

Abstract

Developing Amgen's Random Vibration Test Standards

This paper describes the collaboration of science, engineering, industry, academia, and consultants to develop testing profiles to meet your qualification needs. The test standards were developed based on the concept, if you can measure it, you can develop it. Confidence in testing for the distribution process is increased by applying the correct science to sufficient data.

Introduction

At Amgen, our mission is to serve every patient every time. We use scientific discovery and innovation to dramatically improve people's lives, by discovering, developing, and commercializing proteins, antibodies, and small molecules that can extend the reach of medicine. Following Amgen's core values, the same approach is applied to developing our packaging and testing standards.

Amgen's engineers collaborated with Eric Joneson of Lansmont Corporation and Professor S. Paul Singh, PhD. of Michigan State University to create Amgen vibration test standards. Data was collected from Amgen's transportation lanes and through building random vibration profiles based on that data; Amgen will be able to better replicate its transportation environment in a lab. This paper follows Amgen's approach on the data collection, analysis of the data, creation of the profiles, and the application of the profiles.

Data Collection

Amgen's data collection efforts focused on collecting data from air ride trucks and airplanes. These are the two modes of transportation Amgen uses most frequently. Truck data was gathered by attaching four vibration data loggers to two trucks just behind the rear axle (Figure 1 – *Air Ride Truck Data Collection*). The two trucks chosen are the two main trucks Amgen uses to transport Amgen products. Data collection took place continuously over 30 days anywhere the trucks traveled. Over the 30 days Amgen collected data on different road conditions, East Coast vs. West Coast, different trailer load conditions, and different truck velocities.



Figure 1 – Air Ride Truck Data Collection

Airplane data was gathered using a different approach, based on FAA regulations. The preferred method to collect data was to attach vibration data loggers directly to an airplane to gather the best possible vibration data, similar to the approach used on the trucks. Based on the regulations, Amgen determined the best approach to collect data would be to attach the vibration data loggers to an LD3 shipping container (Figure 2 — Airplane Data Collection). This shipping container was selected because the containers are secured directly to the airplane. To determine exactly when the airplane was in the air, Amgen included pressure loggers with the airplane shipments to assist with data analysis.

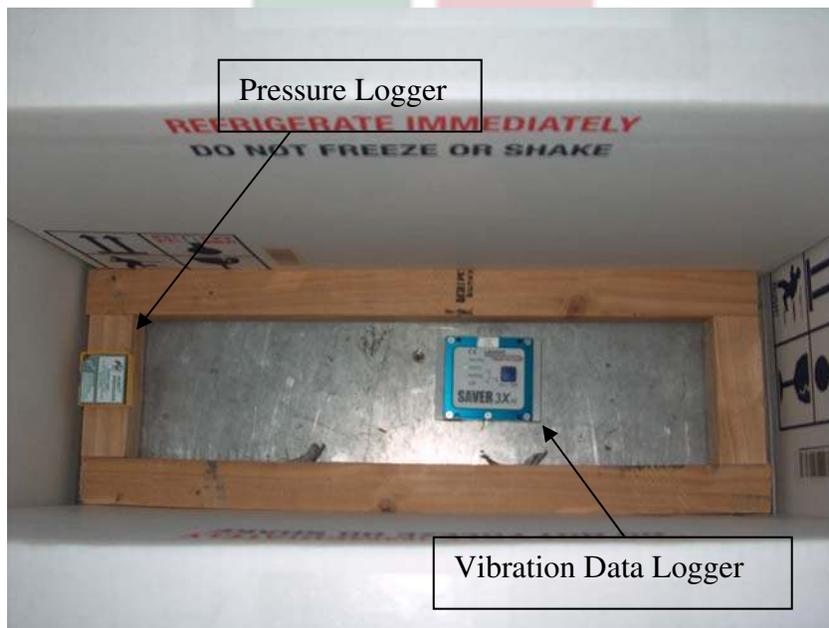


Figure 2 – Airplane Data Collection

Vibration Profile Development Method

Following the collection of the vibration data Amgen had to determine a method to analyze the data and create the Amgen profiles. Amgen followed the vibration simulation of truck transport environment method developed and published by the Consortium of Distribution Packaging Research [1]. This method required the creation of two random vibration profiles, a high 30% and a low 70% profile, based on the data gathered. Amgen took a more stringent approach by creating a high 20% and low 80% profile. The two profiles are created to complete one test. The high 20% profile is used to increase the confidence in testing, by testing at a higher level for a portion of a test, using more of the higher level data gathered that is muted out by averaging.

