



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: -

Standard Section 1

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Department

BP 2016

| Specification | | | |
|---|--|--|--|
| White, crystalline powder, odorless. | | | |
| Freely soluble in water, soluble in alcohol. | | | |
| | | | |
| 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. | | | |
| Examine under ultraviolet light (365 nm) 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 ethanolic sulphuric acid (10%) 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. | | | |
| The melting point is about 192 °C. | | | |
| A red color develops. | | | |
| A curdled, white precipitate is formed. | | | |
| Between 1.6 and 2.5. | | | |
| 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%). | | | |
| Not more than 1.5%. | | | |
| Not more than 0.1%, determined on 1.0 g. | | | |
| 99.0 - 101.0% of C ₂₁ H ₂₆ Cl ₂ F ₃ N ₃ S, calculated with reference to the dried substance. | | | |
| | | | |

| Prepared by: | Reviewed by : | \s. 0 / | Approved by : | Eff. Date |
|--|--|---|-------------------------------|-----------|
| SUWONIVE / 30/05/16 Head of Raw Material | Walapay 30 05 116 Director of Raw Material | Vilhing Kwingwngroj /07 (06/16 Director of Regulatory | Director of Quality Assurance | 23/06/16 |

Compliance and Documentation

Division



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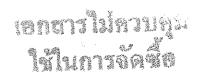
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Product Information

| Refer to current version of Approved Vendor List of Trifluoperazine HCl BP (Item No. 41011530 | | |
|---|--|--|
| P plan : for Identification | | |
| $\sqrt{N} + 1$: for other tests | | |
| Tests to be performed as per current version of WI-AK30-T14. | | |
| Store in an airtight container, protect from light. | | |
| 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 | 23/06/16 |
| | เหมือนกัน | |
| | | |
| | | |



| Prepared by: | Reviewed by: | No. 8. June | Approved by : | Eff. Date |
|----------------------|--------------------------|----------------------------------|-------------------------------|-----------|
| Surannee , 20105/16 | WMape, 30/05/16 | Vichim Ruungvongroj ,07106/16 | A. Yother 10/06/16 | 23/06/16 |
| Head of Raw Material | Director of Raw Material | Director of Regulatory | Director of Quality Assurance | |
| Standard Section 1 | Standard Division | Compliance and Documentation | Department | |
| | | Division | | |