



STABLITY STUDIES - FP



STABILITY PROTOCOL INDEX

S. NO.	CONTENTS	PAGE NO
i	Approval page	3
1	Purpose	4
2	Test Design	4
2.1	Test Material	4
2.2	Testing Plan	4
3	Number of samples	5
3.1	Accelerated stability studies	5
3.2	Real Time stability studies	6
4	Report content	6



STABILITY REPORT INDEX

S. NO.	CONTENTS	PAGE NO
i	Approval page	3
1	Responsibility	5
2	Summary	5
3	Objective	5
4	Test Material	5
5	Composition	6
6	Packaging	7
7	Storage conditions and testing intervals	7
8	Analytical procedures	7
9	Reference standard	7
10	Results	7
11	Discussion / Conclusions	8
12	Test results in tabular form	8



STABLITY STUDIES - API

Pragya Dossier-DMF Services

Plot No. 63, 76 & 77, Industrial Park (APIIC) Valasapalli, NH 42 Madanapalle -517 325, AP, India

For Quote - info@pdds.in & +91-96522-81814



TABLE I: ACCELERATED STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 40 ⁰ c±2 ⁰ c&RH75%±5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/001	SHELF LIFE: 4 year
BATCH SIZE: 100.0 Kg	DATE STARTED: 10/04/2012
REFERENCE: ICH	DATE COMPLETED: 10/10/2012

Test	Specification	Results				
		Initial	1st Month	2nd Month	3rd Month	6th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification						
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate
pH	3.5 to 5.5	4.5	4.5	4.6	4.6	4.7
Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 296°	+ 296°	+ 296°	+ 297°	+ 298°
Related substances						
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.4 %	0.4 %	0.5 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	9 ppm	10 ppm	10 ppm
Water	11.5 % to 14.5 %	12.4 %	12.4 %	12.5 %	12.5 %	12.6 %
Sulfated ash	Not more than 1.0%	0.4 %	0.4 %	0.5 %	0.5 %	0.6 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.83	99.71	99.48	99.36	99.13



Remarks: The above mention substance under the conditions mention above is stable up to the period of 6 months.

ANALYSED BY:

APPROVEDBY:



TABLE II: ACCELERATED STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 40 ⁰ c±2 ⁰ c&RH75%±5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/002	SHELF LIFE: 4 year
BATCH SIZE: 97.0 Kg	DATE STARTED: 15/04/2012
REFERENCE: ICH	DATE COMPLETED: 15/10/2012

Test	Specification	Results				
		Initial	1st Month	2nd Month	3rd Month	6th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification						
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate
pH	3.5 to 5.5	4.6	4.7	4.7	8.8	8.8
Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 95°	+ 296°	+ 296°	+ 297°	+ 297°
Related substances						
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.3 %	0.4 %	0.4 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	10 ppm	10 ppm	10 ppm
Water	11.5 % to 14.5 %	12.4 %	12.4 %	12.5 %	12.6 %	12.6 %
Sulfated ash	Not more than 1.0%	0.3 %	0.4 %	0.3 %	0.5 %	0.6 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.77	99.65	99.42	99.30	99.07



Remarks: The above mention substance under the conditions mention above is stable up to the period of 6 months.

ANALYSED BY:

APPROVEDBY:



TABLE III: ACCELERATED STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 40 ⁰ c±2 ⁰ c&RH75%±5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/003	SHELF LIFE: 4 year
BATCH SIZE: 97.0 Kg	DATE STARTED: 23/04/2012
REFERENCE: ICH	DATE COMPLETED: 23/10/2012

Test	Specification	Results				
		Initial	1st Month	2nd Month	3rd Month	6th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification						
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate
pH	3.5 to 5.5	4.6	4.6	4.7	4.7	4.8
Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 296°	+ 296°	+ 297°	+ 297°	+ 298°
Related substances						
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.3 %	0.4 %	0.4 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	10 ppm	10 ppm	11 ppm
Water	11.5 % to 14.5 %	12.4 %	12.5 %	12.5 %	12.6 %	12.6 %



Sulfated ash	Not more than 1.0%	0.4 %	0.5 %	0.5 %	0.6 %	0.6 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.86	99.74	99.51	99.39	99.16

Remarks: The above mention substance under the conditions mention above is stable up to the period of 6 months.