Data Analysis - Truck Data

The first truck profile created was the low 80% profile, which Amgen named the *Amgen Low Intensity Air Ride Truck Random Vibration Profile*. This profile was created following the industry approach for profile development, using the average of all the data that is within scope of the profile [2].

First, the data was filtered to remove any out of scope data. Data below 0.04 G_{rms} was filtered out to remove any digital noise that may have been recorded and all non-vibration events were also filtered out. The remaining data after filtering was the data that was averaged to create the *Amgen Low Intensity Air Ride Truck Random Vibration Profile*. Amgen applied a “smoothing” process to the profile that was created. Without the “smoothing” process the *Amgen Low Intensity Air Ride Truck Random Vibration Profile* would have about 400 breakpoints to program into a vibration table. The “smoothing” process finds trends in the data that make up a vibration profile and eliminating the data points between the first and last point in a trend. At the end of the “smoothing” process the profile has the same shape, but in Amgen’s case only has 32 breakpoints to program into a vibration table verses the 400 before the smoothing process. Chart 1 – *Amgen Low Intensity Air Ride Truck Random Vibration Profile Smoothing* shows how the smoothed profile with 32 breakpoints compares to the raw data, and the un-smoothed profile.

Amgen Averaged Low Intensity Profile

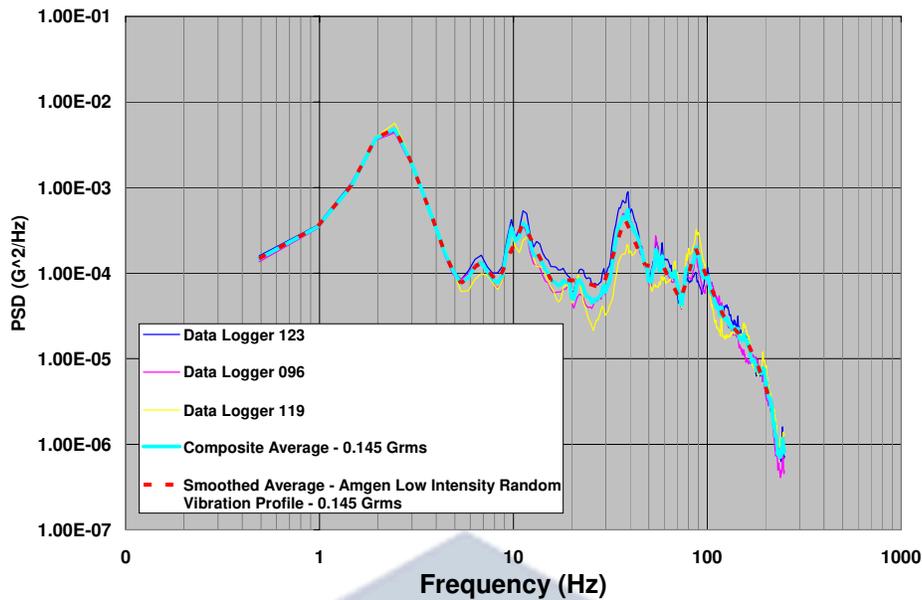


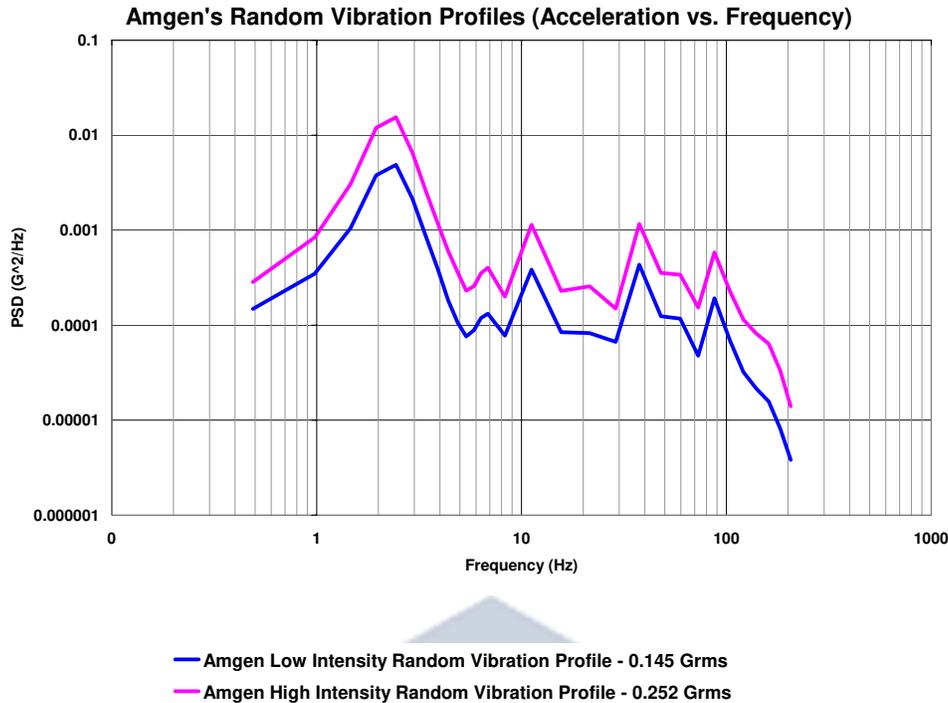
Chart 1 – Amgen Low Intensity Air Ride Truck Random Vibration Profile Smoothing

Once the *Amgen Low Intensity Air Ride Truck Random Vibration Profile* was created, Amgen created the high 20% profile, which Amgen named the *Amgen High Intensity Air Ride Truck Random Vibration Profile*. The creation of the *Amgen High Intensity Air Ride Truck Random Vibration Profile* required the data be analyzed differently than the low profile.

