

STABILITY STUDY RECORD 30 C \pm 2 °C & 35% RH \pm 5 %

SF/QC2/QCS/019.09

PRODUCT	CIPROFLOXACIN INTRAVENOUS INFUSION(0.2%W/V)	MFG. DATE	JAN-2014
BATCH NO.	2A40177	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

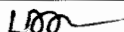
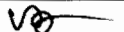

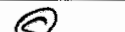


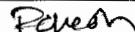

SR. NO.	Test	Limit	Retesting Result After (In Months)							
			Initial	3 rd	6 th	9 th	12 th	18 th	24 th	36 th
1.0	Identification (A) Identification (B) Identification (C)	Should Comply. Should Comply. Should Comply.	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies
2.0	Acidity	Between 3.9 and 4.5	4.24	4.09	4.25	4.19	4.16	4.13	4.23	4.23
3.0	Colour of solution	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
4.0	Related substances	Should comply	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
5.0	Bacterial Endotoxin	NMT 0.5 IU per ml.	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML
6.0	Assay (A)ciprofloxacin	95.0% to 105.0%	103.34 %	101.77 %	102.30 %	102.31 %	102.55 %	102.86 %	102.62 %	101.79 %
	(B)Sodium chloride	95.0% to 105.0%	102.69 %	101.67 %	103.97 %	103.28 %	103.39 %	101.78 %	102.76 %	104.10 %
7.0	Particulate contamination	$\geq 10\mu$ -max 6000 particles per container	80.00	NA	NA	NA	0.00	NA	380.00	80.00
		$\geq 25\mu$ -max 600 particles per container	0.00				0.00		6.67	13.33
8.0	Extractable volume	NLT nominal volume	102.0 ML	NA	NA	NA	100.2 ML	NA	102.0 ML	100.0 ML
9.0	Sterility	Should Comply.	Complies	NA	NA	NA	Complies	NA	Complies	Complies

STABILITY STUDY RECORD 30°C ± 2°C & 35% RH ± 5 %

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BATCH NO.	2A40177	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

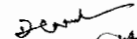
Conclusion: The stability study conducted for CIPROFLOXACIN INTRAVENOUS INFUSION 100 ML at 39°C for 3/6/9/12/18/24/36 months At the condition defined above are confirmed with predefined acceptance criteria.

Analyst Sign.								
Name	JM MEWADA	JM MEWADA	SUVARNA	SUVARNA	SUVARNA	NIKITA	RAKESH	KETAN
Qualification	B SC	B SC	B PHARM	B PHARM	B PHARM	M SC	B SC	B PHARM
Date	06/03/2014	06/06/2014	06/09/2014	06/12/2014	06/03/2015	06/09/2015	06/03/2016	03/03/2017

Q.A. Manager / Executive Sign :

Name :

Date :


H. Sachana
23/03/2017



STABILITY STUDY RECORD 30 C ± 2 ° C & 35% RH ± 5 %

SF/QC2/QCS/019.09

PRODUCT	CIPROFLOXACIN INTRAVENOUS INFUSION(0.2%W/V)	MFG. DATE	JAN-2014
BATCH NO.	2A40192	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

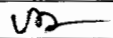
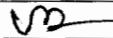




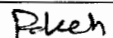

SR. NO.	Test	Limit	Retesting Result After (In Months)							
			Initial	3 rd	6 th	9 th	12 th	18 th	24 th	36 th
1.0	Identification (A)	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Identification (B)	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
	Identification (C)	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
2.0	Acidity	Between 3.9 and 4.5	4.21	4.10	4.13	4.22	4.18	4.12	4.28	4.28
3.0	Colour of solution	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
4.0	Related substances	Should comply	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
5.0	Bacterial Endotoxin	NMT 0.5 IU per ml.	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML	< 0.5 IU/ML
6.0	Assay (A)ciprofloxacin	95.0% to 105.0%	102.59 %	101.73 %	101.58 %	101.80 %	102.66 %	102.96 %	102.45 %	101.04 %
	(B)Sodium chloride	95.0% to 105.0%	102.29 %	103.19 %	103.74 %	104.42 %	103.43 %	102.81 %	102.76 %	103.45 %
7.0	Particulate contamination	≥10µ-max 6000 particles per container	26.67	NA	NA	NA	0.00	NA	288.67	40.00
		≥25µ-max 600 particles per container	0.00				0.00		0.00	0.00
8.0	Extractable volume	NLT nominal volume	102.0 ML	NA	NA	NA	100.2 ML	NA	100.0 ML	101.0 ML
9.0	Sterility	Should Comply.	Complies	NA	NA	NA	Complies	NA	Complies	Complies