ANALYSED BY:

APPROVEDBY:



TABLE IV: REAL TIME STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 25°C ± 2°C & RH 60 % ± 5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/001	SHELF LIFE: 4 year
BATCH SIZE: 97.0 Kg	DATE STARTED: 10/04/2012
REFERENCE: ICH	DATE COMPLETED: 10/04/2016

Test	Specification	Results								
		Initial	3rd Month	6th Month	9th Month	12 th month	18th month	24th Month	36th Month	48th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification										
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate
pH	3.5 to 5.5	4.5	4.5	4.5	4.5	4.6	4.6	4.6	4.7	4.7



Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 296°	+ 296°	+ 296°	+ 297°	+ 297°	+ 297°	+ 298°	+ 298°	+ 298°
Related substances										
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.3 %	0.3 %	0.4 %	0.4 %	0.4 %	0.5 %	0.5 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	9 ppm	9 ppm	10 ppm	10 ppm	10 ppm	11 ppm	11 ppm
Water	11.5 % to 14.5 %	12.4 %	12.4 %	12.4 %	12.4 %	12.5 %	12.5 %	12.5 %	12.5 %	12.6 %
Sulfated ash	Not more than 1.0%	0.4 %	0.4 %	0.5 %	0.5 %	0.5 %	0.6 %	0.6 %	0.6 %	0.6 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.83	99.79	99.56	99.48	99.25	99.02	98.79	98.56	97.87

Remarks: The above mention substance under the conditions mention above is stable up to the period of 4 years.

ANALYSED BY:

APPROVED BY:



TABLE V: REAL TIME STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 25°C ± 2°C & RH 60 % ± 5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/002	SHELF LIFE: 4 year
BATCH SIZE: 97.0 Kg	DATE STARTED: 15/04/2012
REFERENCE: ICH	DATE COMPLETED: 15/04/2016

Test	Specification	Results								
		Initial	3rd Month	6th Month	9th Month	12 th month	18th month	24th Month	36th Month	48th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification										
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate



pH	3.5 to 5.5	4.6	4.6	4.6	4.6	4.6	4.6	4.7	4.7	4.7
Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 95°	+ 95°	+ 296°	+ 296°	+ 297°	+ 297°	+ 297°	+ 298°	+ 298°
Related substances										
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.3 %	0.4 %	0.4 %	0.4 %	0.5 %	0.5 %	0.5 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	9 ppm	10 ppm	10 ppm	10 ppm	10 ppm	11 ppm	11 ppm
Water	11.5 % to 14.5 %	12.4 %	12.4 %	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %	12.6 %	12.6 %
Sulfated ash	Not more than 1.0%	0.3 %	0.3 %	0.4 %	0.4 %	0.5 %	0.5 %	0.5 %	0.6 %	0.6 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.77	99.73	99.50	99.42	99.19	98.96	98.73	98.50	97.99

Remarks: The above mention substance under the conditions mention above is stable up to the period of 4 years.

ANALYSED BY:

APPROVEDBY:



TABLE VI: REAL TIME STABILITY STUDY REPORT

PRODUCT NAME: Amoxicillin Trihydrate BP	MFG.Date: 04/2012
STORAGE CONDITIONS: 25°C ± 2°C & RH 60 % ± 5%	EXP.Date: 03/2016
BATCH.NO: ST/CPT/003	SHELF LIFE: 4 year
BATCH SIZE: 97.0 Kg	DATE STARTED: 23/04/2012
REFERENCE: ICH	DATE COMPLETED: 23/04/2016

Test	Specification	Results								
		Initial	3rd Month	6th Month	9th Month	12 th month	18th month	24th Month	36th Month	48th Month
Characters	A white or almost white, crystalline powder.	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.	Slightly soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides.
Identification										
By Infrared Spectrophotometry	Test IR spectrum should be match with standard IR spectrum	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate	Positive for Amoxicillin Trihydrate
pH	3.5 to 5.5	4.6	4.5	4.6	4.6	4.6	4.6	4.7	4.7	4.7



Specific optical rotation	+ 290° to + 315° (anhydrous substance)	+ 296°	+ 296°	+ 296°	+ 297°	+ 297°	+ 297°	+ 297°	+ 298°	+ 298°
Related substances										
Any impurity	Not more than 1.0 per cent	0.3 %	0.3 %	0.4 %	0.4 %	0.4 %	0.5 %	0.5 %	0.5 %	0.5 %
N,N-Dimethylaniline	Not more than 20 ppm	9 ppm	9 ppm	9 ppm	10 ppm	10 ppm	10 ppm	11 ppm	11 ppm	11 ppm
Water	11.5 % to 14.5 %	12.4 %	12.4 %	12.4 %	12.5 %	12.5 %	12.5 %	12.5 %	12.6 %	12.6 %
Sulfated ash	Not more than 1.0%	0.4 %	0.4 %	0.5 %	0.5 %	0.5 %	0.5 %	0.6 %	0.6 %	0.9 %
Assay (in %)	95.0 per cent to 102.0 per cent	99.86	99.82	99.59	99.51	99.28	99.05	98.82	98.59	98.32

Remarks: The above mention substance under the conditions mention above is stable up to the period of 4 years.

ANALYSED BY:

APPROVEDBY: