

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

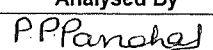
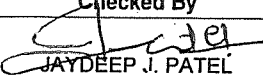
Product Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Generic Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Product Code : BQE442	Batch No. : B016209
Batch Size : 306 KG	
Label Claim : After reconstitution each 5 ml contains: Amoxicillin USP (as Trihydrate) Eq. to Amoxicillin 250 Mg. Excipients Q.S. Colour: Erythrosine	
Location : KHAMBHAT Make : BAROQUE Mfg. Lic No. : G/890 Specification No. : SP/BQE442FP-0 Specification Dt. : 13-06-2016 Test As Per : USP Test Packing : 4.000 BOT Sample Size : 4.000 BOT Mfg. Dt. : NOV-2016 Exp. Dt. : OCT-2018 T.R. Slip No. : BBQ160261 T.R. Slip Dt. : 08-11-2016 Analysis Date : 08-11-2016 A.R. No. : BBQFP16271 A.R. Dt. : 17-11-2016 Released Qty. : 306 KG	

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

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 pink coloured viscous suspension with fruity odour on addition of water up to volume make up to 60 ml.
2	AVERAGE WEIGHT OF POWDER :	20.0183 gm	20.0 gm $\pm$ 9.0%
3	pH:	6.33	Between 5.0 to 7.5
4	WEIGHT / ML:	1.1029 gm/ml	1.150 gm/ml $\pm$ 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 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) 99.61% = 249.02 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) 96.20% = 240.50 mg	Not less than 90.0% of the stated amount of Amoxicillin.
10	MICROBIAL CONTAMINATION : 1 Total Aerobic Microbial Count : 2 Total Yeast and Mould Count : 3 E.Coli :	- 15 CFU/g Nil Absent	- Not more than 10 ³ CFU/gm Not more than 10 ² CFU/gm Should be absent.

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 reasons given above.

Analysed By  PRAGNESH P. PANCHAL Q.C. OFFICER	Checked By  JAYDEEP J. PATEL Q.C. EXECUTIVE	Approved By  VINOD A. PATEL Q.C. MANAGER
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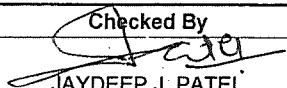
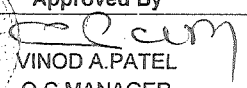
Product Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Generic Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Product Code : BQE442	Batch No. : B016211
Batch Size : 306 KG	
Label Claim : After reconstitution each 5 ml contains: Amoxicillin USP (as Trihydrate) Eq. to Amoxicillin 250 Mg. Excipients Q.S. Colour: Erythrosine	
Location : KHAMBHAT Make : BAROQUE Mfg. Lic No. : G/890 Specification No. : SP/BQE442FP-0 Specification Dt. : 13-06-2016 Test As Per : USP Test Packing : 4.000 BOT Sample Size : 4.000 BOT Mfg. Dt. : NOV-2016 Exp. Dt. : OCT-2018 T.R. Slip No. : BBQ160262 T.R. Slip Dt. : 09-11-2016 Analysis Date : 10-11-2016 A.R. No. : BBQFP16270 A.R. Dt. : 17-11-2016 Released Qty. : 306 KG	

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

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 pink 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 : 2 Total Yeast and Mould Count : 3 E.Coli :	- 18 CFU/g Nil Absent	- Not more than 10 ³ CFU/gm Not more than 10 ² CFU/gm Should be absent.

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 reasons given above.

Analysed By K. B. Patel. KRISHNA B. PATEL Q.C. OFFICER	Checked By  JAYDEEP J. PATEL Q.C.EXECUTIVE	Approved By  VINOD A.PATEL Q.C.MANAGER
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QUALITY CONTROL DEPARTMENT

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

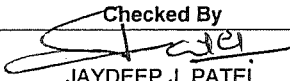
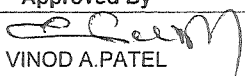
Product Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Generic Name : AMOXICILLIN FOR ORAL SUSPENSION USP 250MG	
Product Code : BQE442	Batch No. : B016212
Batch Size : 306 KG	
Label Claim : After reconstitution each 5 ml contains: Amoxicillin USP (as Trihydrate) Eq. to Amoxicillin 250 Mg. Excipients Q.S. Colour: Erythrosine	
Location : KHAMBHAT Make : BAROQUE Mfg. Lic No. : G/890 Specification No. : SP/BQE442FP-0 Specification Dt. : 13-06-2016 Test As Per : USP Test Packing : 4.000 BOT Sample Size : 4.000 BOT Mfg. Dt. : NOV-2016 Exp. Dt. : OCT-2018 T.R. Slip No. : BBQ160264 T.R. Slip Dt. : 11-11-2016 Analysis Date : 12-11-2016 A.R. No. : BBQFP16275 A.R. Dt. : 19-11-2016 Released Qty. : 306 KG	

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

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 pink coloured viscous suspension with fruity odour on 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 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) 99.79% = 249.47 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) 96.83% = 242.07 mg	Not less than 90.0% of the stated amount of Amoxicillin.
10	MICROBIAL CONTAMINATION : 1 Total Aerobic Microbial Count : 2 Total Yeast and Mould Count : 3 E.Coli :	15 CFU/g Nil Absent	Not more than 10 ³ CFU/gm Not more than 10 ² CFU/gm Should be absent.

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 reasons given above.

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