



瑞阳制药股份有限公司  
REYOUNG PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Factory: Reyoung Pharmaceutical Co., Ltd.

We hereby certify that following medicine comply with respective Pharmacopoeia and release for human medicines. Detail drug information and result reported below:

Date of Analysis: Feb. 2nd, 2021

Products: Vancomycin for Injection 1g	
Batch NO.: 213042002	Date of Mfg.: 01/2021
Date of Expiry: 12/2023	Analytical Reference No.: W304210131001
Quantity: 100,000 vials	Standard: USP43
Analytical Result	

TEST	SPECIFICATION	RESULT
Packing	20ML Molded vials with self-adhesive label, flip off caps; 10 Vials/Box	Complies
Appearance	White, almost white, or tan to brown, free-flowing powder, odorless, and having a bitter taste	Complies
Identification	Complies	Complies
Test		
PH	2.5~4.5	2.85
Water	≤5.0%	1.27%
Uniformity of dosage units	AV≤15.0	3.46
Average weight	1.102g*(±20%)	0.91855g
Sub-visible particles	≥10um, NMT 6000 Particles/Bottle	25.2 Particles/Bottle
	≥25um, NMT 600 Particles/Bottle	5.2 Particles/Bottle
Completeness solubility	No visible residue as undissolved matter	No visible residue as undissolved matter
Clarity of solution	Clarified	Clarified
Particulate matter	Not detected	Not detected
Bacterial endotoxins	NMT 0.33 EU per mg of vancomycin	<0.33 EU/mg
Sterility	Complies	Complies
Assay	Vancomycin B≥80.0%	96.20%
	the area of any other peak≤9.0%	0.72%
	NLT 90.0% and NMT 115.0% of the labeled amount of vancomycin	101.4%

**Conclusion:** The results comply with USP43

ADD: No.1, Ruiyang Road, Yiyuan County, Shandong Province, China..

Tel: 86 533 3227245

E-mail: xie.manyi@reyoung.com

Fax: 86 533 3257886

http://www.reyoung.com