obtained with solution (2). Spray the plate with <i>ethanolic sulphuric acid (10%)</i> and observe the colour produced. The colour of the spot in the chromatogram obtained with solution (1) is the same as that in the chromatogram obtained with solution (2) and has a similar stability over a period of at least 20 minutes after spraying. |
| C. Melting point | The melting point is about 192 °C. |
| D. Chemical Test | A red color develops. |
| E. Chlorides Test | A curdled, white precipitate is formed. |
| pH | Between 1.6 and 2.5. |
| Related substances | Examine in ultraviolet at 254 nm. Any spot in the chromatogram obtained with the test solution, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with the reference solution (0.5%). |
| Loss on drying | Not more than 1.5%. |
| Sulfated ash | Not more than 0.1%, determined on 1.0 g. |
| Assay | 99.0 – 101.0% of $C_{21}H_{26}Cl_2F_3N_3S$, calculated with reference to the dried substance. |

เอกสารนี้เป็นเอกสาร
 ทรัพย์สินของกรม
 ไม่สามารถนำออก

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| Prepared by : Sunanne, 30/05/16 Head of Raw Material Standard Section 1 | Reviewed by : Nalapa, 30/05/16 Director of Raw Material Standard Division | Vithin Kwongroj, 04/06/16 Director of Regulatory Compliance and Documentation Division | Approved by : P. Y. K., 10/06/16 Director of Quality Assurance Department | Eff. Date 23/06/16 |
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Product Information

| | |
|---------------------|---|
| Approved source (s) | Refer to current version of Approved Vendor List of Trifluoperazine HCl BP (Item No. 41011530). |
| 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-T14. |
| Storage condition | Store in an airtight container, protect from light. |
| Retest period | 1 year after first testing date. |

History of changes

| Rev. No. | Description | Effective date |
|----------|---|----------------|
| 02 | Up spec เป็น BP 2012 | 17/12/12 |
| 03 | Up spec เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2012 และ BP 2016 เหมือนกัน | 23/06/16 |

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

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|--|---|--|---|-----------------------|
| Prepared by : Suvannee / 30/05/16 Head of Raw Material Standard Section 1 | Reviewed by : Nalape / 30/05/16 Director of Raw Material Standard Division | Vichin Rungvongroj / 07/06/16 Director of Regulatory Compliance and Documentation Division | Approved by : A. Y. K. / 10/06/16 Director of Quality Assurance Department | Eff. Date 23/06/16 |
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