VHO-GMP Approved An ISO 9001-2008 Certified company

Factory: Sokhada-388 620, Ta.-Khambhat

Dist.-Anand(Guj.) INDIA

Phone:(F) (+91 2698) 302502, 302503 Fax: 302500

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IN: U24230GJ1993PTC020695

PHARMACEUTICALS' PVT. LTD

Page 1 of 1

## QUALITY CONTROL DEPARTMENT THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) CERTIFICATE OF ANALYSIS (FINISHED PRODUCT STAGE)

: AMOXICILLIN FOR ORAL SUSPENSION USP 250MG **Product Name** 

Generic Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG

**Product Code** Batch Size: 306 KG : BQE442 Batch No. : B016209

Label Claim After reconstitution each 5 ml contains: Amoxicillin USP (as Trihydrate)

Eq. to Amoxicillin 250 Mg. Excipients Q.S. Colour: Erythrosine

LC NO.: 827070600002329 DATED.: 06/01/2017

Location

: KHAMBHAT : BAROOUF

Mfg. Lic No. : G/890

Specification No. : SP/BQE442FP-0 Specification Dt. : 13-06-2016

Test As Per

: USP

**Test Packing** Sample Size

4 000 BOT : 4.000 BOT

Mfg. Dt.: NOV-2016 T.R. Slip No. : BBQ160261

Exp. Dt.: OCT-2018

T.R. Slip Dt. **Analysis Date** A.R. No.

: 08-11-2016 : 08-11-2016 : BBQFP16271 : 17-11-2016

A.R. Dt. Released Qty.

: 306 KG

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Sr.	Test	Result	Specification
1	DESCRIPTION:	pinkish white coloured granular powder free	White to pinkish white coloured granular powder
		from foreign particles which converts into pink	free from foreign particles which converts into pin
	•	coloured viscous suspension with fruity odour	coloured viscous suspension with fruity odour on
		on addition of water up to volume make up to	addition of water up to volume make up to 60 ml.
	AVED 105 HEIGHT 01 P. C.	60 ml.	
2	AVERAGE WEIGHT OF POWDER :	20.0183 gm	20.0 gm ± 9.0%
3	pH:	6.33	Between 5.0 to 7.5
4	WEIGHT / ML:	1.1029 gm/ml	1.150 gm/ml ±10 %
			(Between 1.035 to 1.265 gm/ml)
5	DELIVERABLE VOLUME:	60.09 ml	Not less than 60 ml
6	IDENTIFICATION:	The retention time of the major peak of the	The retention time of the major peak of the
		sample solution is corresponds to that of the	sample solution should be corresponds to that of
		standard solution as obtained in the assay.	the standard solution as obtained in the assay.
8	Assay of Amoxicillin USP (as Trihydrate)	1) 99.61% = 249.02 mg	Not less than 90.0% & Not more than 120.0% of
	eq. to Amoxicillin;		the stated amount of Amoxicillin.
9	Assay of Amoxicillin Reconstituted	1) 96.20% = 240.50 mg	Not less than 90.0% of the stated amount of
10	suspension after 7 days: MICROBIAL CONTAMINATION:		Amoxicillin.
10		45.0511	-
	1 Total Aerobic Microbial Count :	15 CFU/g	Not more than 10 <sup>3</sup> CFU/gm
	2 Total Yeast and Mould Count :	Nil	Not more than 10 <sup>2</sup> CFU/gm
	3 E.Coli:	Absent	Should be absent.
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Conclusion : The above sample complies as per USP

n 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 he reasons given above.

Analysed By Checked By Approved By PPPanahal ce M PRAGNESH P. PANCHAL JAYDEEP J. PATEL VINOD A.PATEL Q.C. OFFICER Q.C.EXECUTIVE Q.C.MANAGER

Corp.off.: D-403, Titanium Square, Nr. Thaltej Cross Road, S.G. Highway Ahmedabad-380054. Phone: (079)40009421

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Page 1 of 1

## QUALITY CONTROL DEPARTMENT

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) CERTIFICATE OF ANALYSIS (FINISHED PRODUCT STAGE)

**Product Name** 

: AMOXICILLIN FOR ORAL SUSPENSION USP 250MG

Generic Name

\_abel Claim

Excipients Q.S.

Colour: Erythrosine

: AMOXICILLIN FOR ORAL SUSPENSION USP 250MG

LC NO.: 827070600002329 DATED.: 06/01/2017

**Product Code** 

Amoxicillin USP (as Trihydrate)

Eq. to Amoxicillin 250 Mg.

After reconstitution each 5 ml contains:

Batch No.: 8016211 : BQE442

Batch Size: 306 KG

: KHAMBHAT

Location Make Mfg. Lic No.

: BAROQUE

Specification No.

: G/890 SP/BQE442FP-0

Specification Dt. : 13-06-2016

Test As Per **Test Packing**  : USP

Sample Size

4,000 BOT : 4.000 BOT

Mfg. Dt. : NOV-2016

Exp. Dt.: OCT-2018

T.R. Slip No. T.R. Slip Dt.

: BBQ160262 : 09-11-2016

Analysis Date A.R. No.

: 10-11-2016 : BBQFP16270

A.R. Dt.

