



The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER: RPP-SP-QC-RM-009

DOCUMENT TITLE: SPECIFICATION OF STARCH 1500 ITEM NO.44122750

DOCUMENT NOTES:

Document Information

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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	SPECIFICATION OF STARCH 1500 (ITEM NO. 44122750)	Rev. 04
DEPARTMENT	QUALITY CONTROL DIVISION	PAGE 1 of 3

REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	19 Mar 2012
02	Revise specification as per USP38/NF33 and Ph.Eur.8.0	30 Sep 2015
03	Periodic review and revise specification as per USP40/NF35 (USP40/NF35 is equivalent to USP38/NF33)	28 Jan 2018
04	Periodic review and revise specification as per USP42/NF37 and Ph.Eur. 10.0 (USP42/NF37 and Ph.Eur. 10.0 are equivalent to USP40/NF35 and Ph.Eur. 8.0, respectively)	As per effective date in electronic system

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	SPECIFICATION OF STARCH 1500 (ITEM NO. 44122750)	Rev. 04
DEPARTMENT	QUALITY CONTROL DIVISION	PAGE 2 of 3

A. Specification

No.	Test parameters	Specifications
01	Description	Fine, white to off white powder, odorless.
02	Solubility	Slightly soluble to soluble in cold water, insoluble in alcohol.
03	Identification A. Examined under a microscope** B. Reaction with iodine solution	It presents irregular, translucent, white or yellowish-white flakes or pieces with an uneven surface. Under polarized light (between crossed nicol prisms), starch granules with a distinct black cross intersecting at hilum may be seen. A water slurry of it is colored orange-red to deep blue by iodine TS.
04	Residue on ignition	Not more than 0.5%.
05	Iron	Not more than 20 ppm.
06	Sulfur dioxide**	Not more than 50 ppm.
07	Microbial enumeration tests and Tests for specified microorganisms a. Total aerobic microbial count (TAMC) b. Total combined molds and yeasts count (TMYC) c. <i>Escherichia coli</i> d. <i>Salmonella species</i>	Not more than 1000 cfu/g. Not more than 100 cfu/g. Absence (1g). Absence (1g).
08	pH	4.5 to 7.0.
09	Loss on drying	Not more than 14.0 % w/w.
10	Oxidizing substances	No distinct blue, brown, or purple color is observed.
11	Foreign matter**	Not more than traces of matter other than starch granules are present.
12	Fineness*	Pass through sieve no.100 : Not less than 90.0%.

* According to GPO In-house specification.

** According to Ph.Eur specification.

B. Packaging and Storage

Preserve in well-closed containers. No storage requirements specified.

C. Reference

- USP 42/NF37, Pregelatinized Starch, page 6001-6002.
- Ph.Eur.10.0, Starch Pregelatinised, page 3891-3892.

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	SPECIFICATION OF STARCH 1500 (ITEM NO. 44122750)	Rev. 04
DEPARTMENT	QUALITY CONTROL DIVISION	PAGE 3 of 3

D. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Starch 1500 (Item No. 44122750).
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 Starch 1500 (Item No. 44122750).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

Rev04_RMS_STARCH 1500 ITEM NO.44122750

Step 1. Preparer

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

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Step 4. Notify

Name/Signature	Title	Date	Meaning/Reason
DONNAPA PUEKWATTANA (DONNAPA_P)	QA-IT&Doc	09 Jun 2020, 09:38:48 PM	Email Sent
SIRILUK BUACHAROEN (SIRILUK_B)	HEAD OF IT QUALITY AND DOC SEC	09 Jun 2020, 09:38:48 PM	Email Sent
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