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The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER: RPP-SP-QC-RM-057

DOCUMENT TITLE: SPECIFICATION OF METFORMIN HYDROCHLORIDE (ITEM NO. 44111000)

DOCUMENT NOTES:

Document Information

Revision: 03

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Control Information

Author: PORANEE_S

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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	2 Mar 2016
02	Change document title from " <i>Specification of Metformin HCl (Abhilash)</i> " to " <i>Specification of Metformin Hydrochloride</i> " (Change-0091)	23 Nov 2016
03	Periodic review	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Appearance ^(§)	White or almost white crystals.
02	Solubility	Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone and in methylene chloride.
03	Identification ^(§) A. By Infrared absorption spectrophotometry B. Chloride test	The absorption maxima in the spectrum obtained with the sample should correspond in position and relative size to those in the spectrum obtained with Metformin hydrochloride reference standard. It gives reaction (a) of chlorides.
04	Appearance of solution	Solution S is clear and colourless.
05	Impurity F ^(§)	Not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.05%).
06	Related substances ^(§) a) Impurity A b) Unspecified impurities c) Total impurities	Not more than the area of the corresponding peak in the chromatogram obtained with reference solution (a) (0.02%). For each impurity, not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05%) Not more than 0.2%.
07	Heavy metals	Not more than 10 ppm.
08	Loss on drying ^(§)	Not more than 0.5%.
09	Sulfated ash	Not more than 0.1%.
10	Assay ^(§)	Not less than 98.5% and not more than 101.0% of Metformin HCl (C ₄ H ₁₂ ClN ₅), calculated on dried substance.
11	Tapped density ^(*)	For information.

* :In-house specification.

\$:Tests to be performed at retesting

B. Storage condition

Preserve in a well-closed containers. Store at room temperature.

C. Reference

BP2016, Metformin Hydrochloride monograph, page 233-235.

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D. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Metformin Hydrochloride (Item No. 44111000).
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 Metformin Hydrochloride (Item No. 44111000).
Retest period	1 year.

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All dates and times are in GMT +7.

SP-QC-RM-057, Metformin rev03**Step 1. Preparer**

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

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NOPPAWAN ANGKULSANSANEE (NOPPAWAN_A)	DIRECTOR OF QC DIVISION	25 Nov 2018, 06:22:14 PM	Approved
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SIRIPUN CHUNLAHAWANICH (SIRIPUN_C)	DIRECTOR OF COMPLIANCE DIV.	05 Dec 2018, 04:21:00 PM	Approved

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SIRILUK BUACHAROEN (SIRILUK_B)	HEAD OF IT QUALITY AND DOC SEC	07 Dec 2018, 05:50:12 PM	Email Sent
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TASSANA PRAWISAT (TASSANA_P)	QA IT&Doc	07 Dec 2018, 05:50:12 PM	Email Sent
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WIMWIPA CHAWENGPAAKDEEWET (WIMWIPA_C)	QA IT&Doc	07 Dec 2018, 05:50:12 PM	Email Sent
WITCHAYA KOSAWANG (WITCHAYA_K)	QA IT&Doc	07 Dec 2018, 05:50:12 PM	Email Sent

Review: RPP-SP-QC-RM-057 03 SPECIFICATION OF METFORMIN HYDROCHLORIDE (ITEM NO.

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44111000)**GPO UNCONTROLLED****Review**

Name/Signature	Title	Date	Meaning/Reason
SUTAN OTAMO (SUTAN_O)	DIRECTOR OF QC DIVISION	08 Nov 2020, 01:57:28 PM	Reviewed
CHALITA THAMNIRAT (CHALITA_T)	HEAD OF QC SECTION 6	11 Nov 2020, 08:33:45 AM	Reviewed
SIRILUK BUACHAROEN (SIRILUK_B)	HEAD OF IT QUALITY AND DOC SEC	11 Nov 2020, 02:24:49 PM	Reviewed