

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

(Under Drug & Cosmetic Act 1940 & the rules thereunder)

FINISHED PRODUCT



ARCO LIFESCIENCES (I) PVT. LTD.

C-86, MIDC Area, Hingna, Nagpur -440016

WHO-GMP & ISO 9001-2015 CERTIFIED COMPANY

A.R No.:AR/FP/ FAL23S111

Date 30-09-23

Name of Product	Dimercaprol Injection IP, 50 mg/ml, 2 ml ampoule		
Name of Mfgr./Party	ARCO LIFESCIENCES	Mfg. Lic No.	ND/47
Batch Number	DH23S1	Release date	30-09-23
Batch Size	10.0 Liters	Testing Standard	IP
Sampling Date	16-09-23	Specification No.	F/070-S
Sample Quantity	105 x 2 ml Amp	Expiry Date	02-2026
Manufacturing Date	09-2023		

Tests	Results	Specifications
Description	A clear, yellow, viscous solution, having a pungent disagreeable odour filled in amber colour ampoule	A clear, yellow, viscous solution, having a pungent, disagreeable odour
Particulate Matter	10 µm=1238.0 25µm=504.0	≥10 µm : NMT6000/Cantainer ≥25µm : NMT 600/cantainer
Limit of 1,2,3-trimercaptopropane and related impurities	Complies	NMT 4.5 % of Dimercaprol.
Extractable Volume	2.05 ml 102.50 %	100% - 110%
Weight per ml	0.953 g/ml	About 0.95 g/ml
Sterility Testing Finish Product	Passes	It passes the tests for sterility
Bacterial endotoxins	Passes	NMT 1.0 EU/mg of Dimercaprol
Assay Each ml Contains Dimercaprol IP	Content 49.87 mg Percent 99.74 %	Label Claim 50.00 mg USP 90 % - 110%
Packing a. Container b. Label c. Packing Inserts d. Packing Configuration	2 ml amber colour ampoule Complies NA Complies	2 ml amber colour ampoule It should be properly labelled It should be present /NA Packed in printed carton of 2 ml x [(2 x 1) x 25] x 20, 5 Ply box of 1000 ampoule

Opinion : In the opinion of the undersigned, the sample referred to above is of standard quality/is not of standard quality as defined in the Act & the rules made thereunder for the reasons given below :-

IT COMPLIES / ~~DOES NOT COMPLY~~ TESTING STANDARD IP IN THE ABOVE RESPECT

Analyst *Ashe*
Date 30-09-23

Microbiologist *Sant*
Date 30-09-23

Authorized Signatory
Date

Debeem
30-09-23