

!" #&/
4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

!"®
(MEBSYN RETARD®)

!;:04:

4VNG0 @5G>28=0: 1 :0?AC;0
4>?>28=8: F5;N;>70 :@8AB0;VG=0, <0=VB (421), FC:@>70, =0B@VN ;0C@8;AC;LD0B, 5B8;F5;N;>70.

V:0@AL:0 D>@<0. 0?AC;8.

A=>2=V DV78:>-EVABV: B25@4V 65;0B8=>2V :0?AC;8 1, :>@?CA >@0=652>3> :>;L>@C, :@8H5G:0
1V;>3> :>;L>@C, <0NBL =0?8A8 «S» =0 >1>E G0AB8=0E B0 1V ?5;5B8 1V;>3> :>;L>@C.

\$0@<0:>B5@0?52B8G=0 3@C?0.

0A>18, I> 70AB>A>2CNBLAO ?@8 DC=:FV>=0;L=8E H;C=:>2>.:8H:>28E @>7;040E. !8=B5B8G=V
0=B8E>;V=5@3VG=V 70A>18, 5AB5@8DV:>20=V B@5B8==V 0
>4 "% 0304.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

5E0=V7< 4VW B0 D0@<0:>48=0

51525@8= T B@?>=8< A?07<>;VB8:>< 7 281V@:>2>N 4VTN =0 3;04:V <078 B@02=>3> B@0:BC. V=
CAC20T A?07<8 157 ?@83=VG5==O =>@<0;L=>W <>B>@8:8 :8H5G=8:0. A:V;L:8 FO 4VO =5
>?>A5@54:>-20=0 02B=>=<=>N =5@2>2>N A8AB5<>N, B8?>28E 0=B8E>;V=5@3VG=8E ?>1VG=8E
5D5:BV2 =5 28=8:0T.

;V=VG=0 5D5:B82=VABL B0 157?5:0.

;V=VG=0 5D5:B82=VABL B0 157?5:0 70AB>AC20==O @V7=8E ;V:0@AL:8E D>@< <51525@8=C 1C;8
282G5=V C ?>=04 1500 ?0FVT=BV2. =0G=5 ?>A;01;5==O ?5@5206=8E A84@07=5=>3> :8H5G=8:C
(=0?@8;:04, 1V;L C 682>BV, E0@0:B5@8AB8:8 28?>@>6=5==O) 70728G09 A?>AB5@V30;>AO C
@5D5@5=B=8E B0 :>=B@>;L>20=8E 70 >A=>2=8<8 7=0G5==O<8 ;V=VG=8E 4>A;V465==OE.
#AV ;V:0@AL:V D>@<8 <51525@8=C 1C;8 7030;>< 157?5G=8<8 B0 4>1@5 ?5@5=>A8;8AO ?@8 @5:>
<5=4>20=>7C20==O.

VB8.

;V=VG=V 4>A;V465==O 70AB>AC20==O B01;5B>: 01> :0?AC; ?@>2>48;8AO BV;L:8 C 4>@>A;8E. 0=V
;V=VG=>W 5D5:B82=>ABV B0 157?5:8, 0 B0:>6 ?>AB<0@:5B8=3>289 4>A2V4 70AB>AC20==O
ACA?5=7VW <51525@8=C C ?0FVT=BV2 2V:>< 2V4 3 @>:V2 ?@>45<>=AB@C20;8, I> <51525@8= T
5D5:B82=8< 157?5G=8< ;V:0@AL:8< 70A>1><, O:89 4>1@5 ?5@5=>A8BLAO.
;V=VG=V 4>A;V465==O ACA?5=7VW <51525@8=C ?>:070;8, I> 2V= T 5D5:B82=8< 4;O ?>A;01;5==O A8
4@07=5=>3> :8H5G=8:C C 4VB59. >40;LHV 2V4:@8BV :>=B@>;L>20=V 70 >A=>2=8<8 7=0G5==O<8
4>A;V465==O ACA?5=7VW <51525@8=C ?V4B25@48;8 5D5:B82=VABL ?@5?0@0BC.

568< 4>7C20==O B01;5B>: 01> :0?AC; @>7@0E>20=89 =0 >A=>2V 157?5:8 B0 ?5@5=>A8<>ABV
<51525@8=C.

\$0@<0:>:V=5B8:0.

1A>@1FVO.

51525@8= H284:> B0 ?>2=VABN 01A>@1CTBLAO ?VA;O ?5@>@0;L=>3> 70AB>AC20==O C D>@.
024O:8 ?@>;>=3>20=>3> <>6=0 ?@89<0B8 420 @078 =0 45=L.

>7?>4V:.

@8 1030B>@07>2>AC20==V ?@5?0@0BC 51AV= 5B0@4® =VO:>W 7=0G=>W :C

V>B@0=AD>@<0FVO.

