



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142103 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611

Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

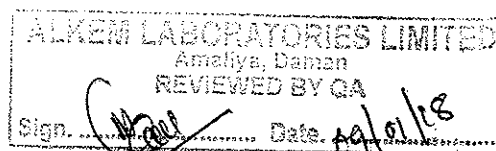
Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date

09/01/18



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

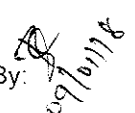
Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 20'S HDPE pack
Pack Code : NT9611
Batch No : 6142103 (Mother Batch:6142103)

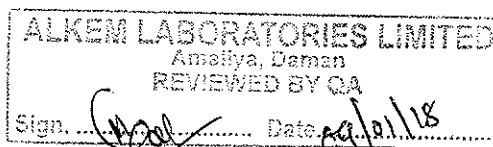
API Details

Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000790, 614R000824

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 40 CC, 33 MM	Shriji Polymers India Ltd.	614P001283, 614P001332	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 33 MM	Shriji Polymers India Ltd.	614P001672	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG
(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142104 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611

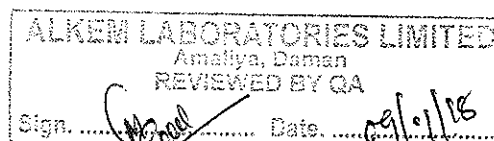
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	—	Absent
	b) Pseudomonas aeruginosa	Absent	—	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	—	Absent
	e) Candida albicans	Absent	—	Absent
Date of Sample Withdrawn			—	14.09.17
Date of Analysis			13.09.16	03.01.18

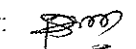
Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 20'S HDPE pack
Pack Code : NT9611
Batch No : 6142104 (Mother Batch:6142104)

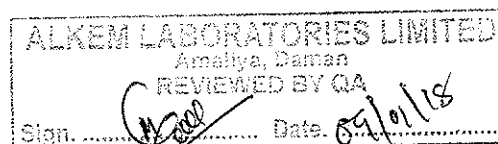
API Details

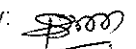
Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000824

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 40 CC, 33 MM	Shriji Polymers India Ltd.	614P001332	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 33 MM	Shriji Polymers India Ltd.	614P001672	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142196 (Mother Batch:6142105)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611

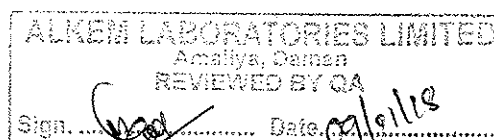
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 20'S HDPE pack
Pack Code : NT9611
Batch No : 6142196 (Mother Batch:6142105)

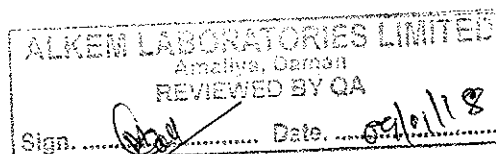
API Details

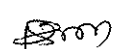
Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000825, 614R000791

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 40 CC, 33 MM	Shriji Polymers India Ltd.	614P001332	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 33 MM	Shriji Polymers India Ltd.	614P001672	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142176 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

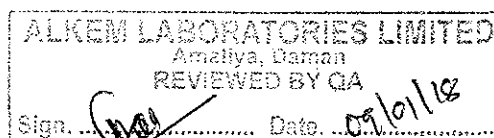
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

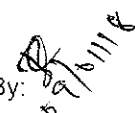
Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 100'S HDPE pack
Pack Code : NT9612
Batch No : 6142176 (Mother Batch:6142104)

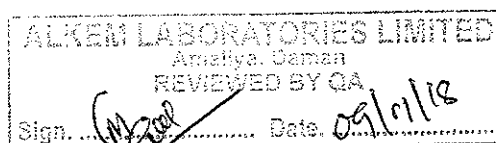
API Details

Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000824

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 100 CC, 38 MM	Shriji Polymers India Ltd. Unit-I	614P001571	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 38 MM	Shriji Polymers India Ltd. Unit-I	614P001589	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date: 09/01/18



