

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)

Packing : 20x10 TAB

Generic Name : AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS USP

Product Code : BQE441B

Batch No. : P019041

Actual Batch Size : 150000 TAB (750 BOX)

Packing Batch Size : 150000 TAB

Sample Size : 120.000 TAB

Released Qty : 150000.000 TAB (750 BOX)

Mfg. Dt. : APR-2019

Exp. Dt. : MAR-2021

Test Packing : 120 TAB

Mfg. Lic No. : G/890

Country : CHILE

Test As Per : USP

LC NO.: I021072 DATED.: 13/05/2019

A.R. No. : BFP190045

Rel. Dt. : 20-05-2019

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

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 $\pm$ 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 $\pm$ 0.2 mm
7	LENGHT	19.74 mm	19.70 mm $\pm$ 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
for *Vm* 20/05/2019
DEVENDRA PATEL
Q.C. OFFICER

Checked By / Date
Ripatel 20/05/2019
RIKEN R. PATEL
Q.C. OFFICER

Approved By / Date
Orland 20/05/2019
ASHVIN PATEL
Q.C.EXECUTIVE

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Analysis Date : 08-05-2019

Specification No. : SP/BQE441BFP-0

Specification Dt. : 01-06-2017

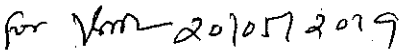
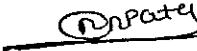
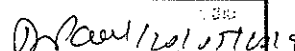
Location : PENICILLIN

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%	Acceptance value should not more than 15.0
		Maximum: 106.12%	
		Acceptance value: 1.43	
2	Clavulanic acid (By Content uniformity):	Minimum: 102.32%	Acceptance value should not more than 15.0
		Maximum: 106.12%	
		Acceptance value: 3.58	
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 detected	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

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Analysed By / Date	Checked By / Date	Approved By / Date
for  DEVENDRA PATEL Q.C. OFFICER	 2010512019 RIKEN R. PATEL Q.C. OFFICER	 ASHVIN PATEL Q.C.EXECUTIVE

