SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
KETOMOX (Moxifloxacin Ophthalmic Solution USP 0.5%w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml contains:
Moxifloxacin Hydrochloride USP
Equivalent to Moxifloxacin …..… 0.5%w/v
Sterile Aqueous Base…….Q.S.

3. PHARMACEUTICAL FORM
Dosage Form: Ophthalmic Solution
Description of Product: Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.

4. Clinical particulars
4.1 Therapeutic indications
Topical treatment of purulent bacterial conjunctivitis, caused by moxifloxacin susceptible strains. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration
For ocular use only. Not for injection. Moxifloxacin Eye Drops, should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

Use in adults including the elderly (≥ 65 years)

The dose is one drop in the affected eye(s) 3 times a day.

The infection normally improves within 5 days and treatment should then be continued for a further 2-3 days. If no improvement is observed within 5 days of initiating therapy, the diagnosis and/or treatment should be reconsidered. The duration of treatment depends on the severity of the disorder and on the clinical and bacteriological course of infection.

Paediatric patients

No dosage adjustment is necessary.

Use in hepatic and renal impairment

No dosage adjustment is necessary.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.

In order to prevent the drops from being absorbed via the nasal mucosa, particularly in new-born infants or children, the nasolacrimal ducts should be held closed for 2 to 3 minutes with the fingers after administering the drops. After cap is removed, if tamper evident snap collar is loose, remove before using the product.

If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.3 Contraindications

Hypersensitivity to the active substance, to other quinolones, or to any of the excipients.

4.4 Special warnings and precautions for use

In patients receiving systemically administered quinolones, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria, and itching.

If an allergic reaction to Moxifloxacin Eye Drops occurs, discontinue use of the medicinal product. Serious acute hypersensitivity reactions to moxifloxacin or any other product ingredient may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated.

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including moxifloxacin, particularly in older patients and those treated concurrently with corticosteroids. Following ophthalmic administration of Moxifloxacin Eye Drops plasma concentrations of moxifloxacin are much lower than after therapeutic oral doses of moxifloxacin, however, caution should be exercised and treatment with Moxifloxacin Eye Drops should be discontinued at the first sign of tendon inflammation.

Data are very limited to establish efficacy and safety of Moxifloxacin Eye Drops in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.

Moxifloxacin Eye Drops should not be used for the prophylaxis or empiric treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant *Neisseria gonorrhoeae*. Patients with eye infections caused by *Neisseria gonorrhoeae* should receive appropriate systemic treatment.

The medicinal product is not recommended for the treatment of *Chlamydia trachomatis* in patients less than 2 years of age as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by *Chlamydia trachomitis*should receive appropriate systemic treatment.

Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by *Chlamydia trachomitis* or *Neisseria gonorrhoeae*.

Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies have been performed with Moxifloxacin Eye Drops 0.5%w/v. Given the low systemic concentration of moxifloxacin following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.

4.6 Pregnancy and Lactation

Pregnancy

There are no adequate data from the use of Moxifloxacin Eye Drops in pregnant women. However, no effects on pregnancy are anticipated since the systemic exposure to moxifloxacin is negligible. The medicinal product can be used during pregnancy.

Breastfeeding

It is unknown whether moxifloxacin/metabolites are excreted in human milk. Animal studies have shown excretion of low levels in breast milk after oral administration of moxifloxacin. However, at therapeutic doses of Moxifloxacin Eye Drops no effects on the suckling child are anticipated. The medicinal product can be used during breast-feeding.

Fertility

Studies have not been performed to evaluate the effect of ocular administration of Moxifloxacin Eye Drops on fertility.

4.7 Effects on ability to drive and use machines

Moxifloxacin Eye Drops has no or negligible influence on the ability to drive and use machines, however, as with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

4.8 Undesirable effects

Summary of the safety profile

In clinical studies involving 2,252 patients, Moxifloxacin Eye Drops was administered up to 8 times a day, with over 1,900 of these patients receiving treatment 3 times daily. The overall safety population that received the medicinal product consisted of 1,389 patients from the United States and Canada, 586 patients from Japan and 277 patients from India. No serious ophthalmic or systemic undesirable effects related to the medicinal product were reported in any of the clinical studies. The most frequently reported treatment-related undesirable effects with the medicinal product were eye irritation and eye pain, occurring at an overall incidence of 1 to 2%. These

reactions were mild in 96% of those patients who experienced them, with only 1 patient discontinuing therapy as a result.

The following adverse reactions are classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness.