First, Amgen determine what G_{rms} level the upper 20% of all the data collected was at or above. Amgen determined that the upper 20% of the data collected was greater than or equal to 0.167 G_{rms} using Microsoft Excel's Rank & Percentile function. Based on this data, Amgen was ready to filter the truck vibration data again to remove any out of scope data.

All data less than or equal to 0.167 G_{rms} was filtered out to remove any out of scope data and all non vibration data was also filtered out. The remaining data, after filtering, represents the upper 20th% of all the vibration data gathered. This data is averaged to create the *Amgen High Intensity Air Ride Truck Random Vibration Profile*. The same smoothing process, as before, was applied to the *Amgen High Intensity Air Ride Truck Random Vibration Profile*.

The resulting profiles using the 80-20 method are shown in Chart 2 – *Amgen High and Low Intensity Air Ride Truck Random Vibration Profiles*.



Graph 2 – Amgen High and Low Intensity Air Ride Truck Random Vibration Profiles

Amgen only created random vibration profiles for an air ride truck. Using the data gathered from this study, Amgen compared their data to ISTA's data for an air ride truck in test procedure 3H. Based on this comparison of the data Amgen determined it has a high level of confidence in ISTA's profiles. Amgen adopted the ISTA Over-the-Road Truck profile, and the ISTA Pick-up and Delivery Truck profile from the ISTA 3A test procedure [3]. Amgen chose not to develop its own profiles for these transport modes because of our high confidence in the ISTA profiles.

Data Analysis - Airplane Data

The airplane data collected by Amgen was not consistent with prior profiles and validated why Amgen must collect its own data. When compared to the ASTM air profiles, the Amgen data demonstrates lower amounts of vibration (*Chart 3 - Amgen Air Data vs. Amgen Truck and ASTM Data*). Due to the low energy level Amgen's first approach with the airplane data was to not create an airplane profile. The final strategy determined was to replicate actual shipments in a laboratory as closely as possible, which required the creation of Amgen airplane profiles.

