

POLESTAR POWER INDUSTRIES (PHARMA DIVISION), BAROTIWALA (H.P.)

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product Name	Amoxyheal-CV DDS		
Generic Name	Amoxycillin & Potassium Clavulanate Oral Suspension IP		
Batch No.	DB240083C	Mfg. date	07/2024
A. R. No.	FP2409476	Expiry date	12/2025
Pack Size	6.6gm/30ml	Batch Size	6,000 Bottles
Date of receiving	25/07/2024	Type of Bottle	Glass
Date of preparation	08/08/2024	Page No.	1 of 2

S. No.	Test	Specification	Result
1	Description	A White to off white powder filled in HDPE/Glass bottle. After reconstitution gives milky suspension	Off white powder filled in Glass bottle. After reconstitution gives milky suspension
2	Identification By HPLC	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution should be corresponds to those in the chromatogram obtained with the reference solution.	In the assay, the retention time of the two principal peaks in the chromatogram obtained with the test solution corresponds to those in the chromatogram obtained with the reference solution.
3	Contents of packaged dosage forms		
	Average net weight of the content	Not less than labeled amount.	6.69500 gm
	Uniformity of weight	Not less than 90% of the labelled amount	6.62000 gm 100.30 %
	Average net volume of the content	Not less than labeled amount.	30.7 ml
	Uniformity of volume	Not less than 95% of the labelled amount	29.0 ml 96.67 %
4	pH	3.80 to 6.60	5.56
5	Water	Not more than 11.0 %w/w	8.54 %
6	Assay		
	Each 5 ml of the reconstituted suspension contains:		
	Amoxicillin Trihydrate I.P. eq. to Amoxicillin-400 mg	Not less than 360.00 mg and not more than 480.00 mg of Amoxycillin (Not less than 90.00% and not more than 120.00 % of state amount of amoxicillin)	389.25 mg 97.31 %
	Potassium Clavulanate Diluted I.P. eq. to Clavulanic acid-57 mg	Not less than 51.30 mg and not more than 71.25 mg of Clavulanic acid (Not less than 90.00% and not more than 125.00% of state amount of clavulanic acid)	61.77 mg 108.37 %

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Dilip Kumar	Charan Singh Yadav
Designation	Trainee Officer-QC	Sr. Officer-QC	Manager-QC
Signature			
Date	08/08/2024	08/08/2024	08/08/2024

Format No.: F/QC/024/02/00

Works: Village -Damuwala, Haripur Road, Barotiwala, Tehsil-Baddi, Distt. - Solan, H.P.- 174103

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CERTIFICATE OF ANALYSIS
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6	Each 5 ml of the constituted suspension when store at the temperature and for the period stated on the label contains:		
	Amoxicillin Trihydrate I.P. eq. to Amoxicillin-400 mg	Not less than 320.00 mg of Amoxycillin (Not less than 80.00% of state amount of amoxicillin)	359.91 mg 89.98 %
	Potassium Clavulanate Diluted I.P. eq. to Clavulanic acid-57 mg	Not less than 45.60 mg of Clavulanic acid (Not less than 80.00% of state amount of clavulanic acid)	57.42 mg 100.74 %

MOTHER BATCH DETAILS
(FOR RESULTS)

Batch No.	DB240083	A.R.No.	IP242381
Stage	After Filling & Sealing	Sample Qty.	30 Bottles
Date of Receiving	24/07/2024	Batch Size	38,000 Bottles
Start Date of Analysis	25/07/2024	Date of Release	08/08/2024

Remarks: The above sample of finished product **complies** as per specification no. QC/FPS/052/02

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Dilip Kumar	Charan Singh Yadav
Designation	Trainee Officer-QC	Sr. Officer-QC	Manager-QC
Signature			
Date	08/08/2024	08/08/2024	08/08/2024

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