System Organ Classification	**Frequency**	**Adverse reactions**
Blood and lymphatic system disorders	Rare	haemoglobin decreased
Immune system disorders	Not known	Hypersensitivity
Nervous system disorders	Uncommon Rare Not known	headache paresthesia dizziness
Eye disorders	Common Uncommon Rare Not known	eye pain, eye irritation punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort, corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, vision blurred, visual acuity reduced, asthenopia, erythema of eyelid endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, intraocular pressure increased, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, corneal oedema, photophobia, eyelid oedema, lacrimation increased, eye discharge, foreign body sensation in eyes
Cardiac disorders	Not known	palpitations
Respiratory, thoracic and mediastinal disorders	Rare Not known	nasal discomfort, pharyngolaryngeal pain, sensation of foreign body (throat) dyspnoea
Gastrointestional disorders	Uncommon Rare Not known	dysgeusia vomiting nausea
Hepatobiliary disorders	Rare	alanine aminotransferase increased, gamma-glutamyltransferase increased
Skin and subcutaneous tissue disorders	Not known	erythema, rash, pruritus, urticaria

Description of selected adverse reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following first dose, have been reported in patients receiving systemic quinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnoea, urticaria and itching.

Ruptures of the shoulder, hand, Achilles, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving systemic fluoroquinolones. Studies and post marketing experience with systemic quinolones indicate that a risk of these ruptures may be increased in patients receiving corticosteroids, especially geriatric patients and in tendons under high stress, including Achilles tendon.

Paediatric population

In clinical trials, Moxifloxacin Eye Drops has shown to be safe in paediatric patients, including neonates. In patients under 18 years old, the two most frequent adverse reactions were eye irritation and eye pain, both occurring at an incidence rate of 0.9%.

Based on data from clinical trials involving paediatric patients, including neonates, the type and severity of adverse reactions in the paediatric population are similar to those in adults.

4.9 Overdose

The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product.

The total amount of moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; anti-infectives, other anti-infectives, ATC code: S01A E07.

Mode of Action:

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair, and recombination.

Resistance:

Resistance to fluoroquinolones, including moxifloxacin generally occurs by chromosomal mutations in genes encoding DNA gyrase and topoisomerase IV. In Gram-negative bacteria, moxifloxacin resistance can be due to mutations in *mar* (multiple antibiotic resistance) and the *qnr* (quinolone resistance) gene systems. Resistance is also associated with expression of bacteria efflux proteins and inactivating enzymes. Cross-resistance with beta-lactams, macrolides and aminoglycosides is not expected due to differences in mode of action.

Susceptibility Testing Breakpoints

There are no pharmacological data correlated with clinical outcome for moxifloxacin administered as a topical agent. As a result, the European Committee on Antimicrobial Susceptibility Testing (EUCAST) suggests the following epidemiological cut-off values (ECOFF mg/l) derived from MIC distribution curves to indicate susceptibility to topical moxifloxacin:

Corynebacterium	ND
Staphylococcus aureus	0.25 mg/l
Staphylococcus, coag-neg.	0.25 mg/l
Streptococcus pneumoniae	0.5 mg/l
Streptococcus pyogenes	0.5 mg/l
Streptococcus, viridans group	0.5 mg/l
Enterobacter spp.	0.25 mg/l
Haemophilus influenzae	0.125 mg/l
Klebsiella spp.	0.25 mg/l
Moraxella catarrhalis	0.25 mg/l
Morganella morganii	0.25 mg/l
Neisseria gonorrhoeae	0.032 mg/l
Pseudomonas aeruginosa	4 mg/l
Serratia marcescens	1 mg/l

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of moxifloxacin in at least some types of infections is questionable.

COMMONLY SUSCEPTIBLE SPECIES
Aerobic Gram-positive micro-organisms: *Corynebacterium* species including *Corynebacterium diphtheriae* *Staphylococcus aureus* (methicillin susceptible) *Streptococcus pneumoniae* *Streptococcus pyogenes* *Streptococcus viridans* Group **Aerobic Gram-negative micro-organisms*:*** *Enterobacter cloacae* *Haemophilus influenzae* *Klebsiella oxytoca* *Moraxella catarrhalis* *Serratia marcescens* **Anaerobic micro-organisms:** *Proprionibacterium acnes* **Other micro-organisms:** *Chlamydia trachomatis*
SPECIES FOR WHICH ACQUIRED RESISTANCE MAY BE A PROBLEM
Aerobic Gram-positive micro-organisms: *Staphylococcus aureus* (methicillin resistant) *Staphylococcus,* coagulase-negative species (methicillin resistant) **Aerobic Gram-negative micro-organisms*:*** *Neisseria gonorrhoeae* **Other micro-organisms:** None
INHERENTLY RESISTANT ORGANISMS
Aerobic Gram-negative micro-organisms*:* *Pseudomonas aeruginosa* **Other micro-organisms:** None

5.2 Pharmacokinetic properties

Following topical ocular administration of Moxifloxacin Eye Drops, moxifloxacin was absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state Cmax and AUC were 2.7 ng/ml and 41.9 ng·hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times lower than the mean Cmax and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin was estimated to be 13 hours.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess
of the maximum human exposure following administration to the eye indicating little relevance to clinical use.

