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Date of Sample Withdrawn			--	14.09.17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

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REVIEWED BY QA
Sign. ..... Date. 10/01/18

Checked By:
Date 09/01/18

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 09/01/18

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Date 09/01/18

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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:
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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 09/01/18

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Date 09/01/18

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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 09/01/18

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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 09/01/18

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Date 09/01/18

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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 09/01/18

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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 8/1/18

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Date 09/01/18

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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

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Date 09/01/18

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 09/01/18

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Date 09/01/18

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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 09/01/18

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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: 09/01/18
Date

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Date

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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 09/01/18

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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 09/01/18

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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 09/01/18

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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 09/01/18

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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).

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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

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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).

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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	
			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).

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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).

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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).

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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).

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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).

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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).

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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).

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(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).

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