51525@8=C 3V4@>E;>@84 3>;>2=8< G8=>< <5B01>;V7CTBLAO 5AB5@070<8, O:V =0 ?5@H>
715?;NNBL 5DV@=V 72O7:8 7 CB2>@5==O< 25@0B@>2>W :8A;>B8 V <51525@8=>2>3> A?8@BC. # ?;07
T >A=>2=8< <5B01>;VB>4 =0?V2282545==O C @V2=>206=>48=8. @8 1030B>@07>2>AC20==V :0?AC;

(?> 200 <3 2 @078 =0 4>1C) C_{max} 4;O AB0=>28;0 804 =3/<;, 0 t_{max} 1;87L:> 3 3>48=. V4=>A=0
1V>4>ABC?=VABL :0?AC; ?@>;>=3>20=>W 4VW 28O28;0AO >?B8<0;L=>N 7 A5@54=V<
A?V22V4=>H5==O< 97 %.

82545==O.

51525@8= =5 5:A:@5BCTBLAO C =57

VB8.

\$0@<0:>:V=5B8G=V 4>A;V465==O C 4VB59 =5 ?@>2>48;8AO.

;V=VG=V E0@0:B5@8AB8:8.

>:070==O.

>@>A;V B0 4VB8 2V:< 2V4 10 @>:V2:

□ A8<0B8G=5 ;V:C20==O 014>3> 1>;N V A?077;04V2 :8H5G=8:C V 2V4GCBBO 48A:>@BC C 4V;O=FW
:8H5G=8:C ?@8 A8=4@>4@07=5=>3> :8H5G=8:C;

□ ;V:C20==O H;C=:>2>-.8H:>28E A?07@8==>3> '5=57C, A?@8G8=5=8E >@30=VG=8<8
70E2>@N20==O<8.

@>B8?>:070==O.

V?5@GCB;82VABL 4> 0:B82=>W @5G>28=8 01> 4> 1C4L-O:>3> 7 :>5=BV2 ?@5?0@0BC.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

@>2>48;8AO 4>A;V465==O 270T<>4VW BV;L:8 7 0;:>3>;5A;V465==O in vitro B0 in vivo ?@>45

<>=AB@C20;8 2V4ACB=VABL 1C4L-O:>W 270T<>4VW ?@5?0@0BC B0 5B0=>;C.

A>1;82>ABV 70AB>AC20==O.

A;V;L:8 ?@5?0@0B @, ?0FVT=B0< 7 @V4:VA=8<8 A?04:>28<8 D>@<0<8, B0:8<8 O: =5?5@5=>A878 01>
D@C:B>78, 45DVF8B ;0:B078, <0;L01A>@1FVO 3;N:>78-30;0:B>78 01> =54>AB0B=VABL A0E0@078-
V7><0;LB078, =5 A;V4 ?@89<0B8 F59 ?@5?0@0B.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

@5?0@0B 51AV= 5B0@4[®]=5 @5:><5=4CTBLAO 70AB>A>2C20B8 C ?5@V>4 203VB=>ABV 01>
3>4C20==O 3@C44N.

40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>1>BV 7
V=H8<8 <5E0=V7<0<8.

>A;V465==O 2?;82C =0 740B=VABL :5@C20B8 02B>>1V;5< V ?@0FN20B8 7 <5E0=V7<0<8 =5
?@>2>48;8AO. \$0@<0:>48=0

!>AV1 70AB>AC20==O B0 4>78.

@5?0@0B ?@87=0G5=89 4;O ?5@>@0;L=>3> 70AB>AC20==O.

0?AC;8 A;V4 70?820B8 4>AB0B=L>N :V;L:VABN 2>48 (=5<5=H5 100 <);. 5 @5:><5=4CTBLAO

@>76>2C20B8 :0?AC;8, >A;V;L:8 ?>:@8BBO :0?AC; ?@87=0G5=5 4;O ?@>;>=3>20=>3> 282V;L=5==O
?@5?0@0BC.

>@>A;8< B0 4VBO< 2V:< 2V4 10 @>:V2 A;V4 ?@89<0B8 ?> 1 :0?AC;V 2 @078 =0 4>1C (2@0=FW B0
225G5@V).

"@820;VABL 70AB>AC20==O =5>1<565=0. /:I> >4=C 01> 1V;LH5 4>7 ?@>?CI5=>, ?0FVT=BC A;V4
?@89=OB8 =0ABC?=C 4>7C, O: ?@87=0G5=>. @>?CI5=C 4>7C =5 A;V4 ?@89<0B8 4>40B:>2> 4>
=0ABC?=>W ?@87=0G5=>W 4>78.

A>1;82V 3@C?8 ?0FVT=BV2.

>A;V465=L 4>7C20==O 4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0
/01> ?5GV=:8 =5 ?@>2>48;>AO. >3;O4C =0 =0O2=V ?>AB<0@:5B8=3>2V 40=V, A?5F8DVG=>3> @878:C
4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0/01> ?5GV=:8 =5
28O2;5=>. >@5:FVO 4>78 4;O 28I5707=0G5=8E 3@C? ?0FVT=BV2 =5 ?>B@V1=0.

