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BEARING DISTRIBUTION PACKS OF THE PHARMACEUTICAL PRODUCTS IN DYNAMIC LAB AND IN THE REAL DISTRIBUTION ENVIRONMENT

by
Ivan Berljak

A Thesis

Submitted to
the Department of Packaging Science
of Rochester Institute of Technology

Executive Leader Program

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Masters of Science Degree

Department of Packaging Science
of Rochester Institute of Technology
Rochester, New York

CERTIFICATE OF APPROVAL

M.S. Degree

The M.S. degree thesis of Ivan Berljak
has been examined and approved
by the thesis committee as satisfactory
for the thesis requirements for the
Master of Science degree

Daniel L. Goodwin
Dave L. Olsson
Carl de Winter
Karen Proctor
Dea Jacobs

Date: 30 JUNE 2001

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I would like to thank my family for a lifetime of love, support, patience and encouragement.

-Thank you-

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NAME AND ADDRESS DATE

Bearing distribution Packs of the Pharmaceutical Products in dynamic lab and in the real distribution environment

by
Ivan Berljak

2001

ABSTRACT

The main purpose of the package testing is to determine whether or not the package can provide adequate protection of the product. The purpose of this study is to detect bearing of different pharmaceutical products in the dynamic laboratory and in real distribution environment.

Pharmaceutical industry in normal operation applies many regulations and rules. One of those is to record all events in the distribution process.

The analysis compared the results reached in dynamic lab with those of the real distribution cycle and all losses and damages entered in the Belupo Ltd. Data base during last 12 months. As test methods used: ASTM D 5276 - Drop Test of Loaded Containers by Free Fall; ASTM D 642 - Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads; ASTM D 999 - Vibration Testing of Shipping Containers; ASTM D 4728 - Random Vibration Testing of Shipping Containers.

Results obtained in a laboratory and in real situation are not comparable. Therefore it is important to include new tests with focused simulation witch will confirm accuracy of results.

Database of damages shows the protection and security measures in distribution cycles for our products, and financial losses caused within distribution can be calculated from those data.

CONTENTS:

Table of Photographs

List of tables:

1. INTRODUCTION

The quality of medicines has been controlled since earliest times to ensure the safe, effective treatment of patients. As the development and manufacturing of pharmaceuticals has become more complex the measures required to ensure quality, safety and efficacy have continued to evolve. Quality assurance through all stages from drug discovery through development, manufacture, control, storage and distribution has become and remains of crucial importance. During transport, and to some extent during use, impact, crushing, and vibration can damage packed medicaments... (Table 1: Mechanical hazards of distribution [5]) The shipping container and necessary internal packing provide protection. Damage in transport is one of the oldest problems in packaging. In this respect the packaging of medicines is no exception. It is important that the packaging is adequate for all methods of distribution, with perhaps even greater safety margin to take care of the slightly above normal situation. The complete eradication of damage is not realistic goal, because every hazard, including accidents, which packages meet cannot be anticipated. Protection is normally required against the average hazards encountered, and not against the most severe that might occur on any particular journey. In practice, the absence of any damage to any specific product over a long period of time usually indicates excessive packaging.

The main purpose of the package testing is to determine whether or not a package can protect the product. If the product damage occurs, the package deemed inadequate; damage is the critical criterion for judging the effectiveness of the package.

"What is a product damage?"

Damage can be simple breakage, the shortening of the shelf life of a product, or something as subtle as a mar or scratch. This should be defined precisely prior to testing of a package.

To test the protective ability of packaging various methods can be used, such as[4]:

Integrity Tests - Integrity testing challenges the strength of a product and package by subjecting them to various punishing inputs. The inputs and test types used for this approach include various types of drops, bounces and impacts. The inputs are generalized and to level and form, and typically not specific to defined transport mode or method. An overall objective of Integrity Testing is to foresee and prevent damage in transport trough the mechanism of product and package strength. ISTA Standards could be included in this category of testing.

General Simulation - General Simulation challenges the performance of product and package working together to overcome the hazards of the logistic environment. Testing seeks to simulate the motions and events of distribution along with the effects of distribution.

ASTM 4169-99 protocol would fall into this category of General Simulation protocol.

Focused Simulation – is an extension of the General Simulation, and challenges the product and package. Electronic devices capable of recording dynamic events in transport are used for this purpose. The data collected in transport is analyzed on a PC, and the results converted to laboratory test levels.

