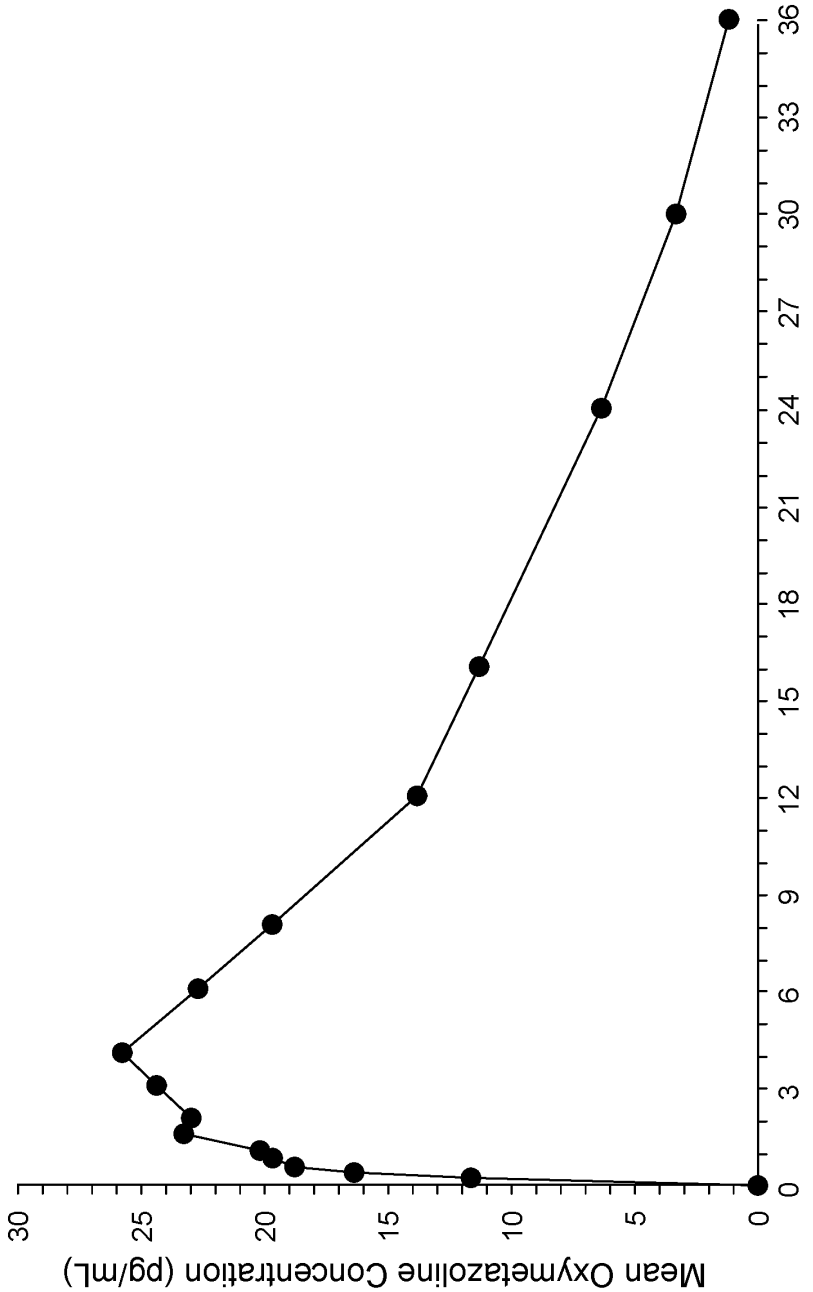

Mean Oxymetazoline Concentration (pg/mL)
0
5
10
15
20
25
30
Time (h)
0
3
6
9
12
15
18
21
24
27
30
33
36

