



**The Post-reconstitution and/or the Post-dilution Stability Data with Recommended  
Shelf-life and Storage Condition**



CONFIDENTIAL



## **Stability Study of Reconstituted Solution of Vancomycin Hydrochloride Finished**

### **Product**

Stability studies of reconstituted solution were being performed on Vancomycin Hydrochloride finished formulation to assess the stability of Vancomycin Hydrochloride for injection after reconstitution, and to demonstrate that the reconstituted drug product will remain within specification during the defined storage period when stored at the recommended storage condition.

The reconstituted solution of Vancomycin Hydrochloride was stored separately for 24 hours when stored under 25 °C and for 48 hours when stored under 2~8 °C.

Stability studies of Reconstituted solution are provided for three batches of dosages of Vancomycin Hydrochloride finished product of 1.0g/vial

Details are given in the subsequent pages.



## **Stability Study of Reconstituted Solution of Vancomycin Hydrochloride Finished Product, 1.0g/vial**

The stability protocol was written taking into consideration the current guidelines from the United States Pharmacopoeia and Chinese Pharmacopoeia guidelines for stability study.

Stability studies of Reconstituted solution were being performed on Vancomycin Hydrochloride finished formulation to assess the stability of Vancomycin Hydrochloride for injection after reconstitution. The reconstituted solution of Vancomycin Hydrochloride was stored separately for 24 hours when stored under 25 °C and for 48 hours when stored 2~8°C. The reconstituted solution of Vancomycin Hydrochloride samples were tested against an initial control which was reconstituted immediately prior to testing.

For assay used to monitor the stability of reconstituted solution of Vancomycin Hydrochloride finished formulation, the studies including Appearance of reconstituted solution, pH, particulate matter, bacterial endotoxins, sterility and content should be performed at a certain time point after being reconstituted compare with initial analysis.

### **Results analysis**

The test results of these reconstitution stability studies indicated that the data remained within the specified limits, and there was no significant change in entire specification items for Vancomycin Hydrochloride for injection 1.0g/vial when stored at either 2~8°C for 48 hours or 25°C for 24 hours following reconstitution.(Refer to attached tables for detail.)

### **Conclusion**

Results from the stability studies of reconstituted solution demonstrated no change in product up to 48 hours post-reconstitution when stored under 2~8°C or 24 hours post-reconstitution when stored under 25°C. **Anyhow, it is recommended to use at once to protect from contamination, once opened.**

Manufacturing place: No. 1, Ruiyang road, Yiyuan county, Shandong Province, China.



瑞 阳 制 药 有 限 公 司  
**REYOUNG PHARMACEUTICAL CO., LTD.**

Stability Data: Reconstituted Solution of Vancomycin Hydrochloride for injection 1.0g/vial

Batch No: 080411 (Date of manufacture: Apr. 2008)

Storage for 24 hours or 96 hours following reconstitution (Solvent: sterile water for injection, 20 ml)

Packaging material:

20ml mould vial with flip off cap

Items	Specification	Initial	48 hours, 2-8°C	96 hours, 2-8°C	12 hours, 25°C	24 hours, 25°C
Appearance	Clear colourless to pale yellow solution free from visible particles	Complies	Complies	Complies	Complies	Complies
particulate matter	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Bacterial endotoxin	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Sterility	Meet the requirements	Complies	Complies	Complies	Complies	Complies
pH	2.5~4.5	3.34	3.23	3.16	3.09	2.97
Assay	90.0 - 115.0% of the labeled amount of vancomycin	101.7%	99.90%	98.82%	99.77%	98.69%

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Storage for 24 hours or 48 hours following reconstitution (Solvent: sodium chloride solution 0.9%, 200 ml)

Packaging material:

20ml mould vial with flip off cap

Items	Specification	Initial	24 hours, 2-8℃	48 hours, 2-8℃	12 hours, 25℃	24 hours, 25℃
Appearance	Clear colourless to pale yellow solution free from visible particles	Complies	Complies	Complies	Complies	Complies
particulate matter	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Bacterial endotoxin	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Sterility	Meet the requirements	Complies	Complies	Complies	Complies	Complies
pH	2.5~4.5	3.41	3.29	3.20	3.22	3.15
Assay	90.0 - 115.0% of the labeled amount of vancomycin	101.5%	99.90%	99.12%	98.72%	97.89%

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Storage for 24 hours or 48 hours following reconstitution (Solvent: Glucose solution 5%, 200 ml)

Packaging material:

20ml mould vial with flip off cap

Items	Specification	Initial	24 hours, 2-8℃	48 hours, 2-8℃	12 hours, 25℃	24 hours, 25℃
Appearance	Clear colourless to pale yellow solution free from visible particles	Complies	Complies	Complies	Complies	Complies
particulate matter	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Bacterial endotoxin	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Sterility	Meet the requirements	Complies	Complies	Complies	Complies	Complies
pH	2.5~4.5	3.41	3.23	3.10	3.18	3.06
Assay	90.0 - 115.0% of the labeled amount of vancomycin	101.5%	100.1%	98.71%	98.04%	97.77%

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Storage for 24 hours or 48 hours following reconstitution (Solvent: Glucose solution 5%+Sodium chloride solution 0.9%, 200 ml)

Packaging material:

20ml mould vial with flip off cap

Items	Specification	Initial	24 hours,2-8℃	48 hours,2-8℃	12 hours,25℃	24 hours,25℃
Appearance	Clear colourless to pale yellow solution free from visible particles	Complies	Complies	Complies	Complies	Complies
particulate matter	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Bacterial endotoxin	Meet the requirements	Complies	Complies	Complies	Complies	Complies
Sterility	Meet the requirements	Complies	Complies	Complies	Complies	Complies
pH	2.5~4.5	3.19	3.05	3.00	2.98	2.91
Assay	90.0 - 115.0% of the labeled amount of vancomycin	101.5%	99.90%	97.58%	96.62%	96.41%

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