

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION



Title : Dicloxacillin Sodium Compacted (Item No. 41021030)	Spec. No. : SP-AQ30-PRD01
Reference (s) : USP42 p.1329-1330	Rev. No. : 09
Other Requirements : GPO Specification	Page : 1 / 3

USP42

Test Items	Specification
Identification (FT-IR)	Conforms to reference IR spectrum.
Identification (HPLC)	Conforms to standard HPLC chromatogram.
Crystallinity	Conforms to USP42.
Solubility	Conforms to USP42 (Freely soluble in water).
pH	4.5-7.5, in a solution containing 10 mg/mL.
Water	3.0-5.0%w/w (Method I).
Assay	Not less than 850 µg/mg of dicloxacillin (C ₁₉ H ₁₇ Cl ₂ N ₃ O ₅ S).
Impurities	Total impurities : not more than 5.0%. Individual impurities : not more than 1.0%.
Dimethylaniline	Not more than 0.002%w/w.

GPO Specification

Test Items	Specification
Description	White granules; odour, characteristic.
Tapped density	Not less than 0.75 g/mL (USP42 Method II).
Expiry date	The expiry date is beyond the date of material receipt at GPO warehouse for at least two years and eight months.

Prepared by Kanyaporn / 10/10/20	Reviewed by Sukarni / 20/10/20	Approved by Kanyaporn / 10/11/20	Eff. Date 01/12/20
Director of Beta-lactam Antibiotics QC Group	Manager of Beta-lactam Antibiotics Plant	Director of Quality System Development Division	Director of Quality Assurance Department (Acting)

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Copy No. 4

Title : Dicloxacillin Sodium Compacted (Item No. 41021030)	Spec. No. : SP-AQ30-PRD01
Reference (s) : USP42 p.1329-1330	Rev. No. : 09
Other Requirements : GPO Specification	Page : 2 / 3

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-AQ30-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.

Prepared by Kanyaspm, 20/10/20	Reviewed by S. K. Sharma, 20/10/20	Approved by Umangam, 10/11/20	Eff. Date 01/12/20
Director of Beta-lactam Antibiotics QC Group	Manager of Beta-lactam Antibiotics Plant	Director of Quality System Development Division	Director of Quality Assurance Department (Acting)

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION



COPY No. 2

Title : Dicloxacillin Sodium Compacted (Item No. 41021030)	Spec. No. : SP-AQ30-PRD01
Reference (s) : USP42 p.1329-1330	Rev. No. : 09
Other Requirements : GPO Specification	Page : 3 / 3

History of Changes

Rev. No.	Description / Reason	Eff. Date
09	-Update to USP42. -Change work center from AQ13 to AQ30.	01/12/20

Prepared by Kanyaporn, 20/10/20	Reviewed by Suearni, 20/10/20	Approved by Umaporn W, 02/11/20	Eff. Date 01/12/20
Director of Beta-lactam Antibiotics QC Group	Manager of Beta-lactam Antibiotics Plant	Director of Quality System Development Division	Director of Quality Assurance Department (Acting)