

Title: Dimercaprol Injection IP, 50 mg/ml			Reference: IP	
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STP No.: F/092-STP		Rev. No.: 02		Supersedes No. F/092-STP, Rev.No.01
Prepared by		Checked by	Approved by	
Quality Control		Quality Assurance	Head - QC	Head - QA
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Signature				
Date	05-08-22	06-08-22	07-08-22	08-08-22

Effective Date: **1 AUG 2022**

1.0 Description

1.1 Examine the test sample visually.

2.0 Particulate Matter

2.1 For procedure Refer GTP No. ARCO/008-GTP.

3.0 Refractive index

3.1 Determine refractive index by using Refractometer

4.0 pH

4.1 Apparatus:

pH Meter

4.2 Procedure:

4.2.1 Test solution:

4.2.1.1 Pipette out and transfer about 7.8 ml of injection and transfer in 10 ml volumetric flask.

4.2.1.2 Dilute up to the mark with water.

4.2.2 Take test solution in a beaker.

4.2.3 Wash the electrode and wipe with the tissue paper.

4.2.4 Dip the electrode in the test solution.

4.2.5 Measure the pH with previously calibrated pH meter.

4.2.6 Note down the reading.

4.2.7 Remove the electrode from test solution.

5.0 Extractable Volume

5.1 Determined on 3 numbers of vials/Ampoules.

5.2 For procedure refer GTP No. ARCO/018-GTP.

6.0 Sterility

6.1 For the procedure refer GTP No. ARCO/001-MGTP.



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7.0 Bacterial endotoxins

7.1 For procedure refer GTP No. ARCO/002-MGTP.

8.0 Weight Per Milliliter:

8.1 Apparatus:

Pycnometer

8.2 Procedure:

- 8.2.1 Take clean and dry pycnometer.
- 8.2.2 Weigh the empty pycnometer (W).
- 8.2.3 Fill the pycnometer with freshly boiled and cooled water at 25°C (W₁)
- 8.2.4 Calculate the capacity (Volume) of the pycnometer.
- 8.2.5 Fill the Pycnometer with the sample and adjust the temperature of the sample being examined to about 25°C.
- 8.2.6 Remove excess of the sample and weigh the pycnometer (W₂).

Calculations:

$$\text{Volume of Pycnometer (V)} = \frac{W_1 - W}{D}$$

$$\text{Weight per mL} = \frac{W_2 - W}{V}$$

Where,

W = Weight of empty Pycnometer at 25°C (g)

W₁ = Weight of empty Pycnometer + water at 25°C (g)

W₂ = Weight of empty Pycnometer + Sample at 25°C (g)

V = Volume of Pycnometer (mL)

D = Density of water (0.99602)

9.0 Assay:



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9.1 Reagents:

9.1.1 0.1 M Hydrochloric Acid

9.1.2 0.05M Iodine

9.2 Reagent preparation :

9.2.1 0.1 M Hydrochloric Acid:

9.2.1.1 Diluted 85 ml of hydrochloric acid to 1000 ml with water.

9.2.2 0.05 M Iodine:

9.2.2.1 Dissolve 14 g of Iodine in a solution of 36 g of potassium iodide in 100 ml of water.

9.2.2.2 Add 3 drops of hydrochloric acid and dilute with water to 1000 ml.

9.2.2.3 Standardize the solution as follows .

9.2.2.3.1 Weight accurately about 0.15 g of arsenic trioxide ,previously dried at 105° for 1 hour and dissolve in 20 ml of 1 M sodium hydroxide by warming ,if necessary.

9.2.2.3.2 Dilute with 40 ml of water ,add 0.1 ml of methyl orange solution and add dropwise dilute hydrochloric acid until the yellow colour is change to pink.

9.2.2.3.3 Add 2 g of sodium carbonate,diluted with 50 ml of water and add 3 ml of starch solution.

9.2.2.3.4 Titrate with the iodine solution until a permanent blue colour is produced.

9.2.2.3.5 Each ml of 0.05 M Iodine is equivalent to 0.004946 g of As₂O₃.

$$\text{Normality} = \frac{\text{Weight of Arsenic Trioxide}}{\text{Required volume} \times 0.04946}$$

9.3 Procedure :

9.3.1 Weight 1.0 g,add 20 ml of 0.1 M hydrochloric acid and titrate with 0.05 M iodine.

9.3.2 1 ml of 0.05 M iodine is equivalent to 0.00621 g of C₃H₈OS₂.

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			Poonam Phamdar 08-08-22

9.3.3 Determine the weight per ml of the Injection and calculate the content.

Calculations:

$$\text{Content} = \frac{\text{Burette Reading} \times \text{Actual Molarity} \times \text{Factor} \times 1000}{\text{Theoretical molarity} \times \text{Volume of Injection}}$$

$$\% \text{ Content} = \frac{\text{Content}}{\text{Label Claim}} \times 100$$

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Label Claim

10.0 Abbreviations

- AR : Analytical Reagent
 GTP : General Test Procedure
 M : Molar
 ml : Milliliter
 mg : Milligram
 g : gram

