

## RECONSTITUTION SOLUTION STABILITY STUDY

### **Benzathine penicillin for Injection 1.2 mega/vial BP**

Batch No.	Reconstitution solution	Storage condition
091004	Sterile water for injection	2°C to 8°C Room temperature
091005	0.9% Saline solution	
091006	5.0% Dextrose solution	

Under 2°C to 8°C: The samples were withdrawn at 0, 24, 48 hours;

Under room temperature (25°C): The samples were withdrawn at 0, 4, 8 hours.

The samples were analyzed for description, pH, related substance and assay at all the stability stations.

#### **Methodology:**

**Sample dilution:** Transferred the 1 vial of the sample (equivalent to 1.2 mega Benzathine penicillin) to 4ml sterile water for injection, 0.9% Saline solution, and 5.0% Dextrose solution to produce a solution separately.

**Standard dilution:** Prepare the same concentration of sample solution.

#### **Discussion:**

From the result of stability data, it is observed that Benzathine penicillin for Injection remains well within the specifications with respect to its physical, chemical when constituted.

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SHIJIAZHANG PHARMA, ZHONGNUO PHARMACEUTICAL (SHIJIAZHANG) CO., LTD.

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq$ 2%;	0.55	0.26	0.47
	Any impurity $\leq$ 1%;	0.09	0.17	0.20
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	25.2	25.0	24.5
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	98.6	97.9	96.5

The complied data is printed on: Oct, 28th, 2009.

Prepared by: Liu Hui

QC manager: Gao Huiqin



# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.94	1.29	1.30
	Any impurity $\leq 1\%$ ;	0.04	0.09	0.17
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.1	25.8	24.4
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.9	98.9	97.5

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SHIJIAZHUANG PHARMA. ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.  
石家莊華藥股份有限公司

### STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	1.10	1.07	0.99
	Any impurity $\leq 1\%$ ;	0.15	0.15	0.35
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.8	25.1	24.3
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	99.2	98.9	96.8

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 石家莊藥業股份有限公司  
 石家莊藥業股份有限公司

## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.55	0.69	0.80
	Any impurity $\leq 1\%$ ;	0.09	0.18	0.27
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	25.2	25.0	24.4
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	98.6	97.0	96.2

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 (INCORPORATED IN CANADA)  
 7700 SHEPPARD AVENUE EAST SUITE 200

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.94	0.98	1.24
	Any impurity $\leq 1\%$ ;	0.04	0.12	0.15
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	25.1	25.8	24.8
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	98.9	98.4	97.2

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 石家庄制药厂 中诺制药(石家庄)有限公司

## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091004

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	1.10	1.27	1.30
	Any impurity $\leq 1\%$ ;	0.15	0.25	0.33
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.8	25.7	25.3
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	99.2	98.9	97.1

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SHIJIAZHUANG PHARMA. ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.

10/28/2009

10/28/2009

## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.35	0.77	0.82
	Any impurity $\leq 1\%$ ;	0.10	0.15	0.20
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.3	25.1	24.4
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.7	97.8	96.6

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 石家庄制药(集团)有限公司



# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq$ 2%;	0.95	0.29	0.41
	Any impurity $\leq$ 1%;	0.05	0.09	0.17
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	25.2	25.7	24.5
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>4</sub> S <sub>2</sub> ) 96.0%-100.5%	99.0	98.8	97.4

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## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	1.11	1.34	1.32
	Any impurity $\leq 1\%$ ;	0.16	0.26	0.27
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.9	25.1	24.2
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	99.3	98.8	97.2

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 PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.  
 石家庄中美药业(石药集团)有限公司

## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.35	0.39	0.57
	Any impurity $\leq 1\%$ ;	0.10	0.17	0.28
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.3	25.0	24.4
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.7	98.0	96.9

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石家莊華藥股份有限公司

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$	0.95	0.98	1.28
	Any impurity $\leq 1\%$	0.05	0.12	0.25
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	25.2	25.1	24.7
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	99.0	98.5	97.1

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Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091005

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 15,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq$ 2%;	1.11	1.57	1.69
	Any impurity $\leq$ 1%;	0.16	0.54	0.72
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	25.9	25.6	25.2
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	99.3	98.8	97.3

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SHIJIAZHANG PHARMA. ZHONGNUO PHARMACEUTICAL (SHIJIAZHANG) CO., LTD.

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	1.04	1.34	1.50
	Any impurity $\leq 1\%$ ;	0.26	0.25	0.47
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	26.3	25.4	24.9
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	98.7	98.5	96.8

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QC manager: Gao Huiqin

SHIJIAZHUANG PHARMA. ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.  
10/28/2009 10:28:27

## STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	1.05	1.14	1.23
	Any impurity $\leq 1\%$ ;	0.27	0.35	0.44
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	26.4	25.4	24.9
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.8	98.1	96.9

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SHIJIAZHUANG PHARMA. ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO., LTD.  
 石家庄制药集团（中诺）制药有限公司  
 10/28/2009

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: 2°C to 8°C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	24 hours	48 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.62	0.84	1.05
	Any impurity $\leq 1\%$ ;	0.17	0.15	0.47
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine (C <sub>16</sub> H <sub>20</sub> N <sub>2</sub> ) 24.0%-27.0%	26.0	25.4	24.9
	Penicillins, (calculated as C <sub>48</sub> H <sub>56</sub> N <sub>6</sub> O <sub>8</sub> S <sub>2</sub> ) 96.0%-100.5%	98.9	97.4	96.2

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石家莊華藥(石家莊)有限公司



# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: Sterile water for injection

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$	1.04	1.08	1.40
	Any impurity $\leq 1\%$	0.26	0.15	0.37
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	26.3	25.5	24.9
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.7	98.9	96.8

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石家莊中藥業(石家莊)有限公司

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: Room temperature 25°C

Reconstitution solution: 0.9% Saline solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$	1.05	0.98	1.22
	Any impurity $\leq 1\%$	0.27	0.26	0.46
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	26.4	24.4	24.7
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.8	98.1	97.2

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石家莊神州藥業(石家莊)有限公司

# STABILITY DATA

Product name: Benzathine penicillin for Injection 1.2 mega/vial BP

Batch No.: 091006

Manufacturing date: 10/2009

Expiry date: 10/2013

Batch size: 17,000 vials

Storage condition: Room temperature 25 °C

Reconstitution solution: 5.0% Dextrose solution

Test carried out		Results		
Time interval		Initial	4 hours	8 hours
Description (A white powder)		A white powder	A white powder	A white powder
pH (Meet the requirements)		Conform	Conform	Conform
Related substances	Impurity C $\leq 2\%$ ;	0.62	1.07	1.17
	Any impurity $\leq 1\%$ ;	0.17	0.42	0.39
Assay (anhydrous substance)	N,N'-Dibenzylethylenediamine ( $C_{16}H_{20}N_2$ ) 24.0%-27.0%	26.0	25.3	24.5
	Penicillins, (calculated as $C_{48}H_{56}N_6O_8S_2$ ) 96.0%-100.5%	98.9	97.0	96.8

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