In the late 1940s the Porcelain Institute's members were experiencing considerable shipping damage. They conducted studies to identify a standard pre-shipment test procedure that would asses the protective characteristics of packaging. Modified and updated under the sponsorship of International Safe Transit Association (ISTA), these test methods continue to be used today. ISTA methods are quick, economical and simple [1].

Four basic types of hazards exist in distribution: compression, shock, vibration and atmospheric, and each hazard type is reflected in a laboratory test type. Each of these test types has been incorporated into ISTA Procedures in some form, although all ISTA protocols do not include all test types. Within each test type are sub-types of more specific tests that are used to simulate specific hazards in distribution. Table 3. summarizes these relationships.

It is important to note that test protocols can evaluate the effectiveness of packaging only for hazards represented in the protocol. For example, a test procedure that does not include a compression test is inappropriate to evaluate a resistance of a packaged product to warehousing stacking loads. By knowing their distribution environment in detail, users can select an appropriate test to evaluate the performance of packaging in light of all known hazards. Without this selection process, real hazards may not be addressed as part of a package's protective ability and significant damage could result.

In response to the needs, more flexible pre-shipment testing method was introduced by American Society for Testing and Materials (ASTM). It was a new standard pre-shipment testing procedure, ASTM 4169 Standard Practice for Performance Testing of Shipping Containers and systems [2]. Standardized test methods are accepted by the packaging industry. The final goal of laboratory testing with standardized test procedures is to simulate the dynamics of the distribution environment. Ship tests of product can generate enormous expenses and yet give results of little confidence. Laboratory testing can reduce the cost of product test shipments performed in real distribution environment and produce objective results.

The ASTM method recognizes that different distribution elements impose different hazards on the product and package (Table 2. Summary of ASTM 4169 distribution testing elements). It further recognizes that different products might require different levels of assurance against product damage.

The ASTM procedure is capable of simulating more types of the hazards encountered in distribution, and in a more realistic way than the ISTA methods. ASTM procedures also provide valuable design information.

Table 1. Mechanical hazards in distribution [5]

Basic hazards	Typical circumstances
Vertical impact	Package dropped on the floor during loading and unloading on-to nets, pallets, vehicles, landing boards etc. Package rolled over or tipped over to impact face Fall from chutes or conveyors Throwing
Horizontal impact	Rail or road vehicle stopping and starting Swinging crane impacts wall etc. Arrest by stop or other packs on chute or conveyor Arrest when cylindrical package stop rolling Throwing
Stationary package impacted by another	All the above circumstances caused the falling pack to impact another
Vibration	Handling equipment machine vibration (in factory, depot and at transshipment points) Vehicle engine and transmission vibration Running gear – suspension vibration on rail Ship engine vibration Engine and aerodynamic vibration on aircraft
Compression	Static-stack in a factory, warehouse and store Transient-loads during transport in vehicles Compression caused by handling methods, e.g. crane, grabs, slings nets, squeeze clamps etc. Compression due to restraint
Racking or deformation	Uneven support due to poor floor and/or storage conditions, etc. Uneven lifting due to bad slinging localized suspension, etc.
Piercing, puncturing, tearing, snagging	Hooks projections, misuse of handling equipment, improper handling

[5]H. Lockhart and F. A. Pain p.19

Table 2: Summary of ASTM 4169 distribution testing elements [2]

Shipping Element	Hazard
Element A: Manual handling up to 90.7 kg	Drop
Element B: Manual handling up to 45.4 kg	Rotational drop
Element C: Warehouse stacking	Static load
Element D: Vehicle stacking	Static load
Element E: Vehicle transport, unitized load	Vibration
Element F: Loose load vibration	Repetitive shock
Element G: Vehicle vibration	Vibration
Element H: Rail switching	Horizontal impact
Element I : Climate, Atmospheric condition	Temperature and humidity
Element J: Environmental hazard	Similar to military MIL-P-116

[2]W. Soroka page 419

Table 3. Hazards and ISTA Test Type [7]

Distribution Hazards	Warehousing Stacking Load	Handling Drop and Impact	Transportation Vibration	Atmospheric Conditions
Major Test Type	Compression	Shock	Vibration	Atmospheric
Associated Tests	Static Machine Apply & release Apply & hold	Drop Free-fall Rotational On hazards Incline Horizontal Vertical	Fixed Displacement Rotary Vertical linear Variable Displacement Vertical Horizontal Random Vertical Horizontal Multi-axis	Temperature Soak Cycle Humidity Soak Cycle Pressure Soak Cycle

2. EXPERIMENTAL DESIGN OF THE STUDY

During the production and warehousing phases all the operations remain under control. When delivery phase starts, goods turn to be out of producer's control. From time to time damages occur and it has to be investigated if these damages are to be attributed to the distribution cycles from warehouse to the customer.