Checked By: 
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142174 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

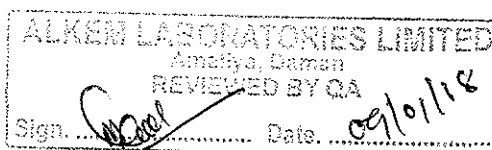
Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date

09/01/18



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

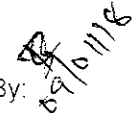
Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 100'S HDPE pack
Pack Code : NT9612
Batch No : 6142174 (Mother Batch:6142103)

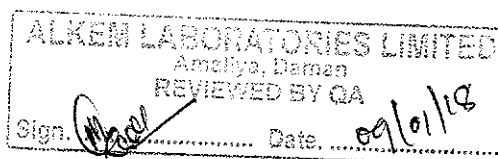
API Details

Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000790, 614R000824

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 100 CC, 38 MM	Shriji Polymers India Ltd. Unit-I	614P001571	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 38 MM	Shriji Polymers India Ltd. Unit-I	614P001079, 614P001589	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142105 (Mother Batch:6142105)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

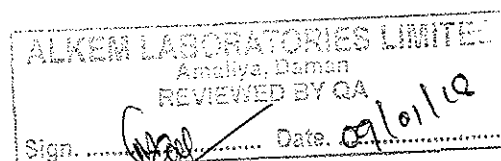
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

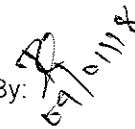
Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 100'S HDPE pack
Pack Code : NT9612
Batch No : 6142105 (Mother Batch:6142105)

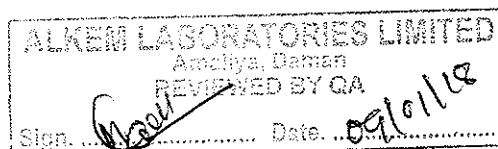
API Details

Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000825, 614R000791

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 100 CC, 38 MM	Shriji Polymers India Ltd. Unit-I	614P001571	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Child Resistant 38 MM	Shriji Polymers India Ltd. Unit-I	614P001589	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142175 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613

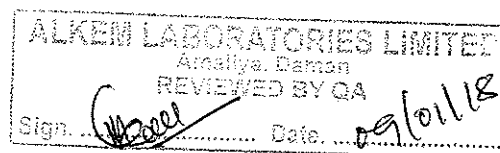
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	01 cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 500'S HDPE pack
Pack Code : NT9613
Batch No : 6142175 (Mother Batch:6142103)

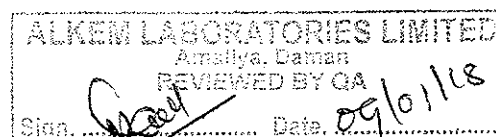
API Details

Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000824, 614R000790

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 500 CC, 53 MM	Shriji Polymers India Ltd.	614P001505	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Non Child Resistant 53 MM	Shriji Polymers India Ltd.	614P001591	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142177 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613

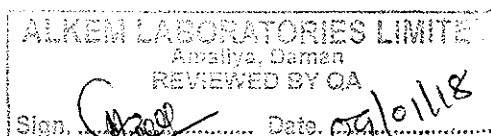
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

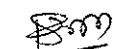
Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

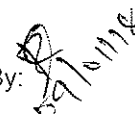
Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 500'S HDPE pack
Pack Code : NT9613
Batch No : 6142177 (Mother Batch:6142104)

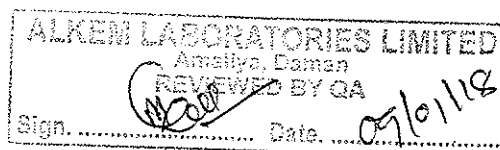
API Details

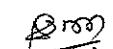
Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000824

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 500 CC, 53 MM	Shriji Polymers India Ltd.	614P001505	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Non Child Resistant 53 MM	Shriji Polymers India Ltd.	614P001591	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date



