

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

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product Name	Amoxyheal-CV		
Generic Name	Amoxycillin & Potassium Clavulanate Oral Suspension IP		
Batch No.	DB240091W	Mfg. date	08/2024
A. R. No.	FP2410598	Expiry date	01/2026
Pack Size	3.3gm/30ml	Batch Size	6,000 Bottles
Date of receiving	19/08/2024	Type of Bottle	Glass
Date of preparation	02/09/2024	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 or pink	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.	3.32200 gm
	Uniformity of weight	Not less than 90% of the labelled amount	3.26200 gm 98.85 %
	Average net volume of the content	Not less than labeled amount.	30.3 ml
	Uniformity of volume	Not less than 95% of the labelled amount	29.0 ml 96.67 %
4	pH	3.80 to 6.60	5.09
5	Water	Not more than 8.5 %w/w	7.68 %
6	Assay		
	Each 5 ml of the reconstituted suspension contains:		
	Amoxicillin Trihydrate I.P. eq. to Amoxicillin-200 mg	Not less than 180.00 mg and not more than 240.00 mg of Amoxycillin	186.40 mg
		(Not less than 90.00% and not more than 120.00 % of state amount of amoxicillin)	93.20 %
	Potassium Clavulanate Diluted I.P. eq. to Clavulanic acid-28.5 mg	Not less than 25.65 mg and not more than 35.625 mg of Clavulanic acid	31.59 mg
		(Not less than 90.00% and not more than 125.00% of state amount of clavulanic acid)	110.84 %

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Rahul	Charan Singh Yadav
Designation	Trainee Officer-QC	Officer-QC	Manager-QC
Signature			
Date	02/09/2024	02/09/2024	02/09/2024

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

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

CERTIFICATE OF ANALYSIS

FINISHED PRODUCT

Product Name	Amoxyheal-CV		
Generic Name	Amoxicillin & Potassium Clavulanate Oral Suspension IP		
Batch No.	DB240091W	Mfg. date	08/2024
A. R. No.	FP2410598	Expiry date	01/2026
Pack Size	3.3gm/30ml	Batch Size	6,000 Bottles
Date of receiving	19/08/2024	Type of Bottle	Glass
Date of preparation	02/09/2024	Page No.	2 of 2

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- 200 mg	Not less than 160.00 mg of Amoxicillin (Not less than 80.00% of state amount of amoxicillin)	196.04 mg 98.02 %
	Potassium Clavulanate Diluted I.P. eq. to Clavulanic acid-28.5 mg	Not less than 22.80 mg of Clavulanic acid (Not less than 80.00% of state amount of clavulanic acid)	29.24 mg 102.60 %

**MOTHER BATCH DETAILS
(FOR RESULTS)**

Batch No.	DB240091	A.R.No.	IP242603
Stage	After Filling & Sealing	Sample Qty.	30 Bottles
Date of Receiving	14/08/2024	Batch Size	75,000 Bottles
Start Date of Analysis	14/08/2024	Date of Release	23/08/2024

Remarks: The above sample of finished product **complies** as per specification no. QC/FPS/051/02

	Prepared by	Checked by	Approved by
Name	Sahil Singh	Rahul	Charan Singh Yadav
Designation	Trainee Officer-QC	Officer-QC	Manager-QC
Signature			
Date	02/09/2024	02/09/2024	02/09/2024

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

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