VB8.

5 70AB>A>2CNBL 4VBO< 2V:< 4> 10 @>:V2 G5@57 28A>;89 2W @5G>28=8 2 ?@5?0@0BV 51AV=
5B0@4[®].

5@54>7C20==O.

@8 ?5@54>7C20==V B5>@5B8G=> <>65 A?>AB5@V30B8AO 71C465==O F5=B@0;L=>W =5@2>2>W A8AB5<8. # 28?04:0E ?5@54>7C20==O <51525@8=C A8<8 1C;8 2V4ACB=V 01> 1C;8 ;53:8<8 V H284:> 7=8:0;8. !8<8 ?5@54>7C20==O, I> A?>AB5@V30;8AO, 1C;8 =52@>;>3VG=>3> 01> :0@4V>20A:C;O@=>3> ?>E>465==O. V:C20==O. !?5F8DVG=89 0=B84>B =52V4><89. 5:><5=4>20=5 A8<0B8G=5 ;V:C20==O. @><820==O H:C=0 @5:><5=4CTBLAO BV;L:8 C 28?04:C V=B>:A8:0FVW :V;L:>0 @V7=8<8 ?@5?0@0B0<8, O:C 4V03=>AB>20=> ?@>BO3>< 1 3>48=8 7 <><5=BC ?@89>1V2. 0E>48 4;O 7=865==O 01A>@1FVW =5 T =5>1EV4=8<8.

>1VG=V @50:FVW.

>2V4><;O;>AO ?@> =0ABC?=V ?>1VG=V @50:FVW, I> 28=8:0;8 A?>=B0==> ?@>BO3>< ?>AB <0@:5B8=3>2>3> A?>AB5@565==O. '0AB>BC 70 =0O2=8<8 40=8<8 B>G=> 287=0G8B8 =5<>6;82>. !?>AB5@V30;8AO 0;5@3VG=V @50:FVW ?5@5206=> 7 1>:C H:V@8. 1>:C H:V@8 V ?V4H:V@=>W ;:VB:>28=8: :@>?82O=:0, 0=3V>=52@>B8G=89 =01@O:, =01@O: >1;8GGO, 3V?5@5 28A8?8 =0 H:V@V, C B> 1>:C =5@2>2>W A8AB5<8: 3>;>2=89 1V;L, 70?0<>@>G5==O, 45?@5AVO. 1>:C B@02=>3> B@0:BC: 4V0@50 01> 70?>@. 030;L=V @>7;048: 3V?5@GCB;82VABL(0=0DV;0:B8G=V @50:FVW).

"5@ABV. 2 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV, C =54>ABC?=>

#?0:>2:0.

> 10 :0?AC; C 1;VAB5@V. > 3 1;VAB5@8 C :0@B>==V9 ?0GFV.

0B53>@VO 2V4?CA:C. 0 @5F5?B>

8@>1=8:.

!V=<548: 01>@0B>@V7 / Synmedic Laboratories.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.

106-107, H A 9 V !V =40AB@V0; AB59B, !5:B>@-31, \$0@V40104-121003, %0@O=0, =4VO/

106-107, HSIDC Industrial Estate, Sector-31, Faridabad-121003, Haryana, India.

!" #&/

4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

!"®

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!;;04:

4VNG0 @5G>28=0: 1 :0?AC;0

4>?>28=8: F5;N;>70 :@8AB0;VG=0, <0=VB (421), FC:@>70, =0B@VN ;0C@8;AC;LD0B, 5B8;F5;N;>70.

V:0@AL:0 D>@<0. □0?AC;8.

A=>2=V DV78:>-EVABV: B25@4V 65;0B8=>2V :0?AC;8 1, :>@?CA >@0=652>3> :>;L>@C, :@8H5G:0 1V;>3> :>;L>@C, <0NBL =0?8A8 «S» =0 >1>E G0AB8=0E B0 1V ?5;5B8 1V;>3> :>;L>@C.

\$0@<0:>B5@0?52B8G=0 3@C?0.

0A>18, I> 70AB>A>2CNBLAO ?@8 DC=:FV>=0;L=8E H;C=:>2>:8H:>28E @>7;040E. !8=B5B8G=V
0=B8E>;V=5@3VG=V 70A>18, 5AB5@8DV:>20=V B@5B8==V 0
>4 "% 0304.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

5E0=V7< 4VW B0 D0@<0:>48=0

51525@8= T B@>?=8< A?07<>;VB8:>< 7 281V@>2>N 4VTN =0 3;04:V <078 B@02=>3> B@0:BC. V=
CAC20T A?07<8 157 ?@83=VG5==O =>@<0;L=>W @8:8 :8H5G=8:0. A:V;L:8 FO 4VO =5
>?>A5@54:>-20=0 02B>=><=>N =5@2>2>N A8AB5<N, B8?>28E 0=B8E>;V=5@3VG=8E ?>1VG=8E
5D5:BV2 =5 28=8:0T.

