AMGEN®	TECHNICAL ASSESSMENT REPORT	NUMBER 1247-TA(R)
TITLE: Global Distribution Area Represented Within Amgen's Heat and Cold Thermal Profiles One Amgen Center Drive	INITIATOR	PAGE: 1 of 4
	SUPERSEDES: New	EFFECTIVE DATE

OWNER APPROVAL	DATE	OTHER APPROVAL	DATE
CORPORATE QUALITY APPROVAL	DATE	OTHER APPROVAL	DATE
OTHER APPROVAL	DATE	OTHER APPROVAL	DATE

INTRODUCTION

Amgen Drug Product Process Development (DPPD) developed the heat and cold thermal temperature profiles to represent the temperatures that Amgen's insulated shippers encounter while being shipped throughout the continental United States as well as internationally.

The Amgen Global Transportation Heat and Cold Qualification profiles were developed using actual data as well as NASA's historical global temperature data for the geographical locations of Amgen's distribution sites. Temperatures on the Earth are dependent upon how much energy is received from the sun. This varies with both the latitude on the Earth and the time of year, season.

Latitudes provide the location of a place north or south of the equator and are expressed as angular measurements ranging from 0° at the equator to 90° at the poles. More sunlight is received nearer the equator than the poles. The greater amount of sunlight at the lower latitudes keeps the climates there warmer than regions nearer the poles.

From April to September, the Northern Hemisphere is tilted towards the sun, and receives more energy than the Southern Hemisphere. During October to March, the Southern Hemisphere is tilted toward the sun and summer in the Southern Hemisphere occurs at this time.

METHODS & MATERIALS

Refer to Technical Report #1104-TTR, Amgen Global Thermal Qualification Profiles: Heat and Cold

EXCEPTIONAL CONDITIONS

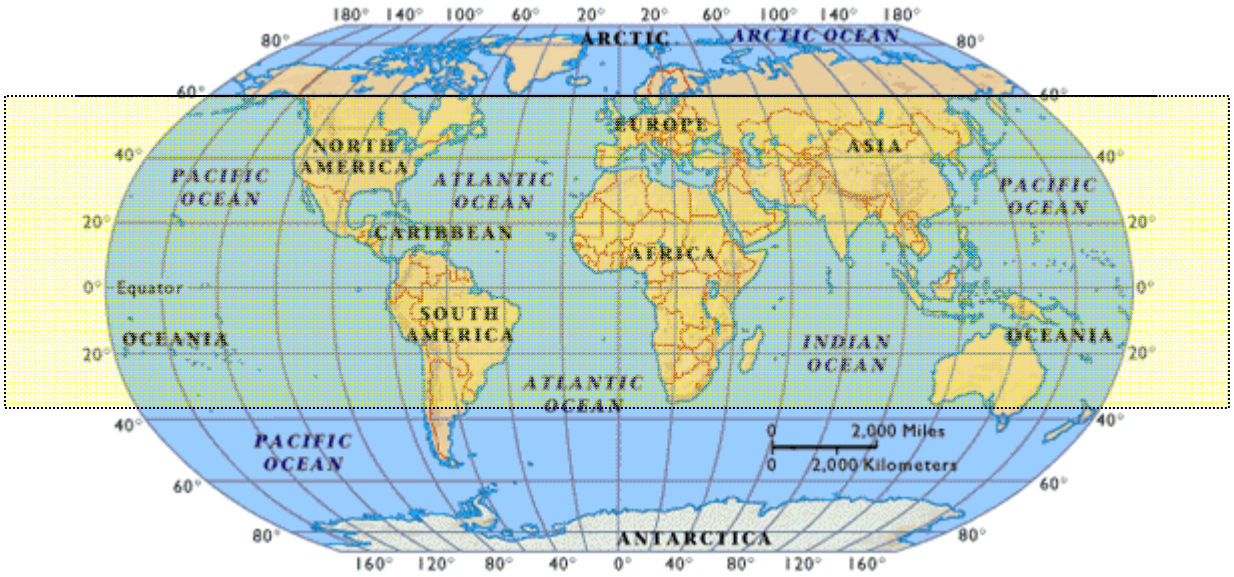
None

RESULTS

Table 1: Geographical Coordinates of Cities Used In Developing The Amgen Heat and Cold Profiles

