

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Hydrogen Peroxide Solution [50% w/w] (Item No. 41032100)	Spec. No. : SP-AK30-H3
Reference(s): GPO Specification	Rev. No. : 04
Other Requirements: BP 2020 page I-1265 to I-1266 [Hydrogen Peroxide Solution 30% w/w]	Page : 1/2

GPO Specification

Test Parameters	Requirement
Description	Colourless, clear liquid.
Identification	A. The solution becomes colourless with evolution of gas.
	B. To 1 mL, add 0.1 mL of dilute hydrochloric acid R and 0.1 mL of potassium iodide solution. A brown colour appears. Black particles may be formed.
Acidity	To 10 mL, add 100 mL of purified water and 0.25 mL of methyl red solution. Not less than 0.05 mL and not more than 0.5 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator.
Organic stabilisers	The residue weighs not more than 10 mg.
Non-volatile residue	The residue weighs not more than 20 mg.
Assay	48.0% w/w to 51.0% w/w of Hydrogen peroxide (H ₂ O ₂).

Prepared by: <i>J. Ropadech</i> 17/06/20 Head of Raw Material Standard Section 2	Reviewed by: <i>Tarnia</i> <i>Lunlunant</i> , 17/06/20 Director of Raw Material Standard Division	Approved by: <i>Nichin</i> <i>Rungroj</i> , 18/06/20 Director of Quality Assurance Department (Aking)	Eff. Date 15/07/20
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Hydrogen Peroxide Solution [50% w/w] (Item No. 41032100).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-H3.
Storage condition	Store at a condition stated on the label from the manufacturer. Protected from light, and if the solution does <u>not</u> contain a stabiliser, at a temperature below 15 °C (It should not be stored for long period).
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
02	ทบทวนเอกสาร อ้างอิงตาม BP2011 และ GPO Specification	19/08/11
03	ทบทวนเอกสาร โดยอ้างอิงตาม GPO Specification และ BP 2014 [Hydrogen Peroxide Solution 30% w/w]	25/10/16
04	ทบทวนเอกสาร โดยอ้างอิงตาม GPO Specification และ BP 2020 [Hydrogen Peroxide Solution 30% w/w]	15/07/20

Prepared by: S. Neppadetch / 17/04/20 Head of Raw Material Standard Section 2	Reviewed by: Turnia Lunthornwit, 17/06/20 Director of Raw Material Standard Division	Approved by: Vichin Rungvongroj, 18/06/20 Director of Drug Registration and Pharmacovigilance Division Department (Aching)	Eff. Date 15/07/20
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