WHO-GMP Approved
An ISO 9001-2008
Certified company

CIN :U24230GJ1993PTC020695

Factory : Sokhada-388 620, Ta. -Khambhat
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BAROQUE
PHARMACEUTICALS PVT. LTD.

QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: AMOXICILLIN AND CLAVULANATE POTASSIUM TAB USP (CHILE 20X10)	**A.R. No.**	: **BPFP190045**
Packing	: 20x10 TAB		
Generic Name	: AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP	**Rel. Dt.**	: 20-05-2019
Product Code	: BQE441B	**Mfg. Dt.**	: APR-2019
Batch No.	: P019041	**Exp. Dt.**	: MAR-2021
Actual Batch Size	: 150000 TAB (750 BOX)	**Test Packing**	: 120 TAB
Packing Batch Size	: 150000 TAB	**Mfg. Lic No.**	: G/890
Sample Size	: 120.000 TAB	**Country**	: CHILE
Released Qty	: 150000.000 TAB (750 BOX)	**Test As Per**	: USP
		T.R. Slip No.	: BP190045
		T.R. Slip Dt.	: 04-05-2019
		Analysis Date	: 08-05-2019
		Specification No.	: SP/BQE441BFP-0
		Specification Dt.	: 01-06-2017
LC NO.: I021072 DATED.: 13/05/2019		**Location**	: PENICILLIN
		Make	: BAROQUE

Sr.	Test	Result	Specification
1	DESCRIPTION:	White coloured oval shape film coated tablet with on both side plain.	White coloured oval shape film coated tablet with on both side plain.
2	UNIFORMITY OF WEIGHT	Minimum: -1.92% Maximum: +0.98% Average weight: 1060.0 mg	Not more than 2 out of 20 tablets should deviate from the average weight by more than 5.0 % and none should deviate by more than 10.0 %
3	AVERAGE WEIGHT OF TABLET:	1057.4 mg	1060.0 mg ± 5.0%
4	DISINTEGRATION TEST:	08 min 13 sec	Not more than 30 minutes
5	HARDNESS:	Minimum: 25.3 kp Maximum: 31.0 kp	Not less than 3.0 kp
6	THICKNESS:	6.95 mm	6.80 mm ± 0.2 mm
7	LENGHT	19.74 mm	19.70 mm ± 0.2 mm
8	IDENTIFICATION:	The retention times of the major peaks of the sample preparation is correspond to those of the standard preparation as obtained in the assay.	The retention times of the major peaks of the sample preparation should be correspond to those of the standard preparation as obtained in the assay.
9	WATER:	7.65%	Not more than 10.0%
10	DISSOLUTION TEST:	-	-
	1 DISSOLUTION OF AMOXICILLIN :	Minimum: 101.37% Maximum: 104.28% Average: 103.13%	Not less than 85% (Q) [Q+5%=90%] of the labeled amounts of Amoxicillin is dissolved 30 minutes.
	2 DISSOLUTION OF CLAVULANIC ACID :	Minimum: 105.63%	Not less than 80% (Q) [Q+5%=85%] of the labeled amounts of Clavulanic acid is dissolved 30 minutes.

Conclusion : The above sample complies as per USP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By / Date	Checked By / Date	Approved By / Date
for Vm 20/05/2019	20/05/2019	20/05/2019
DEVENDRA PATEL Q.C. OFFICER	RIKEN R. PATEL Q.C. OFFICER	ASHVIN PATEL Q.C.EXECUTIVE

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		Specification No.	: SP/BQE441BFP-0
		Specification Dt.	: 01-06-2017
		Location	: PENICILLIN
		Make	: BAROQUE

Sr.	Test	Result	Specification
		Maximum: 109.37% Average: 107.89%	
11	UNIFORMITY OF DOSAGE UNITS:	-	-
	1 Amoxicillin (By mass variation):	Minimum: 104.11% Maximum: 106.12% Acceptance value: 1.43	Acceptance value should not more than 15.0
	2 Clavulanic acid (By Content uniformity):	Minimum: 102.32% Maximum: 106.12% Acceptance value: 3.58	Acceptance value should not more than 15.0
12	ASSAY:	-	-
	1 Amoxicillin USP as(Trihydrate)Eq.to Amoxicillin	104.83% = 524.17 mg	Not less than 90.0% and Not more than 120.0% of the stated amount of Amoxicillin.
	2 Potassium Clavulanate(diluted) Eq.to Clavulanic acid	109.35% = 136.69 mg	Not less than 90.0% and Not more than 120.0% of the stated amount of Clavulanic acid.
13	RESIDUAL SOLVENTS:	-	-
	1 ISOPROPYL ALCOHOL :	304.01 ppm	Not more than 5000 ppm
	2 METHYLENE CHLORIDE :	Not detetcted	Not more than 600 ppm
14	MICROBIAL CONTAMINATION :	-	-
	1 Total Aerobic Microbial Count :	10 CFU/gm	Not more than 10^3 CFU/g
	2 Total Yeast and Mould Count :	Nil	Not more than 10^2 CFU/g

Conclusion : The above sample complies as per USP

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By / Date	Checked By / Date	Approved By / Date
for 20/05/2019	20/05/2019	20/05/2019
DEVENDRA PATEL Q.C. OFFICER	RIKEN R. PATEL Q.C. OFFICER	ASHVIN PATEL Q.C.EXECUTIVE