Table 1.0
Adverse Events by Severity
Safety Population

	ARM A (N=30)		
System Organ Class Preferred Term	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	22 (73.3%)	8 (26.7%)	0 (0.0%)
Gastrointestinal disorders			
Diarrhoea	1 (3.3%)	0 (0.0%)	0 (0.0%)
Stomach Discomfort	1 (3.3%)	0 (0.0%)	0 (0.0%)
Toothache	1 (3.3%)	0 (0.0%)	0 (0.0%)
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infections and infestations			
Rash Pustular	1 (3.3%)	0 (0.0%)	0 (0.0%)
Respiratory Tract Infection	1 (3.3%)	0 (0.0%)	0 (0.0%)
Rhinitis	0 (0.0%)	1 (3.3%)	0 (0.0%)
Upper Respiratory Fungal Infection	0 (0.0%)	1 (3.3%)	0 (0.0%)
Upper Respiratory Tract Infection	1 (3.3%)	0 (0.0%)	0 (0.0%)
Wound Infection	0 (0.0%)	1 (3.3%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Urinary Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tinea Pedis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injury, poisoning and procedural complications			
Heat Cramps	1 (3.3%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
% is defined as Number of Subjects divided by Total Reporting
Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

	ARM B (N=19)		
System Organ Class Preferred Term	Mild	Mod**	Severe

All System Organ Classes
   All Adverse Events   9 (47.4%) 10 (52.6%)   0 (0.0%)

Gastrointestinal disorders
   Diarrhoea   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Stomach Discomfort   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Toothache   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Cheilitis   0 (0.0%)   1 (5.3%)   0 (0.0%)

Infections and infestations
   Rash Pustular   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Respiratory Tract Infection 0 (0.0%)   0 (0.0%)   0 (0.0%)
   Rhinitis   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Upper Respiratory Fungal Infection 0 (0.0%)   0 (0.0%)   0 (0.0%)
   Upper Respiratory Tract Infection   2 (10.5%)   0 (0.0%)   0 (0.0%)
   Wound Infection   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Paronychia   0 (0.0%)   1 (5.3%)   0 (0.0%)
   Sinusitis   1 (5.3%)   0 (0.0%)   0 (0.0%)
   Urinary Tract Infection   0 (0.0%)   2 (10.5%)   0 (0.0%)
   Bronchitis   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Nail Infection   0 (0.0%)   0 (0.0%)   0 (0.0%)
   Tinea Pedis   0 (0.0%)   0 (0.0%)   0 (0.0%)

Injury, poisoning and procedural complications
   Heat Cramps   0 (0.0%)   0 (0.0%)   0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
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Table 1.0
Adverse Events by Severity
Safety Population

	ARM C (N=10)		
System Organ Class Preferred Term	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	4 (40.0%)	6 (60.0%)	0 (0.0%)
Gastrointestinal disorders			
Diarrhoea	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stomach Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)
Toothache	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infections and infestations			
Rash Pustular	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rhinitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Fungal Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Infection	2 (20.0%)	0 (0.0%)	0 (0.0%)
Wound Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Urinary Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bronchitis	0 (0.0%)	2 (20.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	1 (10.0%)	0 (0.0%)
Tinea Pedis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injury, poisoning and procedural complications			
Heat Cramps	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
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Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

	ARM D (N=16)		
System Organ Class Preferred Term	Mild	Mod**	Severe
All System Organ Classes			
All Adverse Events	7 (43.8%)	8 (50.0%)	1 (6.2%)
Gastrointestinal disorders			
Diarrhoea	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stomach Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)
Toothache	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infections and infestations			
Rash Pustular	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rhinitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Fungal Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Infection	1 (6.2%)	0 (0.0%)	0 (0.0%)
Wound Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinusitis	0 (0.0%)	1 (6.2%)	0 (0.0%)
Urinary Tract Infection	0 (0.0%)	1 (6.2%)	0 (0.0%)
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tinea Pedis	0 (0.0%)	1 (6.2%)	0 (0.0%)
Injury, poisoning and procedural complications			
Heat Cramps	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
% is defined as Number of Subjects divided by Total Reporting
Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

