



MMG HEALTHCARE , KALA AMB (HP) , INDIA

CERTIFICATE OF ANALYSIS
FINISHED PRODUCTS

Generic Name	Ceftriaxone Injection IP 1000 mg		
Product name	CEFTABURG-1GM	A.R.No.	QCFP-25-08-30
Batch No.	25DH09G	Batch size	10400 vials
Mfg Date	08/2025	Exp.Date	07/2027
Sample Received Date	30/08/2025	Date Of Completion	13/09/2025
Mfg.Lic.No.	MB/07/627 & S-MNB/08/19	Released Date	13/09/2025

TEST RESULTS

Sr. No.	Parameters	Specifications	Results
1.	Description	A white or almost white powder filled in clear sealed glass vials.	A white powder filled in clear sealed glass vials.
2.	Identification A) By IR	The spectrum obtained with the sample Should correspond to ceftriaxone sodium working standard spectrum.	The spectrum obtained with the Sample is correspond to ceftriaxone sodium working standard spectrum
	B)By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the working standard solution.	In assay, the principal peak in the chromatogram obtained with the test solution is corresponding to the peak in the chromatogram obtained with the standard solution.
	C)By Chemical	A dense white precipitate should be formed.	A dense white precipitate is formed.
3.	pH	6.0 to 8.0	7.21
4.	Average filled weight	1200 mg \pm 10%	1202.3 mg
5.	Uniformity of Weight	Average filled weight \pm 10%	Min: (-0.21 %) Max: (1.24 %)
6.	Appearance of solution A) Clarity of solution	A) The clarity of sample solution should be same as that of the carbon dioxide free water used for preparing the solution	A) The clarity of sample solution is same as that of the carbon dioxide free water used for preparing the solution
	B) Colour of solution	B) The sample solution should be not more intensely coloured than reference solution BYS5 or YS5.	B) The sample solution is not more intensely coloured than reference solution BYS5 or YS5.

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	NEERAJ KUMAR RAJBHAR	SHYAMSUNDAR YADAV	SANTOSH PRAJAPATI
DESIGNATION	QC-OFFICER	SR.EXECUTIVE-QC	HEAD-QC
Edu.Quali./Enrl No.	M.Sc./2244404598	B.Sc./KA2K10301030222	M.Sc./B-7-33012
Univ./Inst.Name/Place	VEER BAHADUR SINGH PURVANCHAL UNIVERSITY / JAUNPUR (U.P.)	MAHATMA GANDHI KASHI VIDYAPITH /VARANASI(U.P.)	BAHADUR SINGH UNIVERSITY BHOPAL M.P.
Sign & Date	 13/09/2025	 13/09/2025	 13/09/2025



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TEST RESULTS

Sr. No.	Parameters	Specifications	Results
7.	Water	Not more than 11.0 % w/w	9.12%w/w
8.	Related Substances (By HPLC):		
	A) Any Secondary peak	Not more than 1.0 % w/w	0.40 %w/w
	B) The sum of areas of all the secondary peaks	Not more than 5.0 % w/w	2.02 %w/w
9.	Assay (By HPLC): Each vial contains:-		
	Ceftriaxone Sodium (Sterile) IP eq. to Ceftriaxone 1000 mg	900.0 mg to 1150.0 mg 90.0 % to 115.0 % of Label claim	1003.9 mg (100.39 %)
10.	Particulate contamination		
	A) Visible particles	No particles should present in more than two container's of reconstituted solution of sample examined visually.	No particles present in container's of reconstituted solution of sample.
	B) Sub-visible particles	≥10 μm, NMT 6000 particles / container ≥25 μm, NMT 600 particles / container	240 particles / container 05 particles / container
11.	Particulate matter	The solution should be essentially free from particles of foreign matter that can be seen on visual inspection.	The solution is free from particles of foreign matter that can be seen on visual inspection.
12.	Bacterial Endotoxins	Not more than 0.20 Endotoxin Unit per mg of Ceftriaxone.	Less than 0.20 Endotoxin Unit per mg of Ceftriaxone.
13.	Sterility	No evidence of microbial growth should be observed within incubation period.	No evidence of microbial growth is observed within incubation period.

Remarks: - The finished product complies / doesn't comply with respect to the above parameter as per given (IP / BP/ USP/IHS) specification

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Sign & Date	 13/09/2025	 13/09/2025	 13/09/2025

