PIL PHARMACEUTICALS LIMITED

Plot No.-71-72, Sector-6A, IIE, SIDCUL Indl. Area, Haridwar, Uttarakhand-249403 (India)

Department: Quality Control

CERTIFICATE OF ANALYSIS-FINISH PRODUCT

Name of Product	FAXICLAV	A.R. No.	S3BFG2100109
Generic Name	Co-Amoxiclav Oral Suspension 250 mg/62.5 mg per 5ml Powder for Suspension		
Batch No.	ABY31001	Receipt Date	09/03/2021
Mfg./Date	03/2021	Sample Quantity	25 Piece
Exp./Date	03/2023	Completion Date	15/03/2021
Batch Size	10350Piece	Release Date	15/03/2021
Theoretical Yield	10350 Piece (100%)	Actual Yield	10000 (97.05%)
Revision No.	00	Revision Date	NA
Manufacturing License No. 56/UA/SC/P-2018			

Reference to Protocol: BP/IHS

Test	Observations		Specifications
Description	Off white granular powder having orange colour suspension after reconstitution.		Off white granular powder having orange colour suspension after reconstitution.
Identification (By TLC)	Complies		The principal spots in the chromatogram obtained with solution (1) should be similar in position , colour and size to that in the chromatogram obtained with solution (2)
Average Deliverable volume	60 ml		The average of volume obtained, not less than 60 ml
Acidity or Alkalinity (2.5 % w/v solution of Amoxicillin)	4.671		4.0 to 7.0 (after reconstitution)
Weight per ml (at a temperature 25°C ±1° C)	1.073g/ml		1.010 to 1.160 g/ml
Uniformity of filled weight	- 0.69% to +0.75 %		± 5.0%w/w of an average filled weight
Average fill weight of 10 bottles	15.12 g		Not less than 15 g.
Water (By KFR)	3.15% w/w		Not more than 8.5 % w/w
Clavulanate Polymer and other fluorescent impurities	Not Detected		Not more than 5.0% w/w
Related substances (By HPLC)			
Amoxicillin Dimer	Not Detected		Not more than 2.0 %
Single maximum impurity	0.14 %		Not more than 1.0 %
Assay (By HPLC) (Initial Day)	Obtained	Claim	Limits
Amoxicillin Trihydrate BP eq. to Anhydrous Amoxicillin	250.96 mg (100.4%)	250.00 mg	Release: 242.5 mg to 262.5 mg (97.0% to 105.0%) Shelf life: 225.0 mg to 300.0 mg (90.0 % to 120.0 %)
Diluted Potassium Clavulanate BP eq. to Clavulanic Acid	68.65mg (109.8 %)	62.50 mg	Release: 61.9 mg to 71.9 mg (99.0% to 115.0%) Shelf life: 56.3 mg to 75.0 mg (90.0 % to 120.0 %)
Microbiological Examination of Non-Sterile Products:			
Total Aerobic Bacterial Count	Less than 10 cfu/g		Not more than 10^3 cfu/g
Total Yeast & Mould Count	Less than 10 cfu/g		Not more than 10^2 cfu/g
Test for specified microorganisms			
Escherichia coli	Absent in 1 g		Escherichia coli should be absent in 1ml or 1g
After 5 days (After reconstitution)			
Assay (By HPLC) (After 5 days when store at 2° C to 8° C)			
Amoxicillin Trihydrate BP eq. to Anhydrous Amoxicillin	246.93 mg (98.8 %)	250 mg	200.00 mg to 300.00 mg (80.0 % to 120.0 %)
Diluted Potassium Clavulanate BP eq. to Clavulanic Acid	61.92 mg (99.1%)	62.50 mg	50.00 mg to 75.00 mg (80.0 % to 120.0 %)
Acidity or alkalinity (After 5 Days) (2.5 % w/v solution of Amoxicillin)	6.135		4.0 to 7.0

Remarks: The Sample complies /~~does not comply~~ with ~~IP~~/BP/~~USP~~/IH specification.

	Prepared By	Reviewed By	Approved By
Name	Gaurav Kumar Singh	Ankit Chauhan	Rupmishra
Designation	Officer	Executive QC	Sr. Manager QC
Signature/Date	15/03/2021	15/03/2021	15/03/2021