;V=VG=0 5D5:B82=VABL B0 157?5:0.

;V=VG=0 5D5:B82=VABL B0 157?5:0 70AB>AC20==O @V7=8E ;V:0@AL:8E D>@< <51525@8=C 1C;8
282G5=V C ?>=04 1500 ?0FVT=BV2. =0G=5 ?>A;01;5==O ?5@5206=8E A84@07=5=>3> :8H5G=8:C
(=0?@8:;04, 1V;L C 682>BV, E0@0:B5@8AB8:8 28?>@>6=5==O) 70728G09 A?>AB5@V30;>AO C
@5D5@5=B=8E B0 :>=B@>;L>20=8E 70 >A=>2=8<8 7=0G5==O<8 ;V=VG=8E 4>A;V465==OE.
#AV ;V:0@AL:V D>@<8 <51525@8=C 1C;8 7030;>< 157?5G=8<8 B0 4>1@5 ?5@5=>A8;8AO ?@8 @5:>
<5=4>20=>7C20==O.

VB8.

;V=VG=V 4>A;V465==O 70AB>AC20==O B01;5B>: 01> :0?AC; ?@>2>48;8AO BV;L:8 C 4>@>A;8E. 0=V
;V=VG=>W 5D5:B82=>ABV B0 157?5:8, 0 B0:>6 ?>AB<0@:5B8=3>289 4>A2V4 70AB>AC20==O
ACA?5=7VW <51525@8=C C ?0FVT=BV2 2V:>< 2V4 3 @>:V2 ?@>45<=>AB@C20;8, I> <51525@8= T
5D5:B82=8< 157?5G=8< ;V:0@AL:8< 70A>1><, O:89 4>1@5 ?5@5=>A8BLAO.

;V=VG=V 4>A;V465==O ACA?5=7VW <51525@8=C ?>:070;8, I> 2V= T 5D5:B82=8< 4;O ?>A;01;5==O A8
4@07=5=>3> :8H5G=8:C C 4VB59. >40;LHV 2V4:@8BV :>=B@>;L>20=V 70 >A=>2=8<8 7=0G5==O<8
4>A;V465==O ACA?5=7VW <51525@8=C ?V4B25@48;8 5D5:B82=VABL ?@5?0@0BC.

568< 4>7C20==O B01;5B>: 01> :0?AC; @>7@0E>20=89 =0 >A=>2V 157?5:8 B0 ?5@5=>A8<>ABV
<51525@8=C.

\$0@<0:>:V=5B8:0.

1A>@1FVO.

51525@8= H284:> B0 ?>2=VABN 01A>@1CTBLAO ?VA;O ?5@>@0;L=>3> 70AB>AC20==O C D>@.
024O:8 ?@>;>=3>20=>3> <6=0 ?@89<0B8 420 @078 =0 45=L.

>7?>4V;.

@8 1030B>@07>2>AC20==V ?@5?0@0BC 51AV= 5B0@4[®] =VO:>W 7=0G=>W :C

V>B@0=AD>@<0FVO.

51525@8=C 3V4@>E;>@84 3>;>2=8< G8=>< <5B01>;V7CTBLAO 5AB5@070<8, O:V =0 ?5@H>
715?;NNBL 5DV@=V 7207:8 7 CB2>@5==O< 25@0B@>2>W :8A;>B8 V <51525@8=>2>3> A?8@BC. # ?;07
T >A=>2=8< <5B01>;VB>4 =0?V2282545==O C @V2=>206=>48=8. @8 1030B>@07>2>AC20==V :0?AC;
(?> 200 <3 2 @078 =0 4>1C) C_{max} 4;O AB0=>28;0 804 =3/<;, 0 t_{max} 1;87L:> 3 3>48=. V4=>A=0
1V>4>ABC?=VABL :0?AC; ?@>;>=3>20=>W 4VW 28O28;0AO >?B8<0;L=>N 7 A5@54=V<
A?V22V4=>H5==O< 97 %.

82545==O.

51525@8= =5 5:A:@5BCTBLAO C =57

VB8.

\$0@<0:>:V=5B8G=V 4>A;V465==O C 4VB59 =5 ?@>2>48;8AO.

;V=VG=V E0@0:B5@8AB8:8.

>:070==O.

>@>A;V B0 4VB8 2V:>< 2V4 10 @>:V2:

□ A8<0B8G=5 ;V:C20==O 014>3> 1>;N V A?077;04V2 :8H5G=8:C V 2V4GCBBO 48A:>@BC C 4V;O=FW
:8H5G=8:C ?@8 A8=4@>4@07=5=>3> :8H5G=8:C;

□ ;V:C20==O H;C=:>2>.:8H:>28E A?07@8==>3> '5=57C, A?@8G8=5=8E >@30=VG=8<8 70E2>@N20==O<8.