The purpose of this study is to detect bearing of different pharmaceutical product in the dynamic laboratory and in real distribution environment. The analysis will be used to compare the results reached in dynamic lab with those of the real distribution cycle and all losses and damages entered in the Belupo Ltd. Data base during last 12 months.

The test plans will define all the information needed for performing tests and analysis.

2.1. LABORATORY TEST PLAN AND EQUIPMENT

ASTM 4169 - 99 Performance Testing of Shipping Containers and Systems was used for testing in dynamic lab as follows[2]:

Distribution Sequence

DC 3 - Single Package Environment - Up to 100 lb. (45.4 kg)

Elements: ACFEA

Assurance Level II

Stack Height Vehicle: 1800 mm

Acceptance Criteria: No visible Damage
Product Intact

2.1.1. Schedule A - Manual Handling

The test levels and the test method for this element of the distribution cycle are intended to determine the ability of the shipping unit to withstand the hazards that might occur during manual handling such as loading, unloading, stacking, sorting, or palletizing. The main hazards from these operations are the impacts caused by dropping or throwing. Size, weight, and shape of the shipping unit will affect the intensity of these hazards. Presented below are recommended drop heights, number of drops, and the shipping unit orientations at impact:

Drop Test

Test Method

ASTM D 5276 - Drop Test of Loaded Containers by Free Fall[2]

DROP SEQUENCE:

Drop height	Impact orientation
381 mm	Top
381 mm	Bottom edge
381 mm	Adjacent bottom edge
381 mm	Bottom corner
381 mm	Diagonally opposite bottom corner
381 mm	Bottom

2.1.1.1. Drop Tester [3]

Precision Drop Tester (PDT) is designed to simulate drops and mechanical hazards that occur in distribution. It is extremely convenient to use and ensure very accurate free-fall drops (flat, edge and corner) on a wide variety of package sizes and shapes designed to test small, light packages that are manually handled in the distribution environment. It consists of a drop leaf assembly housed in a one-piece cast aluminum structure that supports the precision guides, pneumatic drive cylinder, and package support arm. This support structure is mounted on a heavy-duty chrome plated steel column that is rigidly fixed to a thick steel baseplate. Because the drop leaf assembly is counterbalanced, changing drop heights is an easy matter-simply remove the lock pin on the rear of the machine, slide the assembly up or down as required, and reinsert the pin. The on/off switch and power indicator lights are located conveniently on the side of the drop leaf housing. The actual drop cycle is initiated and reset with a foot switch.

Fig. 1 **Precision Drop Tester MODEL PDT-56E Lansmont**

2.1.2. Schedule C - Vehicle Stacking

The test levels and the test methods for these elements of the distribution cycle are intended to determine the ability of the shipping unit to withstand the compressive loads that occur during vehicle transport. The required loading must consider the effects of length of time in transport, vibration, the alignment or stacking pattern of the container, variability in container strength, moisture content, temperature, previous handling, and method of load support. The minimum required loads for typical shipping units, which include the combined effects of the above factors, are recommended below:

Compression Test

Test Method

ASTM D 642 - Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads [2]

Compress the shipping unit to achieve the minimum required test load, as calculated below. Remove the load within three seconds after reaching the specified value.

$F = P(F_p) + C(F_c)$

F_p	=	Factor for compression package or where product supports the load directly
P	=	Percentage of load supported by product
F_c	=	Factor for container
C	=	Percentage of load supported by container

$L = M_f * J * ((l * w * h) / K) * ((H - h) / h) * F$

L	=	Minimum required test load	N
M_f	=	Shipping cargo density factor	kg/m^3
J	=	Conversion factor	9.8 N/kg
l	=	Length of shipping unit	m
w	=	Width of shipping unit	m
K	=	Conversion factor	$1\ m^3/m^3$
H	=	Maximum stack height	m
h	=	Height of shipping unit	m
F	=	Factor to account for individual factors described above	

2.1.2.1. Compression Test Systems & Controls [3]

Compression Test Systems have an important role in package and product design verification and quality monitoring. Compression Testing can help prevent catastrophic damage that might occur due to compression failure, reduce injury and liability costs, help identify problems in the prototype stage, and minimize material costs. Compression control and instrumentation provide closed-loop operation for accurate loading rates and tight control tolerances to ensure premium test performance. Test automation, plus a variety of other operators and accuracy-oriented features make Compression Test Systems the choice of laboratories worldwide.