Amgen Air Data Compared to Amgen Global Random Vibration Profiles

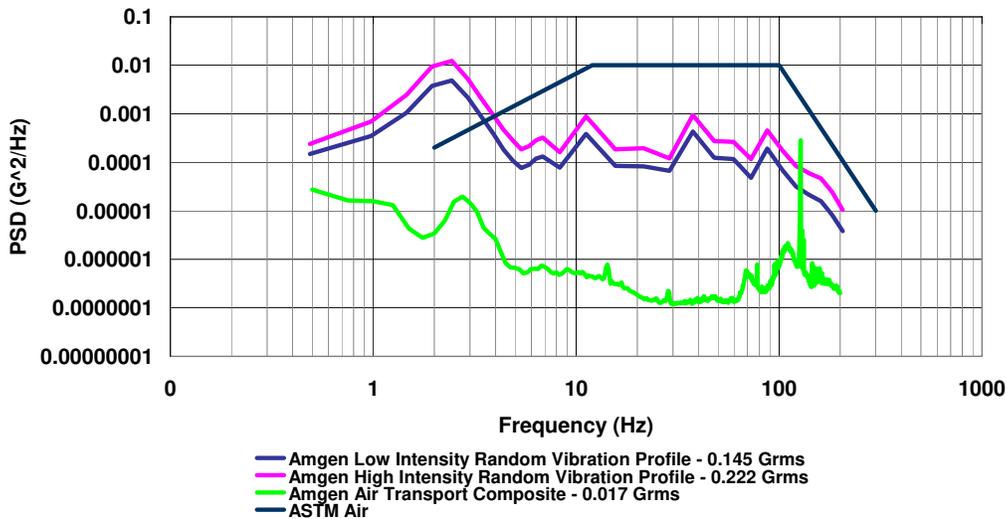


Chart 3 - Amgen Air Data vs. Amgen Truck and ASTM Data

The Amgen airplane random vibration profiles were created following the same data analysis methods used to create the *Amgen High and Low Intensity Air Ride Truck Random Vibration Profiles*, but the airplane profile required different data filtering techniques.

The first step in data analysis was to determine what was causing the large spike in the data at 125 Hz (*Chart 3 - Amgen Air Data vs. Amgen Truck and ASTM Data*). The theory was that this was caused by the resonant frequency of the LD3 container. This theory was proved correct once Amgen performed a resonance search on the container. Based on this data Amgen was able to remove the spike in the data since this was not an input from the airplane. If Amgen were required to simulate a shipment in an LD3 container we would perform our testing with product in an LD3 container on the vibration table.

Next the data was filtered to create the low 80% profile, which Amgen named the *Amgen Low Intensity Airplane Random Vibration Profile*. The data gathered using the pressure logger included in the shipping container allowed the vibration data to be filtered using the known date and time when the airplane was in the air. This filtering method removed the vibration data collected while the LD3 container was in transport to and from the airport, handling at the airport, and idling time while the container was sitting in customs. Finally all non-vibration data was also

filtered out. The resulting data was then averaged and smoothed following the same approach used for the truck profiles to create the Amgen Low Intensity Airplane Random Vibration Profile.

To create the high 20% profile, which Amgen named the *Amgen High Intensity Airplane Random Vibration Profile* the data was analyzed following the same approach used for the *Amgen High Intensity Air Ride Truck Random Vibration Profile data analysis*. The data was analyzed to determine the G_{rms} level that the upper 20% of the data was at or above. The data showed that the upper 20th% of the data was greater than or equal to 0.0305 G_{rms} . The Amgen High Intensity Airplane Random Vibration Profile was then created using the average of the data that remained after it was filtered using the data and time filter, removing all non-vibration data and removing all data less than or equal to 0.0305 G_{rms} . The resulting profiles are shown in Chart 4 – *Amgen High and Low Intensity Airplane Random Vibration Profiles*.