@>B8?>:070==O.

V?5@GCB;82VABL 4> 0:B82=>W @5G>28=8 01> 4> 1C4L-O:>3> 7 :>5=BV2 ?@5?0@0BC.

70T<>4V0 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

@>2>48;8AO 4>A;V465==O 270T<>4VW BV;L:8 7 0;:>3>;5A;V465==O in vitro B0 in vivo ?@>45 <=>AB@C20;8 2V4ACB=VABL 1C4L-O:>W 270T<>4VW ?@5?0@0BC B0 5B0=>;C.

A>I;82>ABV 70AB>AC20==O.

A;V;L:8 ?@5?0@0B @, ?0FVT=B0< 7 @V4:VA=8<8 A?04:>28<8 D>@<0<8, B0:8<8 O: =5?5@5=>A878 01> D@C:B>78, 45DVF8B ;0:B078, <0;L01A>@1FVO 3;N:>78-30;0:B>78 01> =54>AB0B=VABL A0E0@078-V7><0;LB078, =5 A;V4 ?@89<0B8 F59 ?@5?0@0B.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

@5?0@0B 51AV= 5B0@4[®] =5 @5:><5=4CTBLAO 70AB>A>2C20B8 C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>1>BV 7 V=H8<8 <5E0=V7<0<8.

>A;V465==O 2?;82C =0 740B=VABL :5@C20B8 02B>>1V;5< V ?@0FN20B8 7 <5E0=V7<0<8 =5 ?@>2>48;8AO. \$0@<0:>48=0

!>AV1 70AB>AC20==O B0 4>78.

@5?0@0B ?@87=0G5=89 4;O ?5@>@0;L=>3> 70AB>AC20==O.

0?AC;8 A;V4 70?820B8 4>AB0B=L>N :V;L:VABN 2>48 (=5<5=H5 100 <);. 5 @5:><5=4CTBLAO

@>76>2C20B8 :0?AC;8, >A;V;L:8 ?>:@8BBO :0?AC; ?@87=0G5=5 4;O ?@>;>=3>20=>3> 282V;L=5==O ?@5?0@0BC.

>@>A;8< B0 4VBO< 2V:< 2V4 10 @>:V2 A;V4 ?@89<0B8 ?> 1 :0?AC;V 2 @078 =0 4>1C (2@0=FV B0 225G5@V).

"@820;VABL 70AB>AC20==O =5>1<565=0. /:I> >4=C 01> 1V;LH5 4>7 ?@>?CI5=>, ?0FVT=BC A;V4

?@89=OB8 =0ABC?>C 4>7C, O: ?@87=0G5=>. @>?CI5=C 4>7C =5 A;V4 ?@89<0B8 4>40B:>2> 4> =0ABC?>W ?@87=0G5=>W 4>78.

A>I;82V 3@C?8 ?0FVT=BV2.

>A;V465=L 4>7C20==O 4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0 /01> ?5GV=:8 =5 ?@>2>48;>AO. >3;04C =0 =0O2=V ?>AB<0@:5B8=3>2V 40=V, A?5F8DVG=>3> @878:C 4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0/01> ?5GV=:8 =5 28O2;5=>. >@5:FVO 4>78 4;O 28I5707=0G5=8E 3@C? ?0FVT=BV2 =5 ?>B@V1=0.

VB8.

5 70AB>A>2CNBL 4VBO< 2V:< 4> 10 @>:V2 G5@57 28A>:89 2W @5G>28=8 2 ?@5?0@0BV 51AV= 5B0@4[®].

5@54>7C20==O.

@8 ?5@54>7C20==V B5>@5B8G=> <>65 A?>AB5@V30B8AO 71C465==O F5=B@0;L=>W =5@2>2>W A8AB5<8. # 28?04:0E ?5@54>7C20==O <51525@8=C A8<8 1C;8 2V4ACB=V 01> 1C;8 ;53:8<8 V H284:> 7=8:0;8. !8<8 ?5@54>7C20==O, I> A?>AB5@V30;8AO, 1C;8 =52@>;>3VG=>3> 01> :0@4V>20A:C;O@=>3> ?>E>465==O.

V:C20==O. !?5F8DVG=89 0=B84>B =52V4><89. 5:><5=4>20=5 A8<0B8G=5 ;V:C20==O. @><820==O

H;C=:0 @5:><5=4CTBLAO BV;L:8 C 28?04:C V=B>:A8:0FVW :V;L:<0 @V7=8<8 ?@5?0@0B0<8, O:C 4V03=>AB>20=> ?@>BO3>< 1 3>48=8 7 <><5=BC ?@89>1V2. 0E>48 4;O 7=865==O 01A>@1FVW =5 T =5>1EV4=8<8.

>1VG=V @50:FVW.

>2V4><;O;>AO ?@> =0ABC?=V ?>1VG=V @50:FVW, I> 28=8:0;8 A?>=B0==> ?@>BO3× ?>AB
<0@:5B8=3>2>3> A?>AB5@565==O. '0AB>BC 70 =0O2=8<8 40=8<8 B>G=> 287=0G8B8 =5<>6;82>.
!>AB5@V30;8AO 0;5@3VG=V @50:FVW ?5@5206=> 7 1>:C H:V@8.
1>:C H:V@8 V ?V4H:V@=>W ::VB:>28=8: :@>?82O=0, 0=3V>=52@>B8G=89 =01@O:, =01@O:
>1;8GGO, 3V?5@5 28A8?8 =0 H:V@V, C B>
1>:C =5@2>2>W A8AB5<8: 3>;>2=89 1V;L, 70?0<>@>G5==O, 45?@5AVO.
1>:C B@02=>3> B@0:BC: 4V0@5O 01> 70?>@.
030:L=V @>7;048: 3V?5@GCB;82VABL(0=0DV;0:B8G=V @50:FVW).

"5@ABV.2 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV, C =54>ABC?=>

#?0:>2:0.

> 10 :0?AC; C 1;VAB5@V. > 3 1;VAB5@8 C :0@B>==V9 ?0GFV.

0B53>@VO 2V4?CA:C. 0 @5F5?B>

8@>1=8:.

09;0= □01>@0B>@V7 □V / Mylan Laboratories Limited

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.

VAB@V:B 509 302, =4E@0 @045H, =4VO.

Plot S 16 & S 17, SEZ APIIC Green Industrial Park, Polepally (V), Jedcherla (M), Mahaboobnagar District 509
302, Andhra Pradesh, India.

!" #&/

4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

!"®

(MEBSYN RETARD®)

!;:04:

4VNG0 @5G>28=0: 1 :0?AC;0

4>?>28=8: F5;N;>70 :@8AB0;VG=0, <0=VB (421), FC:@>70, =0B@VN ;0C@8;AC;LD0B, 5B8;F5;N;>70.

V:0@AL:0 D>@<0. □0?AC;8.

A=>2=V DV78:>-EVABV: B25@4V 65;0B8=>2V :0?AC;8 1, :>@?CA >@0=652>3> :>;L>@C, :@8H5G:0
1V;>3> :>;L>@C, <0NBL =0?8A8 «S» =0 >1>E G0AB8=0E B0 1V ?5;5B8 1V;>3> :>;L>@C.

\$0@<0:>B5@0?52B8G=0 3@C?0.

0A>18, I> 70AB>A>2CNBLAO ?@8 DC=:FV>=0;L=8E H;C=:>2>-.8H:>28E @>7;040E. !8=B5B8G=V
0=B8E>;V=5@3VG=V 70A>18, 5AB5@8DV:>20=V B@5B8==V 0
>4 "% 0304.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

5E0=V7< 4VW B0 D0@<0:>48=0

51525@8= T B@>?=8< A?07<>;VB8:<> 7 281V@:>2>N 4VTN =0 3;04:V <O78 B@02=>3> B@0:BC. V= CAC20T A?07<8 157 ?@83=VG5==O =>@<0;L=>W @8:8 :8H5G=8:0. A:V;L:8 FO 4VO =5 >?>A5@54:>-20=0 02B>=><=>N =5@2>2>N A8AB5<>N, B8?>28E 0=B8E>;V=5@3VG=8E ?>1VG=8E 5D5:BV2 =5 28=8:0T.

V=VG=0 5D5:B82=VABL B0 157?5:0.

;V=VG=0 5D5:B82=VABL B0 157?5:0 70AB>AC20==O @V7=8E ;V:0@AL:8E D>@< <51525@8=C 1C;8 282G5=V C ?>=04 1500 ?0FVT=BV2. =0G=5 ?>A;01;5==O ?5@5206=8E A84@07=5=>3> :8H5G=8:C (=0?@8:;04, 1V;L C 682>BV, E0@0:B5@8AB8:8 28?>@>6=5==O) 70728G09 A?>AB5@V30;>AO C @5D5@5=B=8E B0 :>=B@>;L>20=8E 70 >A=>2=8<8 7=0G5==O<8 ;;V=VG=8E 4>A;V465==OE. #AV ;V:0@AL:V D>@<8 <51525@8=C 1C;8 7030;>< 157?5G=8<8 B0 4>1@5 ?5@5=>A8;8AO ?@8 @5:> <5=4>20=>7C20==O.

VB8.

