Table 1.0
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term	ARM A (N=30) Mild	 Mod**	 Severe
All System Organ Classes			
All Adverse Events	22 (73.3%)	8 (26.7%)	0 (0.0%)
Gastrointestinal disorders			
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
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%)
Infections and infestations			
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM B (N=19) Mild	 Mod**	 Severe
All System Organ Classes			
All Adverse Events	9 (47.4%)	10 (52.6%)	0 (0.0%)
Gastrointestinal disorders			
Cheilitis	0 (0.0%)	1 (5.3%)	0 (0.0%)
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%)
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%)
Infections and infestations			
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paronychia	0 (0.0%)	1 (5.3%)	0 (0.0%)
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%)
Sinusitis	1 (5.3%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM C (N=10) Mild	 Mod**	 Severe
All System Organ Classes			
All Adverse Events	4 (40.0%)	6 (60.0%)	0 (0.0%)
Gastrointestinal disorders			
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
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%)
Infections and infestations			
Bronchitis	0 (0.0%)	2 (20.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	1 (10.0%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Sinusitis	0 (0.0%)	0 (0.0%)	0 (0.0%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM D (N=16) Mild	 Mod**	 Severe
All System Organ Classes			
All Adverse Events	7 (43.8%)	8 (50.0%)	1 (6.2%)
Gastrointestinal disorders			
Cheilitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
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%)
Infections and infestations			
Bronchitis	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nail Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paronychia	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Sinusitis	0 (0.0%)	1 (6.2%)	0 (0.0%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM A (N=30) Mild	 Mod**	 Severe
Tinea Pedis	0 (0.0%)	0 (0.0%)	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%)
Urinary Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Wound Infection	0 (0.0%)	1 (3.3%)	0 (0.0%)
Injury, poisoning and procedural complications			
Fall	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heat Cramps	1 (3.3%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Procedural Pain	0 (0.0%)	1 (3.3%)	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			
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Nervous system disorders			

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM B (N=19) Mild	 Mod**	 Severe
Tinea Pedis	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%)
Urinary Tract Infection	0 (0.0%)	2 (10.5%)	0 (0.0%)
Wound Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injury, poisoning and procedural complications			
Fall	1 (5.3%)	0 (0.0%)	0 (0.0%)
Heat Cramps	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Procedural Pain	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			
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Nervous system disorders			

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM C (N=10) Mild	 Mod**	 Severe
Tinea Pedis	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%)
Urinary Tract Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Wound Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injury, poisoning and procedural complications			
Fall	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heat Cramps	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	0 (0.0%)	0 (0.0%)
Procedural Pain	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			
Back Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)
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%)
Nervous system disorders			

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM D (N=16) Mild	 Mod**	 Severe
Tinea Pedis	0 (0.0%)	1 (6.2%)	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%)
Urinary Tract Infection	0 (0.0%)	1 (6.2%)	0 (0.0%)
Wound Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injury, poisoning and procedural complications			
Fall	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heat Cramps	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle Injury	0 (0.0%)	1 (6.2%)	0 (0.0%)
Procedural Pain	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			
Back Pain	1 (6.2%)	0 (0.0%)	0 (0.0%)
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%)
Nervous system disorders			

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM A (N=30) Mild	 Mod**	 Severe
Burning Sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dizziness	1 (3.3%)	0 (0.0%)	0 (0.0%)
Headache	10 (33.3%)	1 (3.3%)	0 (0.0%)
Sciatica	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%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nasal Congestion	1 (3.3%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Throat Irritation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pruritus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin Discomfort	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%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM B (N=19) Mild	 Mod**	 Severe
Burning Sensation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dizziness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	1 (5.3%)	1 (5.3%)	0 (0.0%)
Sciatica	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%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 (0.0%)	1 (5.3%)	0 (0.0%)
Nasal Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Throat Irritation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	2 (10.5%)	0 (0.0%)	0 (0.0%)
Pruritus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin Discomfort	1 (5.3%)	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%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM C (N=10) Mild	 Mod**	 Severe
Burning Sensation	1 (10.0%)	0 (0.0%)	0 (0.0%)
Dizziness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	0 (0.0%)	1 (10.0%)	0 (0.0%)
Sciatica	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%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nasal Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Throat Irritation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pruritus	0 (0.0%)	1 (10.0%)	0 (0.0%)
Skin Discomfort	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%)

Date Produced: Time ; 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

System Organ Class Preferred Term	ARM D (N=16) Mild	 Mod**	 Severe
Burning Sensation	0 (0.0%)	0 (0.0%)	1 (6.2%)
Dizziness	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headache	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sciatica	1 (6.2%)	0 (0.0%)	0 (0.0%)
Reproductive system and breast disorders			
Menstrual Discomfort	0 (0.0%)	0 (0.0%)	0 (0.0%)
Respiratory, thoracic and mediastinal disorders			
Cough	0 (0.0%)	1 (6.2%)	0 (0.0%)
Nasal Congestion	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus Congestion	1 (6.2%)	0 (0.0%)	0 (0.0%)
Throat Irritation	1 (6.2%)	0 (0.0%)	0 (0.0%)
Upper Respiratory Tract Congestion	1 (6.2%)	0 (0.0%)	0 (0.0%)
Skin and subcutaneous tissue disorders			
Erythema	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pruritus	1 (6.2%)	2 (12.5%)	0 (0.0%)
Skin Discomfort	0 (0.0%)	1 (6.2%)	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%)

Date Produced: Time ; 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