As with other quinolones, moxifloxacin was also genotoxic in vitro in bacteria and mammalian cells. As these effects can be traced to the interaction with bacterial gyrase and in considerably higher concentrations to the interaction with topoisomerase II in mammalian cells, a threshold level for genotoxicity can be assumed. In in vivo tests, no evidence of genotoxicity was found, despite high doses of moxifloxacin. The therapeutic doses for human use therefore provide adequate safety margin. No indication of a carcinogenic effect was observed in an initiation promotion model in rats.

Unlike other quinolones, moxifloxacin showed no phototoxic or photogenotoxic properties in extensive in vitro and in vivo studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax, Boric Acid, Sodium Chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Don’t store above 30^{o}C. Do not freeze.

6.4 Nature and Contents of container and special equipment for use, administration or implantation

Clear slightly yellow to pale yellow colored solution filled in 10mL plastic vials.

Secondary Packaging

Each vial is packed in a unit carton

6.6 Special precautions for disposal and other handling.

No special requirements

7. Manufacturer

NITIN LIFESCIENCES LIMITED
Rampur Road, Paonta Sahib
Dist. Simour – 173025
Himachal Pardesh, India

Manufactured for:
JAGSOL Healthcare Nig. Ltd
Unit 11-13, Pentcity Estate,
Lokogoma District, Abuja,
Nigeria

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (ACCELERATED)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	ALFP-0001/0113
B. No.	:	13190001	**Humidity**	:	75% ± 5%
D/M	:	01/2013	**Temperature**	:	$40^0C \pm 2^0C$
D/E	:	12/2015	**Sample Qty.**	:	50 Vials
Date of Sampling	:	19/02/2013	**Packing**	:	1x 1 Unit Carton Pack

Test	**Specification**	**Initial Result**	**RESULTS AFTER**	
			3 months	**6 months**
		Date 19/02/2013	**Date 25/05/2013**	**Date 02/09/2013**
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	7.00	6.87	6.90
Related Substances	Should comply	Complies	----	Complies
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	----	Complies
Sterility	Should be sterile	Sterile	----	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.518%w/v	0.494%w/v	0.498%w/v

Remarks: No significant changes observed after completion of 6 months accelerated stability study.

	Analyzed By	**Checked By**	**Approved By**
Name	Mahendra Khandelwal	Amar Singh	Ajay Nautiyal
Signature/Date	Mahedra		QA
Designation	QC-Chemist	Manager-QC	Head-QA

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (ACCELERATED)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	ALFP-0013/0513
B. No.	:	13190002	**Humidity**	:	75% ± 5%
D/M	:	05/2013	**Temperature**	:	$40^0C \pm 2^0C$
D/E	:	04/2016	**Sample Qty.**	:	50 Vials
Date of Sampling	:	27/05/2013	**Packing**	:	1x 1 Unit Carton Pack

Test	**Specification**	**Initial Result**	**RESULTS AFTER**	
			3 months	**6 months**
		Date 27/05/2013	**Date 31/08/2013**	**Date 11/12/2013**
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	6.98	6.93	7.00
Related Substances	Should comply	Complies	----	Complies
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	----	Complies
Sterility	Should be sterile	Sterile	----	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.496%w/v	0.496%w/v	0.503%w/v

Remarks: No significant changes observed after completion of 6 months accelerated stability study.

	Analyzed By	**Checked By**	**Approved By**
Name	Mahendra Khandelwal	Amar Singh	Ajay Nautiyal
Signature/Date	Mahedra		
Designation	QC-Chemist	Manager-QC	Head-QA

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (ACCELERATED)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	A2LFP-0007/0114
B. No.	:	14190001	**Humidity**	:	75% ± 5%
D/M	:	01/2014	**Temperature**	:	$40^0C \pm 2^0C$
D/E	:	12/2016	**Sample Qty.**	:	50 Vials
Date of Sampling	:	10/02/2014	**Packing**	:	1x 1 Unit Carton Pack

Test	**Specification**	**Initial Result**	**RESULTS AFTER**	
			3 months	**6 months**
		Date 19/02/2013	**Date 25/05/2013**	**Date 02/09/2013**
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	6.93	6.87	6.90
Related Substances	Should comply	Complies	----	Complies
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	----	Complies
Sterility	Should be sterile	Sterile	----	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.489%w/v	0.490%w/v	0.484%w/v

Remarks: No significant changes observed after completion of 6 months accelerated stability study.

