

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Trihexyphenidyl Hydrochloride BP (Benzhexol HCl)
(Item No. 41010150)

Spec. No. : SP-AK30-B4

Reference(s) : BP 2016 p. II-1121 to II-1122 (same as BP 2021)

Rev. No. : 05

Other Requirements : ---

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BP 2016

Test Items	Specification
Description	White or almost white, crystalline powder, odorless.
Solubility	Slightly soluble in water, sparingly soluble in ethanol (96%) and in methylene chloride.
Identification - Infrared absorption spectrophotometry - Chloride Test	Conforms to FT-IR standard spectrum. A curdled, white precipitate is formed.
pH	5.2 to 6.2.
Optical rotation	-0.10° to +0.10°.
Related substances - Impurity A - Unspecified impurity - Total impurities	Not more than 0.5%. Not more than 0.10%. Not more than 0.5%.
Loss on drying	Not more than 0.5%.
Sulfated ash	Not more than 0.1%, determined on 1.0 g.
Assay	99.0 - 101.0% of $C_{20}H_{31}NO \cdot HCl$, calculated on dried substance.

Prepared by : (Acting) Thanyaratana / 04/06/21 Head of Raw Material Standard Section 1	Reviewed by : Suvannee (Acting) / 04/06/21 Director of Raw Material Standard Division	Approved by : (Acting) Tuanee / 04/06/21 Director of Quality Assurance Department	Eff. Date 15/07/21
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Trihexyphenidyl Hydrochloride BP (Benzhexol HCl) (Item No. 41010500)
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-B4.
Storage condition	To be stored in well-closed, light resistance container at temperature below 25°C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	Update spec. เป็น BP 2012	15/02/12
04	Update spec. เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2012 และ BP 2016 เหมือนกัน	23/06/16
05	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2016 และ BP 2021 เหมือนกัน	15/07/21

Prepared by : (Acting) Thanyatorn / 04/06/21 Head of Raw Material Standard Section 1	Reviewed by : (Acting) Sundanee / 04/06/21 Director of Raw Material Standard Division	Approved by : (Acting) Tarnsee / 04/06/21 Director of Quality Assurance Department	Eff. Date 15/07/21
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