: 17-11-2016

	•		Released Qty. : 306 KG
Sr.	Test	Result	Specification
1	DESCRIPTION:	Pinkish white coloured granular powder free from foreign particles which converts into pink coloured viscous suspension with fruity odour on addition of water up to volume make up to 60 ml.	White to pinkish white coloured granular powder free from foreign particles which converts into pin coloured viscous suspension with fruity odour on addition of water up to volume make up to 60 ml.
2	AVERAGE WEIGHT OF POWDER :	20.0188 gm	20.0 gm ± 9.0%
3	pH:	6.54	Between 5.0 to 7.5
4	WEIGHT / ML:	1.1154 gm/ml	1.150 gm/ml ±10 % (Between 1.035 to 1.265 gm/ml)
5	DELIVERABLE VOLUME:	60.13 ml	Not less than 60 ml
6	IDENTIFICATION:	The retention time of the major peak of the sample solution is corresponds to that of the standard solution as obtained in the assay.	The retention time of the major peak of the sample solution should be corresponds to that of the standard solution as obtained in the assay.
8	Assay of Amoxicillin USP (as Trihydrate) eq. to Amoxicillin:	1) 99.76% = 249.41 mg	Not less than 90.0% & Not more than 120.0% of the stated amount of Amoxicillin.
9	Assay of Amoxicillin Reconstituted suspension after 7 days:	1) 96.39% = 240.97 mg	Not less than 90.0% of the stated amount of Amoxicillin.
10	MICROBIAL CONTAMINATION:	-	•
	1 Total Aerobic Microbial Count:	18 CFU/g	Not more than 10 <sup>3</sup> CFU/gm
	2 Total Yeast and Mould Count :	Nil	Not more than 10 <sup>2</sup> CFU/gm
	3 E.Coli:	Absent	Should be absent.

Conclusion: The above sample complies as per <u>USP</u>

n 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 he reasons given above.

Analysed By Checked By Approved By 100 - Cur K.B. Patel. KRISHNA B, PATEL JAYDEEP J. PATEL VINOD A.PATEL Q.C. OFFICER Q.C.EXECUTIVE Q.C.MANAGER

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IN: U24230GJ1993PTC020695

After reconstitution each 5 ml contains:

Amoxicillin USP (as Trihydrate)

Eq. to Amoxicillin 250 Mg.

Excipients Q.S.

Colour: Erythrosine

Page 1 of 1

## **QUALITY CONTROL DEPARTMENT**

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) CERTIFICATE OF ANALYSIS (FINISHED PRODUCT STAGE)

: AMOXICILLIN FOR ORAL SUSPENSION USP 250MG **Product Name** : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG Generic Name **Product Code** Batch No.: B016212 : BQE442 Label Claim

LC NO.: 827070600002329 DATED.: 06/01/2017

Batch Size: 306 KG

Location Make Mfg. Lic No. : KHAMBHAT : BAROQUE : G/890

Specification No. : SP/BQE442FP-0

Specification Dt. : 13-06-2016

Test As Per Test Packing

: USP

Sample Size

4 000 BOT : 4.000 BOT

Mfg. Dt. : NOV-2016 T.R. Slip No.

Exp. Dt.: OCT-2018

T.R. Slip Dt. **Analysis Date**  : BBQ160264 : 11-11-2016 : 12-11-2016

A.R. No.

: BBQFP16275 : 19-11-2016

A.R. Dt. Released Qty.

: 306 KG

			1 000 110
Sr.	Test	Result	Specification
1	DESCRIPTION:	pinkish white coloured granular powder free	White to pinkish white coloured granular powder
	,	from foreign particles which converts into pink	free from foreign particles which converts into pir
		coloured viscous suspension with fruity odour	coloured viscous suspension with fruity odour on
		on addition of water up to volume make up to 60 ml.	addition of water up to volume make up to 60 ml.
2 .	AVERAGE WEIGHT OF POWDER:	20.0184 gm	20.0 gm ± 9.0%
3	pH:	6.70	Between 5.0 to 7.5
4	WEIGHT / ML:	1.1531 gm/ml	1.150 gm/ml ±10 %
	•		(Between 1.035 to 1.265 gm/ml)
5	DELIVERABLE VOLUME:	60.28 ml	Not less than 60 ml
6	IDENTIFICATION:	The retention time of the major peak of the	The retention time of the major peak of the
		sample solution is corresponds to that of the	sample solution should be corresponds to that of
		standard solution as obtained in the assay.	the standard solution as obtained in the assay.
8	Assay of Amoxicillin USP (as Trihydrate)	1) 99.79% = 249.47 mg	Not less than 90.0% & Not more than 120.0% of
	eq. to Amoxicillin:		the stated amount of Amoxicillin.
9	Assay of Amoxicillin Reconstituted suspension after 7 days:	1) 96.83% = 242.07 mg	Not less than 90.0% of the stated amount of Amoxicillin.
10	MICROBIAL CONTAMINATION:	•	
	1 Total Aerobic Microbial Count :	15 CFU/g	Not more than 10 <sup>3</sup> CFU/gm
	2 Total Yeast and Mould Count :	Nil	Not more than 10 <sup>2</sup> CFU/gm
•	3 E.Coli:	Absent	Should be absent.
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Conclusion : The above sample complies as per <u>USP</u>

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 reasons given above.

Analysed By Checked By Approved By Co Carr Lese K-B-Patel. JAYDEEP J. PATEL VINOD A.PATEL KRISHNA B. PATEL O.C. EXECUTIVE Q.C. OFFICER

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