	Analyzed By	**Checked By**	**Approved By**
Name	Mahendra Khandelwal	Amar Singh	Ajay Nautiyal
Signature/Date	Mahendra		
Designation	QC-Chemist	Manager-QC	Head-QA

Nitin Lifesciences

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (REAL TIME)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	ALFP-0001/0113
B. No.	:	13190001	**Humidity**	:	75% ± 5%
D/M	:	01/2013	**Temperature**	:	$30^0C \pm 2^0C$
D/E	:	12/2015	**Sample Qty.**	:	100 Vials
Date of Sampling	:	19/02/2013	**Packing**	:	1x 1 Unit Carton Pack

Test	Specification	Initial Result	RESULTS AFTER						
			3 months	6 months	9 months	12 months	18 months	24 months	36 months
		Date 19/02/2013	Date 25/05/2013	Date 24/08/2013	Date 27/11/2013	Date 18/03/2014	Date 13/09/2014	Date 05/03/2015	Date 05/03/2016
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plasti vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	7.00	6.98	6.83	6.91	6.90	6.96	6.95	6.93
Related Substances	Should comply	Complies	---	---	---	---	---	---	Complies
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	---	---	---	---	---	---	Complies
Sterility	Should be sterile	Sterile	---	---	---	---	---	---	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.518%w/v	0.497%w/v	0.498%w/v	0.494%w/v	0.497%w/v	0.490%w/v	0.487%w/v	0.485%w/v

Remarks: No significant changes observed after completion of 36 months real time stability study.

	Analyzed By	Checked By	Approved By
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Signature/Date	Mahendra		
Designation	QC-Chemist	Manager-QC	Head-QA

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (REAL TIME)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	ALFP-0013/0513
B. No.	:	13190002	**Humidity**	:	75% ± 5%
D/M	:	05/2013	**Temperature**	:	$30^0C \pm 2^0C$
D/E	:	04/2016	**Sample Qty.**	:	100 Vials
Date of Sampling	:	27/05/2013	**Packing**	:	1x 1 Unit Carton Pack

Test	Specification	Initial Result	RESULTS AFTER						
			3 months	6 months	9 months	12 months	18 months	24 months	36 months
		Date 27/05/2013	Date 31/08/2013	Date 29/11/2013	Date 20/03/2014	Date 06/06/2014	Date 29/11/2014	Date 16/06/2015	Date 16/06/2016
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	6.98	6.94	6.92	6.93	6.88	6.85	6.82	6.82
Related Substances	Should comply	Complies	---	---	---	---	---	---	Complies
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	---	---	---	---	---	---	Complies
Sterility	Should be sterile	Sterile	---	---	---	---	---	---	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.496%w/v	0.497%w/v	0.508%w/v	0.494%w/v	0.484%w/v	0.485%w/v	0.500%w/v	0.0485%w/v

Remarks: No significant changes observed after completion of 36 months real time stability study.

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Name	Mahendra Khandelwal	Amar Singh	Ajay Nautiyal
Signature/Date	Mahedra		
Designation	QC-Chemist	Manager-QC	Head-QA

Nitin Lifesciences Ltd. QA Quality Assurance Dept.

NITIN LIFESCIENCES LTD.
RAMPUR ROAD PAONTA SAHIB DISTT- SIRMOUR
STABILITY STUDY (REAL TIME)

Product Name	:	Moxifloxacin Ophthalmic Solution USP 0.5%w/v, 10ml	**Analytical Report No.**	:	A2LFP-0007/0114
B. No.	:	14190001	**Humidity**	:	75% ± 5%
D/M	:	01/2014	**Temperature**	:	30°C ± 2°C
D/E	:	12/2016	**Sample Qty.**	:	100 Vials
Date of Sampling	:	10/02/2014	**Packing**	:	1x 1 Unit Carton Pack

Test	**Specification**	**Initial Result**	**RESULTS AFTER**						
			3 months	**6 months**	**9 months**	**12 months**	**18 months**	**24 months**	**36 months**
		Date 10/02/2014	**Date 24/05/2014**	**Date 13/08/2014**	**Date 12/11/2014**	**Date 13/02/2015**	**Date 20/08/2015**	**Date 25/02/2016**	**Date 25/02/2017**
Description	Clear slightly yellow to pale yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.	Clear slightly yellow coloured solution filled in 10ml plastic vials.
pH	Between 6.30 to 7.30	6.93	6.87	6.89	6.85	6.92	7.04	7.01	7.00
Related Substances	Should comply	Complies	---	---	---	---	---	---	
Particulate Matter	The solution should free from foreign particles that can be observed on visual inspection.	Complies	---	---	---	---	---	---	Complies
Sterility	Should be sterile	Sterile	---	---	---	---	---	---	Sterile
Assay : Each ml contains Moxifloxacin Hydrochloride BP eq. to Moxifloxacin	NLT 0.450%w/v & NMT 0.550%w/v	0.489%w/v	0.498%w/v	0.497%w/v	0.488%w/v	0.471%w/v	0.490%w/v	0.489%w/v	0.486%w/v

Remarks: No significant changes observed after completion of 36 months real time stability study

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