	ARM A (N=30)		
System Organ Class Preferred Term	Mild	Mod**	Severe
Procedural Pain	0 (0.0%)	1 (3.3%)	0 (0.0%)
Fall	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Investigations			
Blood Potassium Decreased	0 (0.0%)	1 (3.3%)	0 (0.0%)
Blood Triglycerides Increased	1 (3.3%)	0 (0.0%)	0 (0.0%)
Vitamin D Decreased	1 (3.3%)	0 (0.0%)	0 (0.0%)
Musculoskeletal and connective tissue disorders			
Joint Swelling	0 (0.0%)	1 (3.3%)	0 (0.0%)
Myalgia	0 (0.0%)	1 (3.3%)	0 (0.0%)
Pain In Extremity	1 (3.3%)	0 (0.0%)	0 (0.0%)
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nervous system disorders			
Dizziness	1 (3.3%)	0 (0.0%)	0 (0.0%)
Headache	10 (33.3%)	1 (3.3%)	0 (0.0%)
Burning Sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sciatica	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory, thoracic and mediastinal disorders			
Nasal Congestion	1 (3.3%)	0 (0.0%)	0 (0.0%)
Cough	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
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** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
% is defined as Number of Subjects divided by Total Reporting
Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

	ARM B (N=19)		
System Organ Class Preferred Term	Mild	Mod**	Severe
Procedural Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fall	1 (5.3%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Investigations			
Blood Potassium Decreased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Blood Triglycerides Increased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitamin D Decreased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal and connective tissue disorders			
Joint Swelling	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myalgia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pain In Extremity	0 (0.0%)	1 (5.3%)	0 (0.0%)
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nervous system disorders			
Dizziness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	1 (5.3%)	1 (5.3%)	0 (0.0%)
Burning Sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sciatica	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory, thoracic and mediastinal disorders			
Nasal Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cough	0 (0.0%)	1 (5.3%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
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Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

	ARM C (N=10)		
System Organ Class Preferred Term	Mild	Mod**	Severe
Procedural Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fall	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Investigations			
Blood Potassium Decreased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Blood Triglycerides Increased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vitamin D Decreased	0 (0.0%)	0 (0.0%)	0 (0.0%)
Musculoskeletal and connective tissue disorders			
Joint Swelling	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myalgia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pain In Extremity	0 (0.0%)	0 (0.0%)	0 (0.0%)
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nervous system disorders			
Dizziness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	0 (0.0%)	1 (10.0%)	0 (0.0%)
Burning Sensation	1 (10.0%)	0 (0.0%)	0 (0.0%)
Sciatica	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory, thoracic and mediastinal disorders			
Nasal Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cough	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
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Table 1.0
Adverse Events by Severity
Safety Population

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                                                                                ARM D
                                                                               (N=16)
                                                                ----------------------------------

System Organ Class
    Preferred Term                                               Mild        Mod**       Severe
----------------------------------------------------------------------------------------------------


    Procedural Pain                                            0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Fall                                                       0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Muscle Injury                                              0 (  0.0%)  1 (  6.2%)  0 (  0.0%)


Investigations
    Blood Potassium Decreased                                  0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Blood Triglycerides Increased                              0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Vitamin D Decreased                                        0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Musculoskeletal and connective tissue disorders
    Joint Swelling                                             0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Myalgia                                                    0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Pain In Extremity                                          0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Back Pain                                                  1 (  6.2%)  0 (  0.0%)  0 (  0.0%)


Nervous system disorders
    Dizziness                                                  0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Headache                                                   0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Burning Sensation                                          0 (  0.0%)  0 (  0.0%)  1 (  6.2%)
    Sciatica                                                   1 (  6.2%)  0 (  0.0%)  0 (  0.0%)