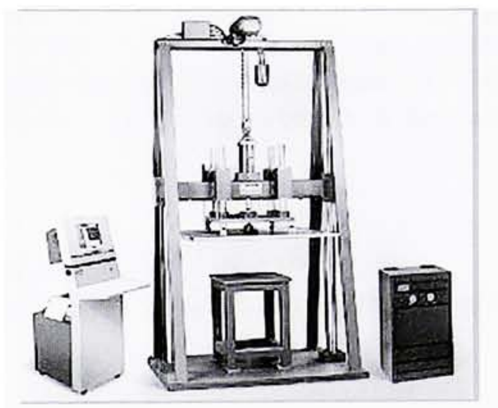


Fig. 2 **Compression Test Systems Lansmont MODEL 122-15**

2.1.3. Schedule F - Loose Load Vibration

The test levels and test method for this element of the distribution cycle are intended to determine the ability of the shipping unit to withstand the repetitive shocks occurring during transportation of bulk or loose loads. The test levels and test method account for amplitude, direction and duration of the repetitive shocks.

Repetitive Shock Test

Test Method

ASTM D 999 - Vibration Testing of Shipping Containers [2]

Method A1 or A2

Place the specimen on the test machine platform in its normal shipping orientation. Starting at about 2 Hz increase the frequency until some portion of the specimen repeatedly leaves the test surface. To ensure that the test specimen is leaving the test surface, insert a 1/16-inch thick shim 4 inches under the package and move intermittently along the entire length of the package.

Dwell Time:

20 minutes in the normal shipping orientation
20 minutes of additional dwell time split evenly among all other possible shipping orientations.

2.1.4. Schedule E - Vehicle Vibration

The test levels and test method for this element of the distribution cycle are intended to determine the ability of the shipping units to withstand the vertical vibration and dynamic compression resulting from transport and vehicle stacking. The test levels and method account for the magnitude, frequency range, duration, and direction of vibration.

Perform the test for each possible shipping orientation. Total test duration should be distributed evenly between all orientations tested.

Random Vibration

Test Method

ASTM D 4728 - Random Vibration Testing of Shipping Containers[2]

Method A or B

The following power spectral densities as defined by their frequency and amplitude breakpoints, and test duration are recommended.

Truck Profile
Overall grms: 0.52
Test Duration: 180 min

Frequency (Hz)	PSD (g^2/Hz)
1	0.00005
4	0.01
16	0.01
40	0.001
80	0.001
200	0.00001

2.1.4.1. Vibration Test Systems [3]

Vibration Systems can help us counteract the damaging effects of vibration. Vibration occurs whenever a product or a package is handled, moved, or shipped. By vibration testing, we can retain product quality and reliability, minimize material costs, lower shipping costs, identify critical components, and solve problems in the prototype stage. Vibration control system combines advanced computer technology and DSP based control to perform a wide array of tests, ranging from simple closed-loop sine sweeps to complex vehicle random vibration simulations.

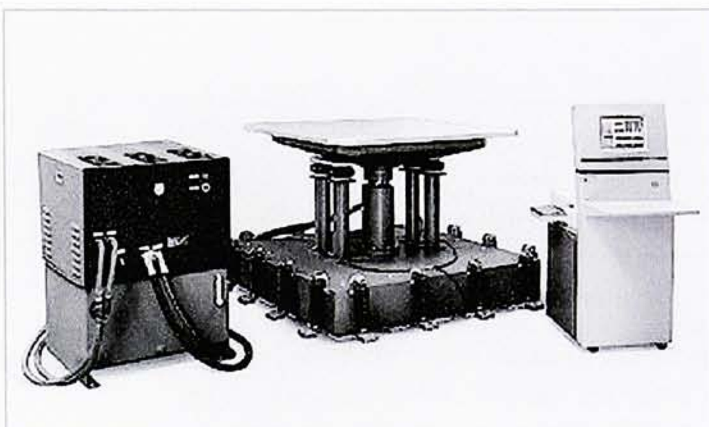


Fig. 3 **Vibration Systems Lansmont MODEL 7000**

2.1.5. Schedule A - Manual Handling

The test levels and the test method for this element of the distribution cycle are intended to determine the ability of the shipping unit to withstand the hazards pertinent to manual handling such as loading, unloading, stacking, sorting, or palletizing. The main hazards from these operations are the impacts caused by dropping or throwing. Size, weight, and shape of the shipping unit will affect the intensity of these hazards. Presented below are recommended drop heights, number of drops, and the shipping unit orientations at impact:

Test Method

ASTM D 5276 - Drop Test of Loaded Containers by Free Fall[2]

DROP SEQUENCE:

Drop height	Impact orientation
381 mm	Vertical edge
381 mm	Side face
381 mm	Adjacent side face
381 mm	Top corner
381 mm	Adjacent top edge
762 mm	Impact orientation most likely to occur, usually the largest face or the bottom. For small parcel environment, use the critical or damage prone orientation.