FIG. 1

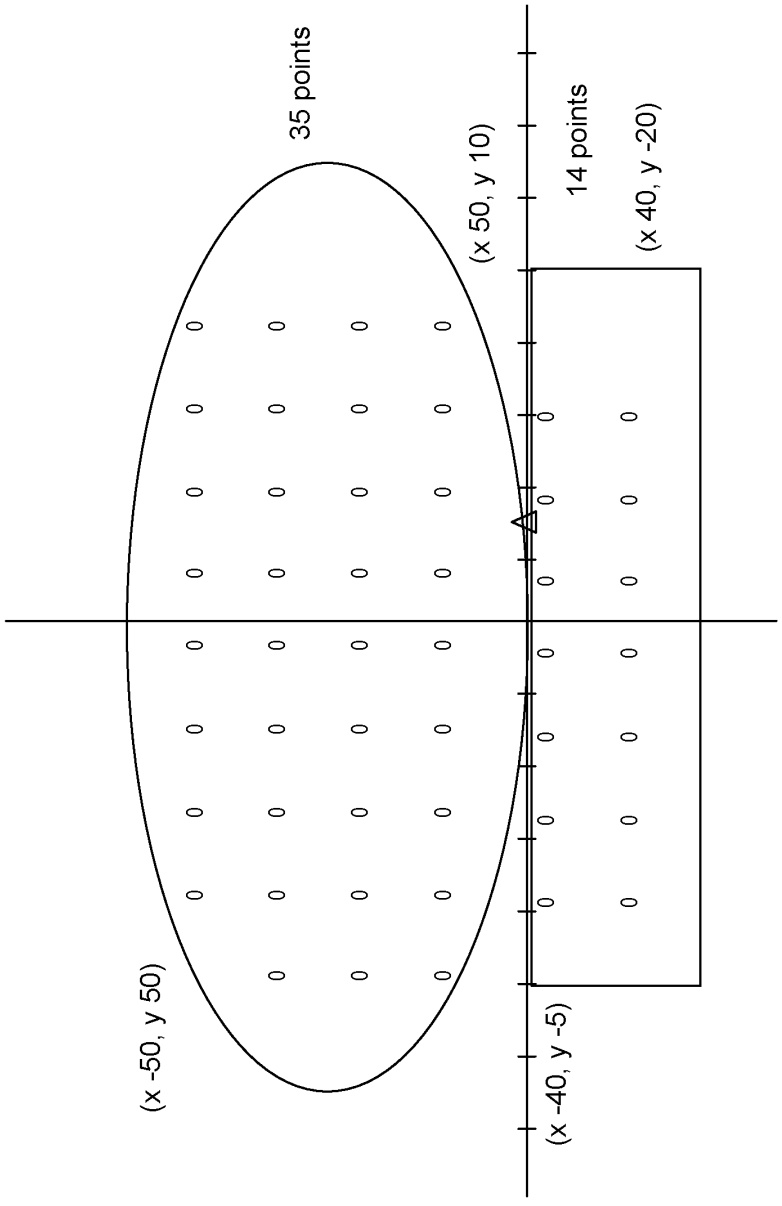


FIG. 2

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60681
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.	TEST	SPECIFICATION	TEST METHOD		
1	Description	Clear, colorless to slightly yellow solution free of any particulates or crystallization.	CTM-SC-AS-6714	Conforms	Conforms
			TEST COMPLETION DATE	12/12/18	07/02/19
2	Osmolality	290 - 365 mOsm/kg	SOP-SC-AS-6428	337 mOsm/kg	325 mOsm/kg
			TEST COMPLETION DATE	12/10/18	07/07/19
3	pH	5.8 - 6.8	SOP-SC-AS-6112	6.4	6.4
			TEST COMPLETION DATE	12/13/18	07/03/19
4	Assay	90.0% - 110.0% label claim	CTM-SC-AS-6540	101.7%	104.4%
			TEST COMPLETION DATE	01/03/19	07/12/19
5	Related Substances	Specifications:	CTM-SC-AS-6548	[1]	[1]
	A. Related Compound A	A. NMT 2.5%		A. 1.0%	A. 0.5%
	B. Mono-Hydroxylated T-Butyl Group of Related Compound A Isomers	B. NMT 1.0%		B. 0.1%	B. ND
	C. Hydroxylated Imidazoline	C. NMT 1.0%		C. 0.3%	C. ND
	D. Hydroxylamine Derivative	D. NMT 1.0%		D. 0.5%	D. ND
	E. Oxymetazoline N-Oxide	E. NMT 1.0%		E. 0.1%	E. ND
	F. Each Individual Unknown Impurity	F. NMT 0.1%		F. <0.1% (RRT 0.293)	F. 0.1 % (RRT 0.305) <0.1% (RRT 1.187) <0.1% (RRT 1.236) <0.1% (RRT 1.288) <0.1% (RRT 1.414) 0.1% (RRT 1.610) 0.1% (RRT 1.827)
	G. Total Impurities	G. NMT 3.5%		G. 1.9%	G. 0.8%
			TEST COMPLETION DATE	01/03/19	07/19/19
6	Viscosity	15-35 cPs	CTM-SC-AS-6660	26 cPs	26 cPs
			TEST COMPLETION DATE	01/02/19	07/09/19