Checked By: 
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142197 (Mother Batch:6142105)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016
Condition	: 25 ± 2°C / 60 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613

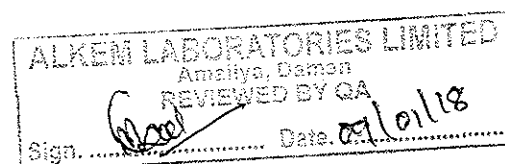
Sr. No	Tests	Specification	Station	
			Initial	12M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	14.09.17
Date of Analysis			13.09.16	03.01.18

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 12 months at 25 ± 2°C / 60 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date



Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

ANNEXURE - I

Active pharmaceutical ingredient (API) & component details of Cefpodoxime Proxetil Tablets USP 200 mg

Protocol No. FRD/P/086/16-00

Product : Cefpodoxime Proxetil Tablets USP
Strength : 200 mg
Pack : 500'S HDPE pack
Pack Code : NT9613
Batch No : 6142197 (Mother Batch:6142105)

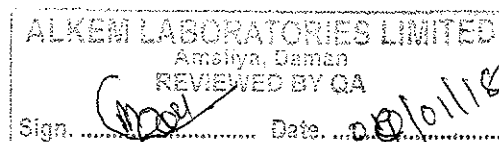
API Details

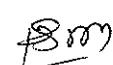
Sr. No.	API	Manufacturer Name	A.R. Number
1.	Cefpodoxime Proxetil USP	Covalent Laboratories Pvt Ltd.	614R000825, 614R000791

MOC/Resin Details

Sr. No.	Packaging Material	Name of Manufacturer	A.R. Number	MOC Details with manufacturer
1	HDPE Bottle 500 CC, 53 MM	Shriji Polymers India Ltd.	614P001505	Resin Grade: Marlex HHM5502BN, Chevron Phillips. Colorant: 11078 white US Ampacet.
2	Cap Non Child Resistant 53 MM	Shriji Polymers India Ltd.	614P001591	Resin Grade: Repol H110MA, Relince Industries Ltd. India. Colorant: 11343 White Ampacet. Liner: HS123.20 White Printed Tri-Seal.
3	Canister Sorb-IT 2 G.	Clariant Corporation USA.	614P000693	Not applicable

Prepared By: 
Date: 09/01/18



Checked By: 
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

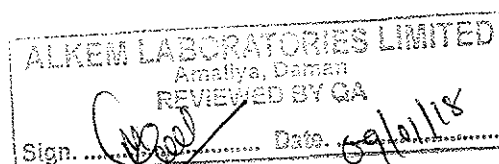
Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142103 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
DateChecked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

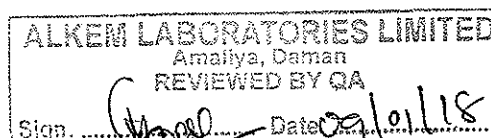
(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142104 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611
Sr. No	Tests	Specification	Station
			Initial6M
1	Microbial Enumeration test and test for Specified Microorganisms		
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/gNil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/gNil cfu/g
	iii) Specified microorganisms		
	a) Staphylococcus aureus	Absent	--Absent
	b) Pseudomonas aeruginosa	Absent	--Absent
	c) Escherichia coli	Absent	AbsentAbsent
	d) Salmonella species	Absent	--Absent
	e) Candida albicans	Absent	--Absent
Date of Sample Withdrawn		--	15.03.17
Date of Analysis		13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
DateChecked By:
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

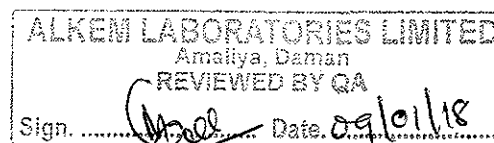
Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142196 (Mother Batch:6142105)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 20's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9611

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
DateChecked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

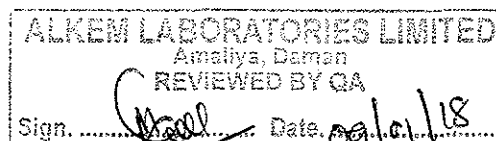
Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142176 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).