;V=VG=V 4>A;V465==O 70AB>AC20==O B01;5B>: 01> :0?AC; ?@>2>48;8AO BV;L:8 C 4>@>A;8E. 0=V ;;V=VG=>W 5D5:B82=>ABV B0 157?5:8, 0 B0:>6 ?>AB<0@:5B8=3>289 4>A2V4 70AB>AC20==O ACA?5=7VW <51525@8=C C ?0FVT=BV2 2V:< 2V4 3 @>:V2 ?@>45<=>=AB@C20;8, I> <51525@8= T 5D5:B82=8< 157?5G=8< ;V:0@AL:8< 70A>1><, O:89 4>1@5 ?5@5=>A8BLAO. ;V=VG=V 4>A;V465==O ACA?5=7VW <51525@8=C ?>:070;8, I> 2V= T 5D5:B82=8< 4;O ?>A;01;5==O A8 4@07=5=>3> :8H5G=8:C C 4VB59. >40;LHV 2V4:@8BV :>=B@>;L>20=V 70 >A=>2=8<8 7=0G5==O<8 4>A;V465==O ACA?5=7VW <51525@8=C ?V4B25@48;8 5D5:B82=VABL ?@5?0@0BC.

568< 4>7C20==O B01;5B>: 01> :0?AC; @>7@0E>20=89 =0 >A=>2V 157?5:8 B0 ?5@5=>A8<>ABV <51525@8=C.

\$0@<0:>:V=5B8:0.

1A>@1FVO.

51525@8= H284:> B0 ?>2=VABN 01A>@1CTBLAO ?VA;O ?5@>@0;L=>3> 70AB>AC20==O C D>@. 024O:8 ?@>;>=3>20=>3> <>6=0 ?@89<0B8 420 @078 =0 45=L.

>7?>4V:.

@8 1030B>@07>2>AC20==V ?@5?0@0BC 51AV= 5B0@4^R =VO:>W 7=0G=>W :C

V>B@0=AD>@<0FVO.

51525@8=C 3V4@>E;>@84 3>;>2=8< G8=>< <5B01>;V7CTBLAO 5AB5@070<8, O:V =0 ?5@H> 715?;NNBL 5DV@=V 72O7:8 7 CB2>@5==O< 25@0B@>2>W :8A;>B8 V <51525@8=>2>3> A?8@BC. # ?;07 T >A=>2=8< <5B01>;VB>4 =0?V2282545==O C @V2=>206=>48=8. @8 1030B>@07>2>AC20==V :0?AC; (?> 200 <3 2 @078 =0 4>1C) C_{max} 4;O AB0=>28;0 804 =3/<;, 0 t_{max} 1;87L:> 3 3>48=. V4=>A=0 1V>4>ABC?=VABL :0?AC; ?@>;>=3>20=>W 4VW 28O28;0AO >?B8<0;L=>N 7 A5@54=V< A?V22V4=>H5==O< 97 %.

82545==O.

51525@8= =5 5:A:@5BCTBLAO C =57

VB8.

\$0@<0:>:V=5B8G=V 4>A;V465==O C 4VB59 =5 ?@>2>48;8AO.

;V=VG=V E0@0:B5@8AB8:8.

>:070==O.

>@>A;V B0 4VB8 2V:< 2V4 10 @>:V2:

□ A8<0B8G=5 ;V:C20==O 014>3> 1>;N V A?077;04V2 :8H5G=8:C V 2V4GCBBO 48A:>@BC C 4V;O=FV :8H5G=8:C ?@8 A8=4@>4@07=5=>3> :8H5G=8:C;

□ ;V:C20==O H;C=:>2>.:8H:>28E A?07@8==>3> '5=57C, A?@8G8=5=8E >@30=VG=8<8 70E2>@N20==O<8.

@>B8?>:070==O.

V?5@GCB;82VABL 4> 0:B82=>W @5G>28=8 01> 4> 1C4L-O:>3> 7 :>5=BV2 ?@5?0@0BC.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

@>2>48;8AO 4>A;V465==O 270T<>4VW BV;L:8 7 0;:>3>;5A;V465==O *in vitro* B0 *in vivo* ?@>45 <=>=AB@C20;8 2V4ACB=VABL 1C4L-O:>W 270T<>4VW ?@5?0@0BC B0 5B0=>;C.

A>I;82>ABV 70AB>AC20==O.

A;V;L:8 ?@5?0@0B @, ?0FVT=B0< 7 @V4:VA=8<8 A?04:>28<8 D>@<0<8, B0:8<8 O: =5?5@5=>A878 01> D@C:B>78, 45DVF8B ;0:B078, <0;L01A>@1FVO 3;N:>78-30;0:B>78 01> =54>AB0B=VABL A0E0@078- V7><0;LB078, =5 A;V4 ?@89<0B8 F59 ?@5?0@0B.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

@5?0@0B 51AV= 5B0@4[®] =5 @5:><5=4CTBLAO 70AB>A>2C20B8 C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

40B=VABL ??:820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>1>BV 7 V=H8<8 <5E0=V7<0<8.

>A;V465==O 2?;82C =0 740B=VABL :5@C20B8 02B>>1V;5< V ?@0FN20B8 7 <5E0=V7<0<8 =5 ?@>2>48;8AO. \$0@<0:>48=0

!>AV1 70AB>AC20==O B0 4>78.