[1] Related Substances tested per CTM-SC-AS-6548.

FIG. 3A

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60681
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.	TEST	SPECIFICATION	TEST METHOD		
7	Weight Loss	NMT 5.0%	CTM-SC-AS-6509	0.4%	Not Tested
	TEST COMPLETION DATE			12/6/18	
8	Particulate Matter A. ≥ 10 µm B. ≥ 25 µm C. ≥ 50 µm	Specifications: A. NMT 50/mL B. NMT 5/mL C. NMT 2/mL	USP<789> microscopic method		A. 1 B. 0 C. 0
	TEST COMPLETION DATE				07/22/19
9	Dye Ingress Immersion Test	No visual evidence of dye ingress and absorbance does not occur at approximately 665 nm.	MTM-SC-MB-6380		Conforms
	TEST COMPLETION DATE				07/11/19
10	Sterility	No microbial growth is observed	MTM-SC-MB-6308 USP<71>	Conforms	Conforms
	TEST COMPLETION DATE			01/01/19	07/19/19

FIG. 3B

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60701
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.		SPECIFICATION	TEST METHOD		
1	Description	Clear, colorless to slightly yellow solution free of any particulates or crystallization.	CTM-SC-AS-6714	Conforms	Conforms
	TEST COMPLETION DATE			12/12/18	07/02/19
2	Osmolality	290 - 365 mOsm/kg	SOP-SC-AS-6428	322 mOsm/kg	341 mOsm/kg
	TEST COMPLETION DATE			12/10/18	07/07/19
3	pH	5.8-6.8	SOP-SC-AS-6112	6.3	6.4
	TEST COMPLETION DATE			12/13/18	07/03/19
4	Assay	90.0% - 110.0% label claim	CTM-SC-AS-6540	102.9%	99.8%
	TEST COMPLETION DATE			01/03/19	07/12/19
5	Related Substances	Specifications:	CTM-SC-AS-6548	[1]	[1]
	A. Related Compound A	A. NMT 2.5%		A. 1.0%	A. 0.5%
	B. Mono-Hydroxylated T-Butyl Group of Related Compound A Isomers	B. NMT 1.0%		B. 0.1%	B. ND
	C. Hydroxylated Imidazoline	C. NMT 1.0%		C. 0.3%	C. ND
	D. Hydroxylamine Derivative	D. NMT 1.0%		D. 0.4%	D. ND
	E. Oxymetazoline N-Oxide	E. NMT 1.0%		E. 0.1%	E. ND
	F. Each Individual Unknown Impurity	F. NMT 0.1%		F. <0.1% (RRT 0.293)	F. <0.1% (RRT 1.186) <0.1% (RRT 1.236) <0.1%(RRT 1.287) <0.1% (RRT 1.413) 0.1% (RRT 1.609) 0.1% (RRT 1.823)
	G. Total Impurities	G. NMT 3.5%		G. 1.9%	G. 0.7%
	TEST COMPLETION DATE			01/03/19	07/19/19
6	Viscosity	15-35 cPs	CTM-SC-AS-6660	30 cPs	26 cPs
	TEST COMPLETION DATE			01/02/19	07/09/19

[1] Related substances tested per CTM-SC-AS-6548.