2.1.6. Conditioning

Test Method

ASTM D 4332 - Conditioning Containers, Packages or Packaging Components for Testing [2]

This practice provides for standard and special conditioning and testing atmospheres that may be used to simulate particular field conditions that a container, package, or packaging component may encounter during its life or testing cycle.

This practice describes procedures for conditioning these containers, packages, or packaging components so that they may reach equilibrium with the atmosphere to which they may be exposed.

2.2. REAL DISTRIBUTION CYCLE TEST PLAN AND EQUIPMENT

Tests were performed in real environment. Distribution containers with goods were loaded to the truck carrying other goods on the route from Koprivnica to Split and back (1000 km approximately). The goods were loaded on the floor and stacked to the maximum high of truck 1.7 – 1.8 m. Dispatch area workers had to follow SOPs (Standard Operating Procedures) for loading a single shipper to the truck. The heaviest shipper had to be loaded on the floor and the lightest on the top of a stack.

Upon return, samples were checked for damages.

Acceptance Criteria as determined at assurance level is as follows:

a) No product damage
b) All packs in sellable condition

Truck: Mercedes Sprinter 313 CDI
Equipped with Truck Refrigeration Unit INTEGRA 20 S
Temperature Set point 15 - 25° C

Fig. 4 **Mercedes Sprinter 313 CDI**

Fig. 5 **Mercedes Sprinter 313 CDI loaded**

2.3. SELECTION OF THE PRODUCTS AND PACKAGES DESIGN

The main interest in this study will be focused on two types of standard shipping container filled with different pharmaceutical products like: tablets, 2 ml ampoules, 100 ml lotion in plastic bottles and 100 ml syrup glass bottles.

The same products were used both in lab and in ship tests.

2.3.1. Product A

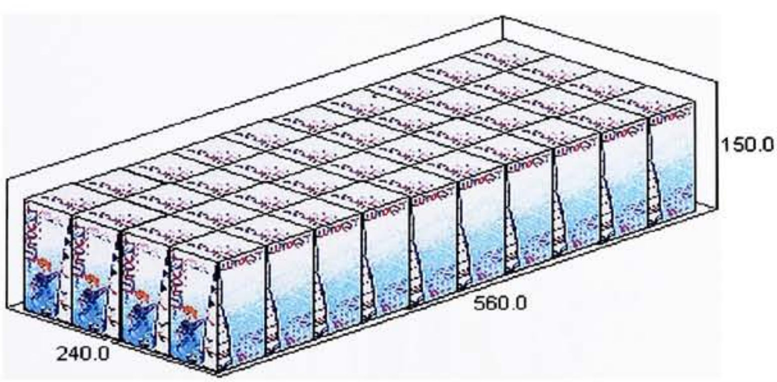
Shipper K 3 – OD 560x240x150 mm

Quality:

Construction: B Flute
White testliner 140 g/m^2
Fluting 127 g/m^2
Kraftliner 125 g/m^2

Thickness:	2.7 – 2.9 mm	ISO 3034
Moisture:	8 %	ISO 287
Weight/Area:	450 g/m^2	ISO 36
Mullen:	950 kN	TAPPI T403
ECT:	4.2 kN/m	ISO 3037
BCT:	3.4 J	ISO 3036

Gross weight incl. goods is 9.60 kg
Volume Used: 98.0%
Carton boxes with leaflets, glass bottles and spoons packed into shipper