STABILITY STUDY RECORD 30 C \pm 2 ° C & 35% RH \pm 5 %

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PRODUCT	CIPROFLOXACIN INTRAVENOUS INFUSION(0.2%W/V)	MFG. DATE	JAN-2014
BATCH NO.	2A40192	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

Conclusion: The stability study conducted for CIPROFLOXACIN INTRAVENOUS INFUSION 100 ML at 30°C for 3/6/9/12/18/24/36 months At the condition defined above are confirmed with predefined acceptance criteria.

Analyst Sign.								
Name	JM MEWADA	JM MEWADA	SUVARNA	SUVARNA	SUVARNA	NIKITA	RAKESH	KETAN
Qualification	B SC	B SC	B PHARM	B PHARM	B PHARM	M SC	B SC	E PHARM
Date	06/03/2014	06/06/2014	06/09/2014	06/12/2014	06/03/2015	06/09/2015	06/03/2016	08/03/2017

Q.A. Manager / Executive Sign:

Name

Date

:

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Devil
Atman 2015
28/1



STABILITY STUDY RECORD 30°C ± 2°C & 35% RH ± 5 %

SF/QC2/QCS/019.09

PRODUCT	CIPROFLOXACIN INTRAVENOUS INFUSION(0.2%W/V)	MFG. DATE	JAN-2014
BATCH NO.	2A40201	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

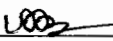
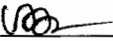






SR. NO.	Test	Limit	Retesting Result After (In Months)							
			Initial	3 rd	6 th	9 th	12 th	18 th	24 th	36 th
1.0	Identification (A) Identification (B) Identification (C)	Should Comply. Should Comply. Should Comply.	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies	Complies Complies Complies
2.0	Acidity	Between 3.9 and 4.5	4.28	4.15	4.25	4.25	4.19	4.20	4.31	4.31
3.0	Colour of solution	Should Comply.	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
4.0	Related substances	Should comply	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
5.0	Bacterial Endotoxin	NMT 0.5 IU per ml.	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML	<0.5 IU/ML
6.0	Assay (A)ciprofloxacin	95.0% to 105.0%	102.18%	101.65%	101.74%	99.19%	102.13%	101.06%	103.39%	102.71%
	(B)Sodium chloride	95.0% to 105.0%	101.45%	101.31%	103.04%	102.90%	101.06%	103.13%	103.41%	103.45%
7.0	Particulate contamination	≥10µ-max 6000 particles per container	33.33	NA	NA	NA	0.00	NA	73.33	40.00
		≥25µ-max 600 particles per container	0.00				0.00		6.67	0.00
8.0	Extractable volume	NLT nominal volume	102.0ML	NA	NA	NA	100.2 ML	NA	100.0ML	100.0ML
9.0	Sterility	Should Comply.	Complies	NA	NA	NA	Complies	NA	Complies	Complies

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SF/QC2/QCS/019.09

PRODUCT	CIPROFLOXACIN INTRAVENOUS INFUSION(0.2%W/V)	MFG. DATE	JAN-2014
BATCH NO.	2A40201	EXP. DATE	DEC-2016
BATCH SIZE	4000 L	KEPT ON	06/03/2014
SPECIFICATION	BP	COMPLETION DATE	23/03/2017
PLASTIC BOTTLE/VIAL	100 ML	STUDY TYPE	LONG TERM

Conclusion: The stability study conducted for CIPROFLOXACIN INTRAVENOUS INFUSION 100 ML at 30°C for 3/6/9/12/18/24/36 months At the condition defined above are confirmed with predefined acceptance criteria.

Analyst Sign.								
Name	JM MEWADA	JM MEWADA	SUVARNA	SUVARNA	SUVARNA	NIKITA	RAKESH	KETAN
Qualification	B sc	B sc	B pharm	B pharm	B pharm	M sc	B sc	B pharm
Date	06/03/2014	06/06/2014	06/09/2014	06/12/2014	06/03/2015	06/09/2015	06/03/2016	06/03/2017

Q.A. Manager / Executive Sign:

Name :

Date :