Amsterdam, Netherlands	Lat/Lon:	**52.3° N 4.8° E**
Arlington, Texas	Lat/Lon:	**32.6° N 97.2° W**
Athens, Greece	Lat/Lon:	**37.9° N 23.7° E**
Auburn, Washington	Lat/Lon:	**37.9° N 23.7° E**
Berlin, Germany	Lat/Lon:	**52.4° N 13.5° E**
Bern, Switzerland	Lat/Lon:	**46.9° N 7.5° E**
Boulder, Colorado	Lat/Lon:	**40.0° N 105.2° W**
Dublin, Ireland	Lat/Lon:	**53.4° N 6.2° W**
Duluth, Georgia	Lat/Lon:	**34.0° N 84.1° W**
El Kheiter, Algiers	Lat/Lon:	**34.2° N 0.1° E**
Jerusalem, Israel	Lat/Lon:	**31.8° N 35.2° E**
Livonia, Michigan	Lat/Lon:	**34.0° N 84.1° W**
Ljubljana, Slovenia	Lat/Lon:	**46.1° N 14.5° E**
London, United Kingdom	Lat/Lon:	**45.0° N 93.1° W**
Los Angeles, California	Lat/Lon:	**49.6° N 6.2° E**
Louisville, Kentucky	Lat/Lon:	**45.0° N 93.1° W**
Luxembourg, Luxembourg	Lat/Lon:	**49.6° N 6.2° E**
Madrid, Spain	Lat/Lon:	**40.5° N 3.5° W**
Melbourne, Australia	Lat/Lon:	**37.8° S 145.0° E**
Methuen, Massachusetts	Lat/Lon:	**42.7° N 71.2° W**
Oslo, Norway	Lat/Lon:	**59.9° N 10.6° E**
Paris, France	Lat/Lon:	**42.7° N 71.2° W**
Phoenix, Arizona	Lat/Lon:	**45.0° N 93.1° W**
Rome, Italy	Lat/Lon:	**41.9° N 12.5° E**
San Juan, Puerto Rico	Lat/Lon:	**18.5° N 66.1° W**
St. Paul Minnesota	Lat/Lon:	**45.0° N 93.1° W**
Stockholm, Sweden	Lat/Lon:	**41.9° N 12.5° E**
Toronto, Canada	Lat/Lon:	**43.6° N 79.4° W**
Tunis, Tunisia	Lat/Lon:	**36.8° N 10.2° E**
Zagreb, Croatia	Lat/Lon:	**45.8° N 16.0° E**

Figure1: Geographical Area of Shipping Lanes Represented Within the Amgen Heat and Cold Profiles



DISCUSSION

Table 1, Geographical Coordinates of Cities Used in Developing the Amgen Heat and Cold Profiles indicates the longitude and latitude of destination cities within Amgen distribution. In the Northern Hemisphere, Oslo Norway is the city with the largest latitude which is 59.9° North. For the Southern Hemisphere, Melbourne Australia is the largest latitude which is 37.8° South. The global areas between Oslo and Melbourne represent geographical locations used to develop Amgen's Heat and Cold Thermal profiles. Within this area, the thermal characteristics of the distribution lanes are represented when applying the Amgen Heat and Cold Thermal Qualification Profiles.

To support this stated distribution area represented within the Amgen Heat and Cold profiles the total amount of shipping excursions is calculated for 2006. In 2006, a total of 2,484 monitored shipments occurred- see Attachment 1, *P and C-Series Shipper Usage*. Out of these shipments a total of 57 excursions were documented. This represents a shipper product temperature success rate of ((2484-57)/2484)*100 = 97.7%.

CONCLUSION

The Amgen Global Thermal Qualification Profiles: Heat and Cold. represent the thermal characteristics of distribution lanes within the latitudes of Oslo, Norway to Melbourne Australia.

Attachment 1, P and C-Series Shipper Usage

NC's Generated from Jan 2006 to Dec. 2006

P-002 Too Cold	P-002 Front End	2 to 8 C-Series Too Cold	C-Series Front End	Frozen P-008 Equilibration exceeded		2 to 10 Trailer	2 to 8 3rd Party	2 to 8 Laminar NC's	E-Series	2 to 8 NC's Human Error	Others	Equipment Failures at the site	Total	Grand Total		
32	5	5	3	11	56	19	5	1	15	4	6	43	93	149	4000	$372,000.00
																$224,000.00
																$596,000.00

Frount End Excursions	P-002	5
Too Cold (Ice)	P-002	32
Frount End Excursions	C-167	2
Too Cold	C-167	5
Frount End Excursions	C-163	1
Too Cold	C-163	0
		45

Year	Total	Commercial	Clinical	
2005	127	59	68	
2006	57	37	20	44.88%
2007	43			75.44%

	Total Shipments C&P-Series	Total Excursions	% Failure
2006	2484	57	2.3