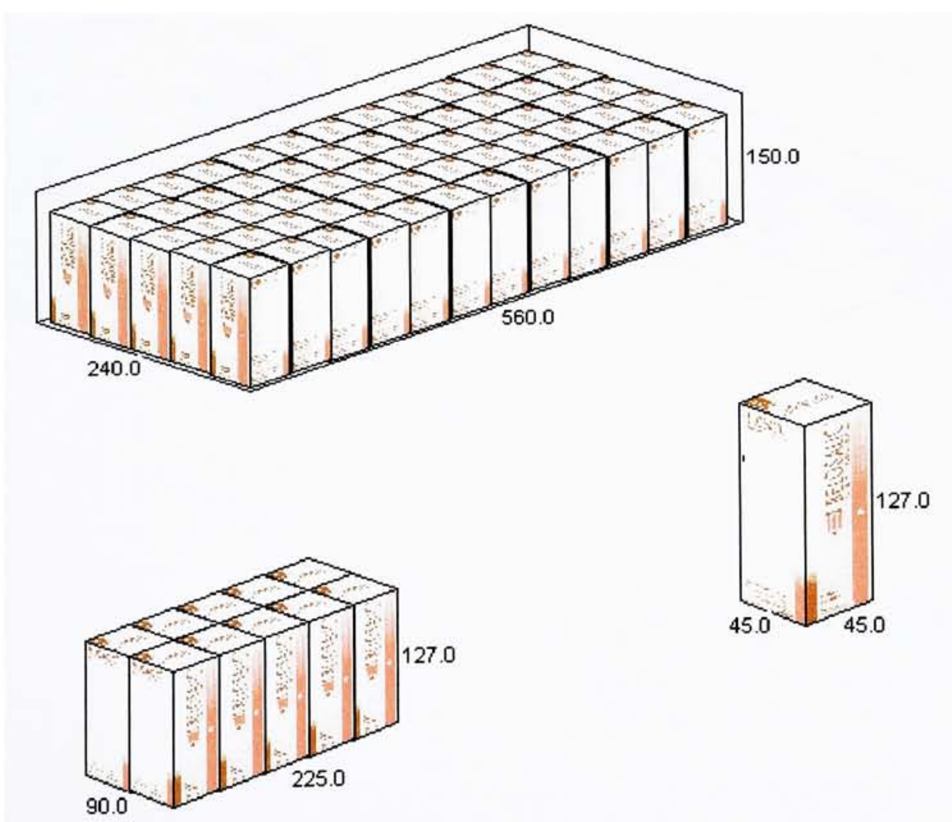
2.3.2. Product B

Shipper K 3 – OD 560x240x150 mm

Quality:

Construction:	B Flute White testliner 140 g/m^2 Fluting 127 g/m^2 Kraftliner 125 g/m^2	
Thickness:	2.7 – 2.9 mm	ISO 3034
Moisture:	8 %	ISO 287
Weight/Area:	450 g/m^2	ISO 536
Mullen:	950 kN	TAPPI T403
ECT:	4.2 kN/m	ISO 3037
BCT:	3.4 J	ISO 3036

Gross weight incl. goods is 7.7 kg
Volume Used: 98.0 %
Carton boxes with leaflets and plastic bottles packed into shipper



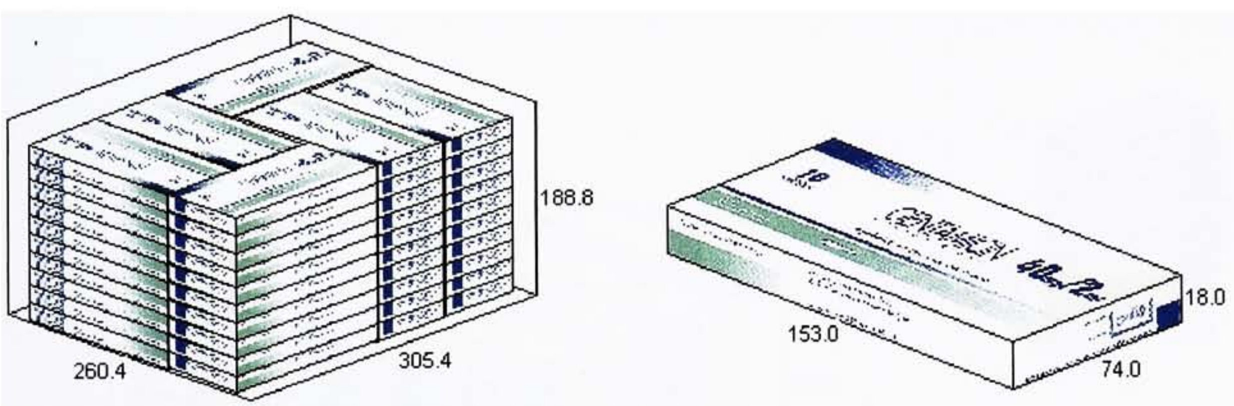
2.3.3. Product C

Shipper K 7 –OD 311x266x200 mm

Quality:

