



The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER: RPP-SP-QC-RM-060

DOCUMENT TITLE: SPECIFICATION OF TITANIUM DIOXIDE USP (ITEM NO. 44123150)

DOCUMENT NOTES:

Document Information

Revision: 03

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Control Information

Author: NATTAPORN_R

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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	08 Mar 2016
02	- Periodic review and revise specification as per USP40/NF35 (USP40/NF35 is equivalent to USP38/NF33) - Add more content specification of Solubility as per USP40/NF35	05 Mar 2018
03	- Periodic review and revise specification as per USP42/NF37 (USP42/NF37 is equivalent to USP40/NF35) -Revise content specification of Solubility as per USP42/NF37 from "White powder, free from grittiness; odourless." to "White, odorless, tasteless powder." - Revise the content specification of Water-soluble substances from "Not more than 0.25%" to "The residue weighs not more than 5 mg (Not more than 0.25%.)" - Revise the content specification of Acid-soluble substances from "Not more than 0.5%" to "The residue weighs not more than 25 mg (Not more than 0.5%.)"	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description	White, odorless, tasteless powder.
02	Solubility	Insoluble in water, in hydrochloric acid, in nitric acid, and in 2N sulfuric acid. Dissolves in hydrofluoric acid and in hot sulfuric acid.
03	Identification Reaction with hydrogen peroxide TS	A yellow-red to orange-red color develops immediately.
04	Assay	Not less than 99.0% and Not more than 100.5% of titanium dioxide (TiO ₂), calculated on the dried basis.
05	Arsenic (Method I)	Not more than 1 ug/g.
06	Loss on drying	Not more than 0.5%.
07	Loss on ignition	Not more than 0.5%.
08	Water-soluble substances	The residue weighs not more than 5 mg (Not more than 0.25%.)
09	Acid-soluble substances	Not more than 0.5%. The residue weighs not more than 25 mg (Not more than 0.5%.)

B. Packaging and Storage

Preserve in well-closed containers.

C. Reference

According to USP42/NF37, Titanium Dioxide monograph, page 4360-4361.

D. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Titanium Dioxide USP (Item No.44123150).
Sampling plan	Identification: Every container. Other tests : $\sqrt{N} + 1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Titanium Dioxide USP (Item No.44123150).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

Rev03_RMS_TITANIUM DIOXIDE USP (ITEM NO. 44123150)

Step 1. Preparer

Name/Signature	Title	Date	Meaning/Reason
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Step 2. Reviewer

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SUTAN OTAMO (SUTAN_O)	DIRECTOR OF QC DIVISION	26 May 2020, 08:48:24 AM	Approved
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Step 3. Approver

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Step 4. Notify

Name/Signature	Title	Date	Meaning/Reason
DONNAPA PUEKWATTANA (DONNAPA_P)	QA-IT&Doc	27 May 2020, 08:17:35 PM	Email Sent
SIRILUK BUACHAROEN (SIRILUK_B)	HEAD OF IT QUALITY AND DOC SEC	27 May 2020, 08:17:35 PM	Email Sent
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