Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

COA NO.:2019-03-01-03

Vancomycin HCl USP/EP

BATCH NUMBER	97181107	**TEST DATE**	03-07-2019
BATCH SIZE	151.05Kg	**MANUFACTURE DATE**	12-01-2018
QUANTITY	100g	**EXPIRATION DATE**	11-30-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

TEST	SPECIFICATION	RESULT
Appearance (USP/EP)	White or almost white powder	Almost white powder
Identification A: IR (USP)	The IR absorption spectrum of sample recorded, as KBr pellet must exhibit maxima at the same wave numbers as exhibitedby the Vancomycin hydrochloride working standard spectrum	Conforms
Identification B: HPLC (EP)	The retention time of the major peak of the sample solution corresponds to that of the reference standard	Conforms
Identification C: Chlorides (EP)	Meets EP tests for chlorides	Conforms
Solubility (USP/EP)	Freely soluble in water; slightly soluble in ethanol(96%), insoluble in ether and chloroform	Conforms
pH (USP)	2.5 to 4.5 (50 mg/mL in water)	2.96
Appearance of Solution (EP)	The solution is clear and its absorbance at 450 nm is not greater than 0.10.	0.029
Water (USP)	Not More Than 5.0%	4.14%
Assay(USP/Microbiological)	Not Less Than 900 μg/mg on the anhydrous basis	1043μg/mg
Assay(EP/Microbiological)	Not Less Than 1050IU/mg on the anhydrous basis	1104IU/mg
Composition of Vancomycin (EP)	Vancomycin B Not Less Than 93.0%	95.1%
Related Substances:		
Monodechlorovancomycin (USP)	Not More Than 4.7%	1.6%
N-demethyl vancomycin B (EP Impurity A)	Not More Than 4.0%	0.93%
Desamidovancomycin B (EP Impurity B)	Not More Than 4.0%	0.28%
Aglucovancomycin B (EP Impurity C)	Not More Than 4.0%	0.10%
Desvancosaminyl vancomycin B EP Impurity D	Not More Than 4.0%	0.32%
Any Other Individual Impurity	Not More Than 4.0%	0.63%
Total Impurities	Not More Than 7.0%	5.00%

Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

Vancomycin HCl USP/EP

BATCH NUMBER	97181107	**TEST DATE**	03-07-2019
BATCH SIZE	151.05Kg	**MANUFACTURE DATE**	12-01-2018
QUANTITY	100g	**EXPIRATION DATE**	11-30-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

Sulfated Ash (EP)	Not More Than 1.0%	0.05%
Residue on Ignition	Not More Than 1.0%	0.07%
Bacterial Endotoxins (USP/EP)	Less Than 0.25 EU/mg	<0.1EU/mg
Total Aerobic Microbial Count(USP/EP)	Not More Than 100 cfu/g	Conforms
Total Combined Yeast and Mould Count(USP/EP)	Not More Than 10 cfu/g	Conforms

Manufactured By: Chongqing Daxin Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION: Approved (√) ☑ By: 2019.04.09

Analyst/Date:	Checker/Date:	Supervisor/Date:
2019.04.09	2019.04.09	2019.04.09

Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

COA NO.:2019-03-02-02

Vancomycin HCl USP/EP

BATCH NUMBER	97181108	**TEST DATE**	03-07-2019
BATCH SIZE	150.55Kg	**MANUFACTURE DATE**	12-03-2018
QUANTITY	100g	**EXPIRATION DATE**	12-02-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

TEST	SPECIFICATION	RESULT
Appearance (USP/EP)	White or almost white powder	Almost white powder
Identification A: IR (USP)	The IR absorption spectrum of sample recorded, as KBr pellet must exhibit maxima at the same wave numbers as exhibitedby the Vancomycin hydrochloride working standard spectrum	Conforms
Identification B: HPLC (EP)	The retention time of the major peak of the sample solution corresponds to that of the reference standard	Conforms
Identification C: Chlorides (EP)	Meets EP tests for chlorides	Conforms
Solubility (USP/EP)	Freely soluble in water; slightly soluble in ethanol(96%), insoluble in ether and chloroform	Conforms
pH (USP)	2.5 to 4.5 (50 mg/mL in water)	3.13
Appearance of Solution (EP)	The solution is clear and its absorbance at 450 nm is not greater than 0.10.	0.017
Water (USP)	Not More Than 5.0%	3.84%
Assay(USP/Microbiological)	Not Less Than 900 μg/mg on the anhydrous basis	1052μg/mg
Assay(EP/Microbiological)	Not Less Than 1050IU/mg on the anhydrous basis	1097IU/mg
Composition of Vancomycin (EP)	Vancomycin B Not Less Than 93.0%	95.7%
Related Substances:		
Monodechlorovancomycin (USP)	Not More Than 4.7%	1.8%
N-demethyl vancomycin B (EP Impurity A)	Not More Than 4.0%	0.72%
Desamidovancomycin B (EP Impurity B)	Not More Than 4.0%	0.16%
Aglucovancomycin B (EP Impurity C)	Not More Than 4.0%	0.04%
Desvancosaminyl vancomycin B EP Impurity D	Not More Than 4.0%	0.22%
Any Other Individual Impurity	Not More Than 4.0%	0.60%
Total Impurities	Not More Than 7.0%	4.07%

Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

Vancomycin HCl USP/EP

BATCH NUMBER	97181108	**TEST DATE**	03-07-2019
BATCH SIZE	150.55Kg	**MANUFACTURE DATE**	12-03-2018
QUANTITY	100g	**EXPIRATION DATE**	12-02-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

Sulfated Ash (EP)	Not More Than 1.0%	0.02%
Residue on Ignition	Not More Than 1.0%	0.02%
Bacterial Endotoxins (USP/EP)	Less Than 0.25 EU/mg	<0.1EU/mg
Total Aerobic Microbial Count(USP/EP)	Not More Than 100 cfu/g	Conforms
Total Combined Yeast and Mould Count(USP/EP)	Not More Than 10 cfu/g	Conforms

Manufactured By: Chongqing Daxin Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION: Approved (√) ☑ By: 2019.04.09

Analyst/Date:	Checker/Date:	Supervisor/Date:
2019.04.09	2019.04.09	2019.04.09

Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

COA NO.:2019-03-03-02

Vancomycin HCl USP/EP

BATCH NUMBER	97181201	**TEST DATE**	03-07-2019
BATCH SIZE	151.67Kg	**MANUFACTURE DATE**	12-05-2018
QUANTITY	100g	**EXPIRATION DATE**	12-04-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

TEST	SPECIFICATION	RESULT
Appearance (USP/EP)	White or almost white powder	Almost white powder
Identification A: IR (USP)	The IR absorption spectrum of sample recorded, as KBr pellet must exhibit maxima at the same wave numbers as exhibitedby the Vancomycin hydrochloride working standard spectrum	Conforms
Identification B: HPLC (EP)	The retention time of the major peak of the sample solution corresponds to that of the reference standard	Conforms
Identification C: Chlorides (EP)	Meets EP tests for chlorides	Conforms
Solubility (USP/EP)	Freely soluble in water; slightly soluble in ethanol(96%), insoluble in ether and chloroform	Conforms
pH (USP)	2.5 to 4.5 (50 mg/mL in water)	3.07
Appearance of Solution (EP)	The solution is clear and its absorbance at 450 nm is not greater than 0.10.	0.038
Water (USP)	Not More Than 5.0%	3.68%
Assay(USP/Microbiological)	Not Less Than 900 μg/mg on the anhydrous basis	1047μg/mg
Assay(EP/Microbiological)	Not Less Than 1050IU/mg on the anhydrous basis	1094IU/mg
Composition of Vancomycin (EP)	Vancomycin B Not Less Than 93.0%	95.5%
Related Substances:		
Monodechlorovancomycin (USP)	Not More Than 4.7%	1.1%
N-demethyl vancomycin B (EP Impurity A)	Not More Than 4.0%	0.91%
Desamidovancomycin B (EP Impurity B)	Not More Than 4.0%	0.08%
Aglucovancomycin B (EP Impurity C)	Not More Than 4.0%	0.13%
Desvancosaminyl vancomycin B EP Impurity D	Not More Than 4.0%	0.21%
Any Other Individual Impurity	Not More Than 4.0%	0.56%
Total Impurities	Not More Than 7.0%	4.28%

Chongqing Daxin Pharmaceutical Co., Ltd.

No. 21, Founder Road, Shuitu Town, BeiBei District,Chongqing 400714, China
Phone Number:+86-23-61301056

Certificate of Analysis

Vancomycin HCl USP/EP

BATCH NUMBER	97181201	**TEST DATE**	03-07-2019
BATCH SIZE	151.67Kg	**MANUFACTURE DATE**	12-05-2018
QUANTITY	100g	**EXPIRATION DATE**	12-04-2020

Storage Condition: Preserve in tight, light resistant containers, Store at 2-8°C

Sulfated Ash (EP)	Not More Than 1.0%	0.04%
Residue on Ignition	Not More Than 1.0%	0.03%
Bacterial Endotoxins (USP/EP)	Less Than 0.25 EU/mg	<0.1EU/mg
Total Aerobic Microbial Count(USP/EP)	Not More Than 100 cfu/g	Conforms
Total Combined Yeast and Mould Count(USP/EP)	Not More Than 10 cfu/g	Conforms

Manufactured By: Chongqing Daxin Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION: Approved (√) ☑ By: 2019.04.09

Analyst/Date:	Checker/Date:	Supervisor/Date:
2019.04.09	2019.04.09	2019.04.09

Supplied by ChemWerth, Inc
Agent and Distributor

.USP-EP 0.06
2018-8-27