Prepared By:
Date: 09/01/18

Checked By:
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142174 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date

09/01/18

ALKEM LABORATORIES LIMITED
Amaliya, Daman
REVIEWED BY QA
Sign. Date: 09/01/18

Checked By:
Date

09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

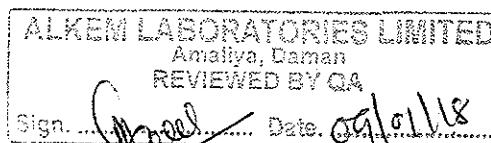
Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142105 (Mother Batch:6142105)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 100's HDPE pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9612

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date: 09/01/18Checked By:
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142175 (Mother Batch:6142103)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613

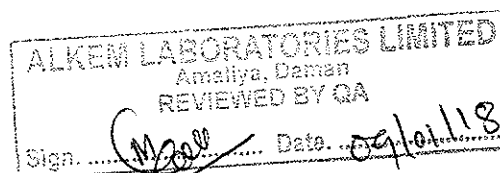
Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test: at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By: 
Date: 09/01/18



Checked By: 
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

(Protocol Number: FRD/P/086/16-00)

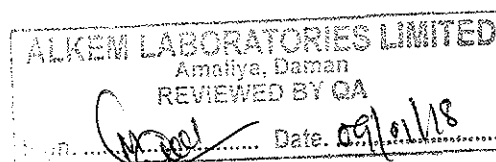
Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142177 (Mother Batch:6142104)
Strength	: 200 mg	Batch Size	: 215000 Tablets
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613

Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn			--	15.03.17
Date of Analysis			13.09.16	29.03.17

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
Date: 09/01/18Checked By:
Date: 09/01/18



ALKEM LABORATORIES LIMITED

STABILITY REPORT FORMAT FOR CEFPODOXIME PROXETIL TABLETS USP 200MG

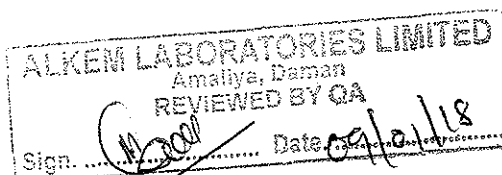
(Protocol Number: FRD/P/086/16-00)

Product	: Cefpodoxime Proxetil Tablets USP	Batch No.	: 6142197 (Mother Batch:6142105)	
Strength	: 200 mg	Batch Size	: 215000 Tablets	
Pack	: 500's HDPE Pack	Mfg. Date	: Aug-2016	
Condition	: 40 ± 2°C / 75 ± 5 % RH	Stability Start Date	: 14/09/2016	
Reason for stability	: Microbiological stability study.	Pack Code	: NT9613	
Sr. No	Tests	Specification	Station	
			Initial	6M
1	Microbial Enumeration test and test for Specified Microorganisms			
	i) Total Viable aerobic microbial count	Not more than 10 ³ cfu/g	<10 cfu/g	Nil cfu/g
	ii) Total combined molds and yeasts count	Not more than 10 ² cfu/g	<10 cfu/g	Nil cfu/g
	iii) Specified microorganisms			
	a) Staphylococcus aureus	Absent	--	Absent
	b) Pseudomonas aeruginosa	Absent	--	Absent
	c) Escherichia coli	Absent	Absent	Absent
	d) Salmonella species	Absent	--	Absent
	e) Candida albicans	Absent	--	Absent
Date of Sample Withdrawn		--	15.03.17	
Date of Analysis		13.09.16	29.03.17	

Cfu: Colony forming unit.

Conclusion: Based on above data, it is concluded that the above product is stable for 6 months at 40 ± 2°C / 75 ± 5 % RH.

Remarks: Microbial test at initial was done as per process validation protocol (PVP/A/C/16-020).

Prepared By:
DateChecked By:
Date

09/01/18