



COPY No. 6

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

L41021030)

TITLE : Dicloxacillin Sodium Compacted	SPEC. NO. : SP-AQ13-PRD01
REFERENCE(S) : USP36 p.3224-3225	REV. NO. : 08
OTHER REQUIREMENTS : GPO Specification	PAGE : 1/2

USP36

Solubility	Conforms to USP36 (Freely soluble in water)
Identification	Conforms to reference IR spectrum
Crystallinity	Conforms to USP36
pH	Between 4.5 and 7.5, in a solution containing 10 mg/mL
Water	Between 3.0 %w/w and 5.0 %w/w (Method I)
Dimethylaniline	Not more than 0.002 %w/w
Assay	Not less than 850 µg of dicloxacillin ( $C_{19}H_{17}Cl_2N_3O_5S$ ) per mg

GPO Specification

Description	White granules; odour, characteristic
Tapped Density	Not less than 0.75 g/mL
Expiry date	The expiry date is beyond the date of material receipt at GPO warehouse for at least two years and eight months

เชกเกอร์ไม่ควบคุม  
ในการผลิต

Prepared by Kanyaporn, 18/12/14	Reviewed by Vongpa, 18/12/14	Approved by P. P. P., 19/12/14	Eff. Date 02/02/15
Beta-lactam Antibiotic Plant QC Manager	Beta-lactam Antibiotic Plant Manager	Beta-lactam Antibiotic Plant QA Manager	Director of Quality Assurance Department

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Product Information

Fineness (Particle size distribution)	Retained on sieve no. 40 mesh : 47-63 %w/w Passed through sieve no. 100 mesh : Not more than 10 %w/w
Approved source(s)	Refer to current version of Approved Vendor List of Dicloxacillin Sodium Compacted
Sampling plan	$\sqrt{N} + 1$
Testing procedure	Tests to be performed as per current version of WI-AQ13-PRD01
Storage conditions	To be stored in tight containers. (Where specific storage conditions are stated on the labels from the manufacturers, the materials should be stored in the conditions stated on the labels)
Retest period	1 year after first testing date

เอกสารนี้ควร  
ใช้ในการจัดซื้อ

Prepared by Kanyaporn, 18/12/14 Beta-lactam Antibiotic Plant QC Manager	Reviewed by Vanapa, 18/12/14 Beta-lactam Antibiotic Plant Manager	Suntharu T., 19/12/14 Beta-lactam Antibiotic Plant QA Manager	Approved by (Signature) 19/12/14 Director of Quality Assurance Department	Eff. Date 02/02/15
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