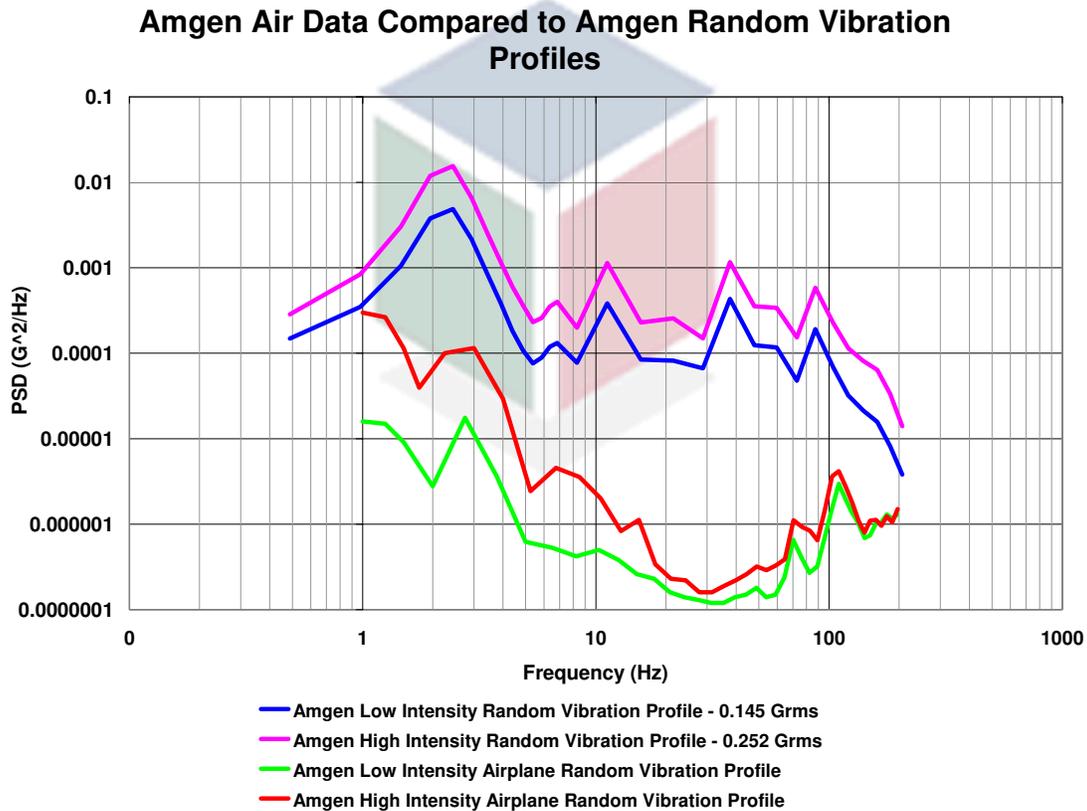


Chart 4 – Amgen High and Low Intensity Airplane Random Vibration Profiles

Accelerating Profiles

Current industry practice is to perform accelerated testing. All industry profiles are accelerated profiles where the rule of thumb is to never accelerate to more than a 1:5 ratio. Profiles are accelerated using the following formula [4].

$$I_T = I_O(T_O/T_T)^5$$

Where

I_T = the test intensity in G_{rms} (the overall intensity of the PSD profile)

I_O = the original intensity (overall G_{rms} of the original profile)

T_O = time duration of the original profile

T_T = the test time

Amgen does not accelerate its random vibration profiles, and executes test durations 1:1 with expected transportation time. Amgen studies have shown our laboratory test data does not match actual shipment data when accelerated testing is performed. Amgen is not stating that accelerated testing is incorrect or there is an error in the formula, but based on the data collection it does not work for Amgen products. This is an example of why engineers need to do their due diligence to understand where industry profiles come from, what do they mean, and how do they apply to their business.

Applying the Profiles

Amgen's laboratory testing strategy is to replicate the transportation environment as closely as possible to actual shipments. To do this Amgen must understand and characterize the transportation lanes used for shipments. This was done by recording ship from and to locations, transportation modes used within each lane, and travel duration. This data can then be used to include several lanes together to create a worst case test transportation lane. This worst case lane will be used to test all of Amgen's products. An example of this is shown in Table 1 – *Amgen Worst Case Transportation Lane*. Also included in the table is how Amgen will apply the Amgen random vibration profiles to each leg of this transport lane.