FIG. 4A

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60701
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.	TEST	SPECIFICATION	TEST METHOD		
7	Weight Loss	NMT 5.0 %	CTM-SC-AS-6509	0.8%	Not Tested
	TEST COMPLETION DATE			12/06/18	
8	Particulate Matter A. ≥ 10 µm B. ≥ 25 µm C. ≥ 50 µm	Specifications: A. NMT 50/mL B. NMT 5/mL C. NMT 2/mL	USP<789> microscopic method		A. 1 B. 1 C. 0
	TEST COMPLETION DATE				07/22/19
9	Dye Ingress Immersion Test	No visual evidence of dye ingress and absorbance does not occur at approximately 665 nm.	MTM-SC-MB-6380		Conforms
	TEST COMPLETION DATE				07/11/19
10	Sterility	No microbial growth is observed	MTM-SC-MB-6308 USP<71>	Conforms	Conforms
	TEST COMPLETION DATE			03/21/19	07/15/19

FIG. 4B

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60711
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.	TEST	SPECIFICATION	TEST METHOD		
1	Description	Clear, colorless to slightly yellow solution free of any particulates or crystallization.	CTM-SC-AS-6714	Conforms	Conforms
	TEST COMPLETION DATE			12/12/18	07/02/19
2	Osmolality	290 - 365 mOsm/kg	SOP-SC-AS-6428	302 mOsm/kg	327 mOsm/kg
	TEST COMPLETION DATE			12/10/18	07/07/19
3	pH	5.8 - 6.8	SOP-SC-AS-6112	6.3	6.4
	TEST COMPLETION DATE			12/13/18	07/03/19
4	Assay	90.0% - 110.0% label claim	CTM-SC-AS-6540	92.8%	105.2%
	TEST COMPLETION DATE			01/03/19	07/12/19
5	Related Substances	Specifications:	CTM-SC-AS-6548	[1]	[1]
	A. Related Compound A	A. NMT 2.5%		A. 0.8%	A. 0.4%
	B. Mono-Hydroxylated T-Butyl Group of Related Compound A Isomers	B. NMT 1.0%		B. 0.1%	B. ND
	C. Hydroxylated Imidazoline	C. NMT 1.0%		C. 0.3%	C. ND
	D. Hydroxylamine Derivative	D. NMT 1.0%		D. 0.4%	D. ND
	E. Oxymetazoline N-Oxide	E. NMT 1.0%		E. 0.1%	E. ND
	F. Each Individual Unknown Impurity	F. NMT 0.1%		F. <0.1% (RRT 0.292)	F. <0.1% (RRT 1.187) <0.1% (RRT 1.239) <0.1% (RRT 1.286) <0.1% (RRT 1.413) 0.1% (RRT 1.605) 0.1% (RRT 1.824)
	G. Total Impurities	G. NMT 3.5%		G. 1.6%	G. 0.6%
	TEST COMPLETION DATE			01/03/19	07/19/19
6	Viscosity	15-35 cPs	CTM-SC-AS-6660	22 cPs	24 cPs
	TEST COMPLETION DATE			01/02/19	07/09/19

[1] Related substances tested per CTM-SC-AS-6548.

FIG. 5A

STABILITY REPORT
Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%; LOT# R60711
Study Purpose: Research and Development
Condition: Real Time (25°C ± 2°C/ 60% ± 5% RH)
Orientation: Horizontal

TIME (MONTH)				24	30
PULL DATE				12/05/18	06/28/19
NO.	TEST	SPECIFICATION	TEST METHOD		
7	Weight Loss	NMT 5.0%	CTM-SC-AS-6509	0.2%	Not Tested
	TEST COMPLETION DATE			12/06/18	
8	Particulate Matter A. ≥ 10 µm B. ≥ 25 µm C. ≥ 50 µm	Specifications: A. NMT 50/mL B. NMT 5/mL C. NMT 2/mL	USP<789> microscopic method		A. 3 B. 1 C. 0
	TEST COMPLETION DATE				07/22/19
9	Dye Ingress Immersion Test	No visual evidence of dye ingress and absorbance does not occur at approximately 665 nm.	MTM-SC-MB-6380		Conforms
	TEST COMPLETION DATE				07/11/19
10	Sterility	No microbial growth is observed	MTM-SC-MB-6308 USP<71>	Conforms	Conforms
	TEST COMPLETION DATE			01/01/19	07/15/19

FIG. 5B