Construction:	B Flute White testliner 140 g/m^2 Fluting 117 g/m^2 Kraftliner 125 g/m^2	
Thickness:	2.7 – 2.9 mm	ISO 3034
Moisture:	8 %	ISO 287
Weight/Area:	435 g/m^2	ISO 536
Mullen:	850 – 900 kN	TAPPI T403
ECT:	4.1 kN/m	ISO 3037
BCT:	3.3 J	ISO 3036

Gross weight incl. goods is 3.5 kg
Volume Used: 81.4 %
Carton box leaflets and with glass ampoules packed into shipper



2.3.4. Product D

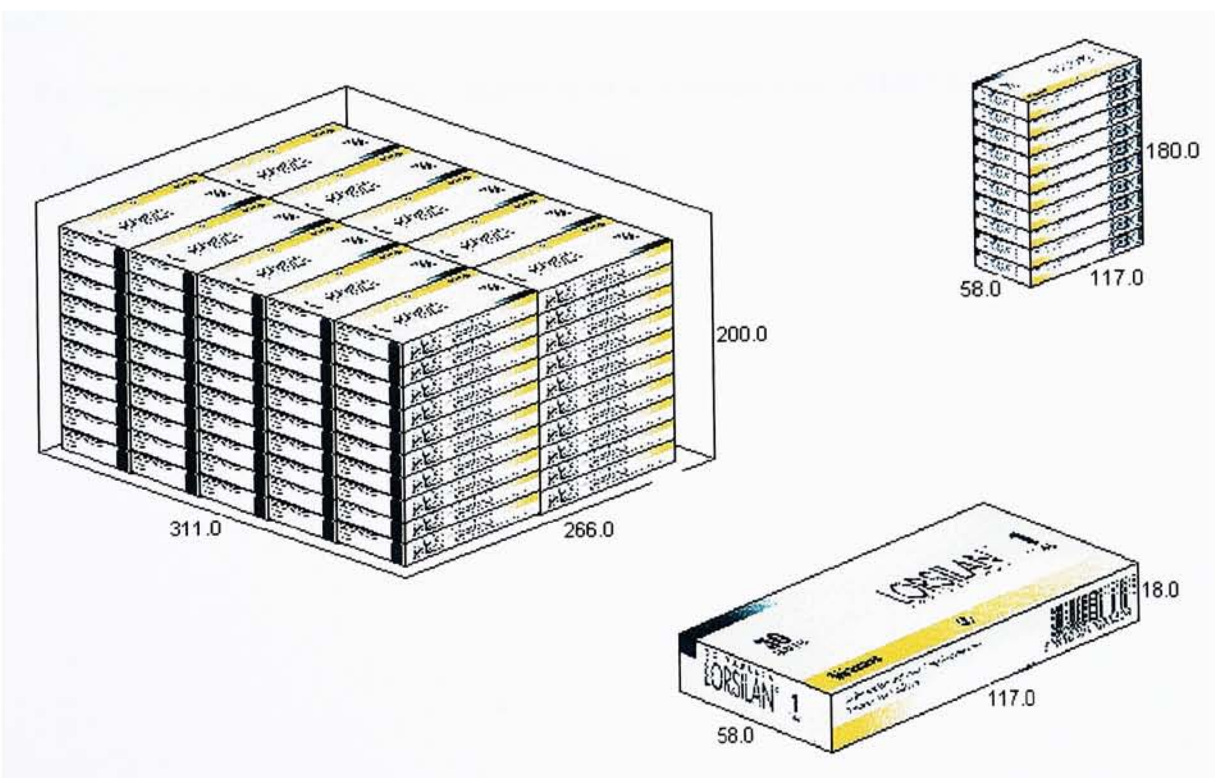
Shipper K3 – OD 311x266x200 mm

Quality:

Construction:	B Flute
	White testliner 140 g/m^2
	Fluting 117 g/m^2
	Kraftliner 125 g/m^2

Thickness:	2.7 – 2.9 mm	ISO 3034
Moisture:	8 %	ISO 287
Weight/Area:	435 g/m^2	ISO 536
Mullen:	850 – 900 kN	TAPPI T403
ECT:	4.1 kN/m	ISO 3037
BCT:	3.3 J	ISO 3036

Gross weight incl. goods is 1.5 kg
Volume Used: 94.8%
Carton boxes with leaflets and PVC/Al blister card packed into shipper



3. RESULTS AND DISCUSSIONS

3.1. LAB RESULTS

Before testing there was a problem with calculation of minimum required test load (L). The main problem was to define percentage of load supported by product. Our products (tablets and liquids) were packed:

