



KWALITY PHARMACEUTICALS LIMITED
1-A, INDUSTRIAL AREA , RAJA KA BAGH, TEHSIL NURPUR, KANGRA-176201
(INDIA)

DEPARTMENT : QUALITY CONTROL

FINISHED PRODUCT COA

Product Name	Bleomycin For Injection USP 15 Units/vial	A. R. Number	KPH/24/FPO/96
Batch Number	OL0639	Sample Received on	16/02/2024
Date of Mfg.	02/2024	Batch Size	1200 Vials
Date of Exp.	01/2027	Specification No.	KPL/SPC/IN/057-01
Date of Analysis	16/02/2024	Date of Release	04/03/2024

Sr. No	Test	Specification	Result
1.	Description		
	Before reconstitution	Off white colored lyophilized cake filled in clear colorless transparent glass vial USP type I.	Off white colored lyophilized cake filled in clear colorless transparent glass vial USP type I.
	After reconstitution	Clear colorless solution produced after reconstitution with water for Injection.	Clear colorless solution produced after reconstitution with water for Injection.
2.	Identification		
	A. By IR	The test spectra should exhibit maxima only at the same wavelength as the spectra obtained from Standard Bleomycin Sulfate USP.	The test spectra should exhibit maxima only at the same wavelength as the spectra obtained from Standard Bleomycin Sulfate USP.
	B. Reaction of Sulfate	Should be complies.	Complies
3.	pH	Between 4.5 to 6.0	5.963
4.	Water	NMT 6.0%	0.0098%
5.	Copper	NMT 0.1%	Not detected
6.	Uniformity of dosage units	For L1 Stage, AV= NMT 15 and For L2 Stage, AV= NMT 25	AV=1.62
7.	Completeness and clarity of solution	The solution should be clear and colorless after reconstitution and it should not significantly less clear than an equal volume of diluents.	The solution is clear and colorless after reconstitution and it should not significantly less clear than an equal volume of diluents.
8.	Content of Bleomycins:		
	Bleomycin A₂	Between 55.0% to 70.0%	67.8%

Prepared By Sign./Date	<i>AP</i> 24/03/24	Reviewed By Sign./Date	<i>HS</i> 24/03/24	Approved By Sign./Date	<i>AS</i> 04/03/24
Name	Anil Pathania	Name	Narinder Singh	Name	Akhil Sharma
Designation	QC Executive	Designation	Anal. Manager	Designation	Dy. Manager QA



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Sr. No	Test	Specification	Result	
	Bleomycin B₂	Between 25.0% to 32.0%	30.3%	
	Bleomycin B₄	NMT 1.0%	0.13%	
	Sum of Bleomycin A₂ and Bleomycin B₂	NLT 90.0%	98.2%	
9.	Bacterial Endotoxins Test	NMT 10.0 EU/Bleomycin unit	Less than 10.0 EU/Bleomycin unit	
10.	Sterility	No growth should be observed.	No growth is observed.	
11.	Particulate matter in injection	≥10µm = NMT 6000 per Container. ≥25µm = NMT 600 per Container.	102 particles 04 particles	
12.	Assay: Each vial contains.			
	Active Ingredient	Label Claim	Limit	Result
	Bleomycin Sulfate USP Eq. to Bleomycin	15 Units	90.0% to 120.0%	15.18 Units 101.2%

Remarks: In the opinion of undersigned the product complies/does not comply with IP/BP/USP/In House specification.

Prepared By Sign./Date	<i>AS</i> 04/03/24	Reviewed By Sign./Date	<i>HS</i> 04/03/24	Approved By Sign./Date	<i>AS</i> 04/03/24
Name	Anil Pathania	Name	Narinder Singh	Name	Arvind Sharma
Designation	Sr. Executive	Designation	Asst. Manager	Designation	Dy. Manager & A