Respiratory, thoracic and mediastinal disorders
    Nasal Congestion                                           0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Cough                                                      0 (  0.0%)  1 (  6.2%)  0 (  0.0%)
    Sinus Congestion                                           1 (  6.2%)  0 (  0.0%)  0 (  0.0%)
```

Date Produced: Time ; SAS Program: Table3_0.R
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Table 1.0
Adverse Events by Severity
Safety Population

	ARM A (N=30)		
System Organ Class Preferred Term	Mild	Mod**	Severe
Throat Irritation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
General disorders and administration site conditions			
Application Site Erythema	0 (0.0%)	0 (0.0%)	0 (0.0%)
Influenza Like Illness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pruritus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgical and medical procedures			
Cholecystectomy	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin Lesion Excision	0 (0.0%)	0 (0.0%)	0 (0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
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Table 1.0
Adverse Events by Severity
Safety Population

	ARM B (N=19)		
System Organ Class Preferred Term	Mild	Mod**	Severe
Throat Irritation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
General disorders and administration site conditions			
Application Site Erythema	1 (5.3%)	0 (0.0%)	0 (0.0%)
Influenza Like Illness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hepatobiliary disorders			
Gallbladder Disorder	0 (0.0%)	1 (5.3%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	2 (10.5%)	0 (0.0%)	0 (0.0%)
Skin Discomfort	1 (5.3%)	0 (0.0%)	0 (0.0%)
Pruritus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgical and medical procedures			
Cholecystectomy	0 (0.0%)	1 (5.3%)	0 (0.0%)
Skin Lesion Excision	0 (0.0%)	1 (5.3%)	0 (0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
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Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

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                                                                       ARM C
                                                                      (N=10)
                                                           ----------------------------------

System Organ Class
   Preferred Term                                            Mild        Mod**        Severe
-------------------------------------------------------------------------------------------------


   Throat Irritation                                       0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
   Upper Respiratory Tract Congestion                      0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


General disorders and administration site conditions
   Application Site Erythema                               0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
   Influenza Like Illness                                  1 ( 10.0%)  0 (  0.0%)  0 (  0.0%)


Hepatobiliary disorders
   Gallbladder Disorder                                    0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Skin and subcutaneous tissue disorders
   Erythema                                                0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
   Skin Discomfort                                         0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
   Pruritus                                                0 (  0.0%)  1 ( 10.0%)  0 (  0.0%)


Surgical and medical procedures
   Cholecystectomy                                         0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
   Skin Lesion Excision                                    0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Reproductive system and breast disorders
   Menstrual Discomfort                                    0 (  0.0%)  1 ( 10.0%)  0 (  0.0%)
```

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
% is defined as Number of Subjects divided by Total Reporting
Note: Adverse events were coded using MedDRA Version 9.1

Table 1.0
Adverse Events by Severity
Safety Population

```
                                                                    ARM D
                                                                   (N=16)
                                                      ----------------------------------

System Organ Class
    Preferred Term                                      Mild        Mod**       Severe
--------------------------------------------------------------------------------------------


    Throat Irritation                                 1 (  6.2%)  0 (  0.0%)  0 (  0.0%)
    Upper Respiratory Tract Congestion                1 (  6.2%)  0 (  0.0%)  0 (  0.0%)


General disorders and administration site conditions
    Application Site Erythema                          0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Influenza Like Illness                             0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Hepatobiliary disorders
    Gallbladder Disorder                               0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Skin and subcutaneous tissue disorders
    Erythema                                           0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Skin Discomfort                                    0 (  0.0%)  1 (  6.2%)  0 (  0.0%)
    Pruritus                                           1 (  6.2%)  2 ( 12.5%)  0 (  0.0%)


Surgical and medical procedures
    Cholecystectomy                                    0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
    Skin Lesion Excision                               0 (  0.0%)  0 (  0.0%)  0 (  0.0%)


Reproductive system and breast disorders
    Menstrual Discomfort                               0 (  0.0%)  0 (  0.0%)  0 (  0.0%)
```

Date Produced: Time ; SAS Program: Table3_0.R
* Total Reporting is defined as number of subjects who reported at least one adverse event.
** Mod = Moderate
# Episodes is defined as the total number of occurances of adverse events
% is defined as Number of Subjects divided by Total Reporting
Note: Adverse events were coded using MedDRA Version 9.1