@5?0@0B ?@87=0G5=89 4;O ?5@>@0;L=>3> 70AB>AC20==O.

0?AC;8 A;V4 70?820B8 4>AB0B=L>N :V;L:VABN 2>48 (=5<5=H5 100 <);. 5 @5:><5=4CTBLAO @>76>2C20B8 :0?AC;8, >A;V;L:8 ?>:@8BBO :0?AC; ?@87=0G5=5 4;O ?@>;>3>20=>3> 282V;L=5==O ?@5?0@0BC.

>@>A;8< B0 4VBO< 2V:< 2V4 10 @>:V2 A;V4 ?@89<0B8 ?> 1 :0?AC;V 2 @078 =0 4>1C (2@0=FV B0 225G5@V).

"@820;VABL 70AB>AC20==O =5>1<565=0. /:I> >4=C 01> 1V;LH5 4>7 ?@>?CI5=>, ?0FVT=BC A;V4 ?@89=OB8 =0ABC?=C 4>7C, O: ?@87=0G5=>. @>?CI5=C 4>7C =5 A;V4 ?@89<0B8 4>40B:>2> 4> =0ABC?=>W ?@87=0G5=>W 4>78.

A>I;82V 3@C?8 ?0FVT=BV2.

>A;V465=L 4>7C20==O 4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0 /01> ?5GV=:8 =5 ?@>2>48;>AO. >3;04C =0 =0O2=V ?>AB<0@:5B8=3>2V 40=V, A?5F8DVG=>3> @878:C 4;O E2>@8E ;VB=L>3> 2V:C, ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>: B0/01> ?5GV=:8 =5 28O2;5=>. >@5:FVO 4>78 4;O 28I5707=0G5=8E 3@C? ?0FVT=BV2 =5 ?>B@V1=0.

VB8.

5 70AB>A>2CNBL 4VBO< 2V:< 4> 10 @>:V2 G5@57 28A>:89 2W @5G>28=8 2 ?@5?0@0BV 51AV= 5B0@4[®].

5@54>7C20==O.

@8 ?5@54>7C20==V B5>@5B8G=> <>65 A?>AB5@V30B8AO 71C465==O F5=B@0;L=>W =5@2>2>W A8AB5<8. # 28?04:0E ?5@54>7C20==O <51525@8=C A8<8 1C;8 2V4ACB=V 01> 1C;8 ;53:8<8 V H284:> 7=8:0;8. !8<8 ?5@54>7C20==O, I> A?>AB5@V30;8AO, 1C;8 =52@>;>3VG=>3> 01> :0@4V>20A:C;O@=>3> ?>E>465==O.

V:C20==O. !?5F8DVG=89 0=B84>B =52V4><89. 5:><5=4>20=5 A8<0B8G=5 ;V:C20==O. @><820==O H;C=:0 @5:><5=4CTBLAO BV;L:8 C 28?04:C V=B>:A8:0FVW :V;L:<0 @V7=8<8 ?@5?0@0B0<8, O:C 4V03=>AB>20=> ?@>BO3>< 1 3>48=8 7 <><5=BC ?@89>1V2. 0E>48 4;O 7=865==O 01A>@1FVW =5 T =5>1EV4=8<8.

>1VG=V @50:FVW.

>2V4><;O;>AO ?@> =0ABC?=V ?>1VG=V @50:FVW, I> 28=8:0;8 A?>=B0==> ?@>BO3< ?>AB <0@:5B8=3>2>3> A?>AB5@565==O. '0AB>BC 70 =0O2=8<8 40=8<8 B>G=> 287=0G8B8 =5<>6;82>.

!>AB5@V30;8AO 0;5@3VG=V @50:FVW ?5@5206=> 7 1>:C H:V@8.

1>:C H:V@8 V ?V4H:V@=>W ::VB:>28=8: :@>?82O=:0, 0=3V>=52@>B8G=89 =01@O., =01@O:

>1;8GGO, 3V?5@5 28A8?8 =0 H:V@V, C B>

1>:C =5@2>2>W A8AB5<8: 3>;>2=89 1V;L, 70?0<>@>G5==O, 45?@5AVO.

1>:C B@02=>3> B@0:BC: 4V0@50 01> 70?>@.

030;L=V @>7;048: 3V?5@GCB;82VABL(0=0DV;0:B8G=V @50:FVW).

"5@ABV.2 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV, C =54>ABC?=>

#?0:>2:0.

> 10 :0?AC; C 1;VAB5@V. > 3 1;VAB5@8 C :0@B>==V9 ?0GFV.

0B53>@VO 2V4?CA:C. 0 @5F5?B>

8@>1=8:.

?BV

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.

;>B A-8, A-9, A-13 B0 A-14, 9 V 9 9 !V, \$0@<0 A 5B, @V= =40AB@V0; 0@:., >;5?0;;V (I), 4G5@;0 (M), 0E01C1=030@, H - 509 301, =4VO/

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