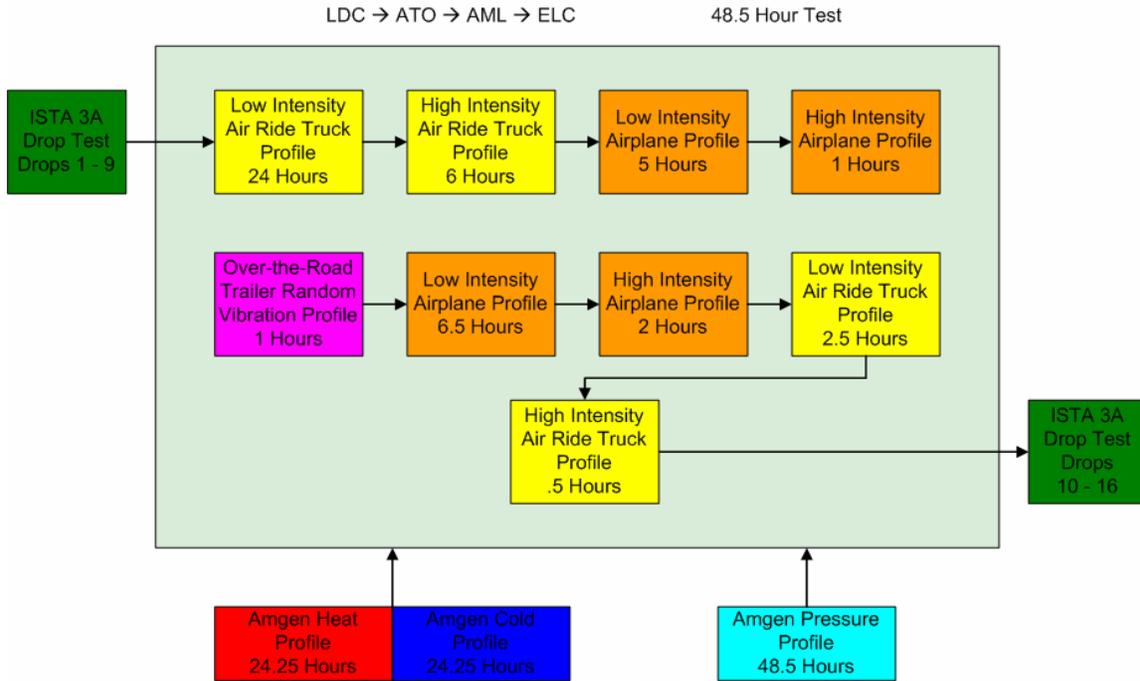
From	To	Transportation Mode	Travel Duration	Amgen Vibration Profile
SITE 1 → SITE 2				Low Intensity Air Ride Truck Profile 24 hr High Intensity Air Ride Truck Profile 6 hr
Site 1	Site 2	Air Ride Truck	29 h 15 min	
SITE 2 → SITE 3				Low Intensity Airplane Profile 5 hr High Intensity Airplane Profile 1 hr
Site 2	Stop 1	Air Ride Truck	42 min	
Stop 1	Stop 2	Airplane	6 h 9 min	
Stop 2	Site 3	Leaf Spring Truck	33 min	Over-the-Road Random Vibration Profile 1 hr
SITE 3 → SITE 4				
Site 3	Stop 1	Leaf Spring Truck	33 min	
Stop 1	Stop 2	Airplane	8 h 2 min	Low Intensity Airplane Profile 6.5 hr High Intensity Airplane Profile 2 hr
Stop 2	Site 3	Air Ride Truck	90 min	Low Intensity Air Ride Truck Profile 2.5 hr High Intensity Air Ride Truck Profile .5 hr

Table 1 – Amgen Worst Case Transportation Lane

To characterize travel duration Amgen is only interested in the duration that any particular mode of transportation is moving during shipping. For example if Amgen were to ship a package by small parcel overnight, it may take 24 hours to arrive at it's destination, but actual in motion travel time was only eight hours. It is those eight hours that are shown in travel duration, and that is the duration that Amgen tests to.

A test simulating the series of lanes shown in Table 1 – *Amgen Worst Case Transport Lane* is shown in Figure 3 – *Amgen Test Plan*. The test would be a 48.5 hour test and cycle through all of the Amgen random vibration profiles in the order they would be experienced during an actual shipment. Amgen also has the capability of applying the Amgen heat and cold profile and pressure profile at the same time the vibration profiles are being run to simulate the transportation environment more closely. This profile combination further increases the confidence that our lab tests produce the same results as actual shipments.

Amgen Transport Validation Lifecycle Planning Operational Qualification Test Sequence



Conclusion

The collaboration of science, engineering, industry, academia and consultants helps companies build test standards that will increase the confidence in the laboratory tests being run. Collecting data on your distribution environment will help you understand your distribution environment and how to better replicate it through the laboratory testing you do. Not all distribution environments are the same, therefore it is important that engineers do their own research before using accepted industry standard profiles.

Acknowledgments

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References

1. Singh, J., S. P. Singh and E. Joneson, Measurement and Analysis of US Truck Vibration for Leaf Spring and Air Ride Suspensions and Development of Test Tests, Packaging Technology and Science, Vol 19, 2006.
2. Singh, S. P. and J. Marcondes, 'Vibration Levels in Commercial Truck Shipments as a Function of Suspension and Payload', Journal of Testing and Evaluation, ASTM, Vol 20, No. 6, 466-469, 1992.
3. International Safe Transit Association (ISTA) Resource Book 2006, Test Procedure 3A.
4. Kipp, William I., Vibration Testing Equivalence, How Many Hours Of Testing Equals How Many Miles Of Transport? Proceedings of ISTA Con 2000.