- tablets in PVC/Al blisters, blisters with leaflet in carton boxes, 10 carton boxes banded with PE foil were fitted into shipper
- injection liquid was filed in glass ampoules, 10 ampoules in PVC tray, tray with leaflet in carton boxes, 10 carton boxes banded with PE foil were fitted into shipper
- plastic bottles were filed with liquid, bottles with leaflets in carton boxes, 10 carton boxes banded with PE foil were fitted into shipper
- glass bottles were filed with liquid, bottles with leaflets and spoons in carton boxes and equipped carton boxes were fitted into shipper

For these kinds of equipped products it is hard to calculate the percentage of load supported by product because there are several levels of packages (primary, secondary and tertiary).
With CAPPE 99[6] computer program we calculated percentage of volume use of shippers but because of the reason mentioned before, these figures could not be used for calculation of minimum required test loade.

Before testing all samples were conditioned in accordance with ASTM D 4332:

Climatic camber: Haraeus mod. HCZ 0050C

3.1.1. Product A

3.1.1.1. DROP TEST

According to ASTM D 5276

Sample Product: **LUPO**
Instrumentation: Drop Tester Lansmont L-PDT227
Drop height: 381 mm
N° of samples: 5

TEST RESULTS

Type of drop	**Box 1**	**Box 2**	**Box 3**	**Box 4**	**Box 5**
Top	OK	OK	OK	OK	OK
Bottom edge	OK	OK	OK	OK	OK
Adjacent bottom edge	OK	OK	OK	OK	OK
Bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Diagonally opposite bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Bottom	OK	OK	OK	OK	OK

Observations after the test:

- Corners of boxes are damaged (Fig. 7).
- Boxes do not show other significant damages.

Fig. 6 **Box Ref. Lupo in the drop tester**

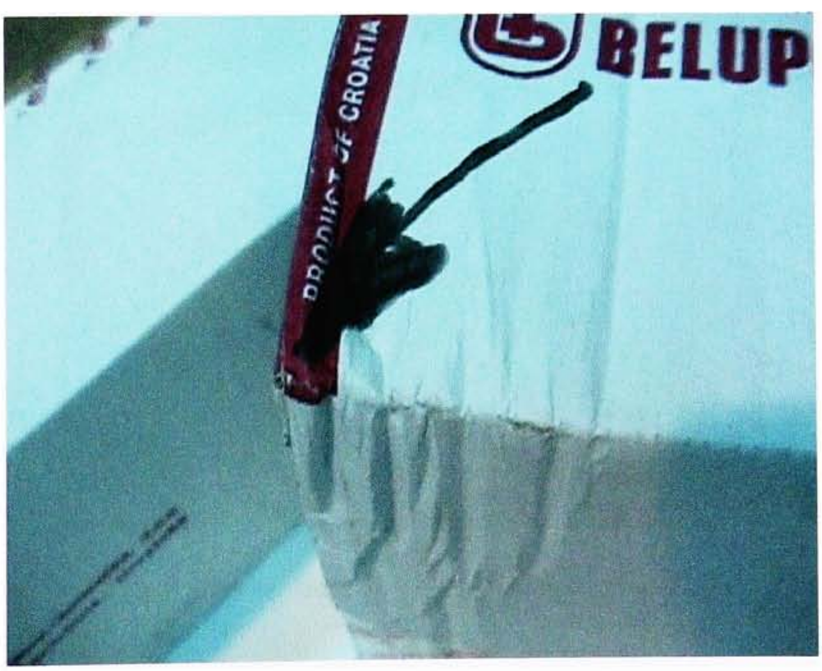


Fig. 7 **Box-corner damage after test**

3.1.1.2. DYNAMIC COMPRESSION TEST

According to ASTM D 642

Sample Product:	**LUPO**
Instrumentation:	Compression Tester Lansmont CCTS 122-15k
Pre-load:	20 kg
Velocity:	10 mm/min
Nº of samples:	5

TEST RESULTS

As the enclosed graph shows, the resistance curves to the compression presents a maximum peak around 125-130 kg and a deflection around 0.30 - 0.40 cm. These values correspond to the maximum resistance of transport packaging. From this point, the curves keep supporting load. This indicates that in that moment, the contained product starts supporting 100% of the load.

<u>Observations after test:</u>

- Lateral face of the boxes is damaged (Fig. 8).
- Boxes do not show other significant damages, except in lateral face.

Fig. 8 **Lateral face of a box damaged after test**

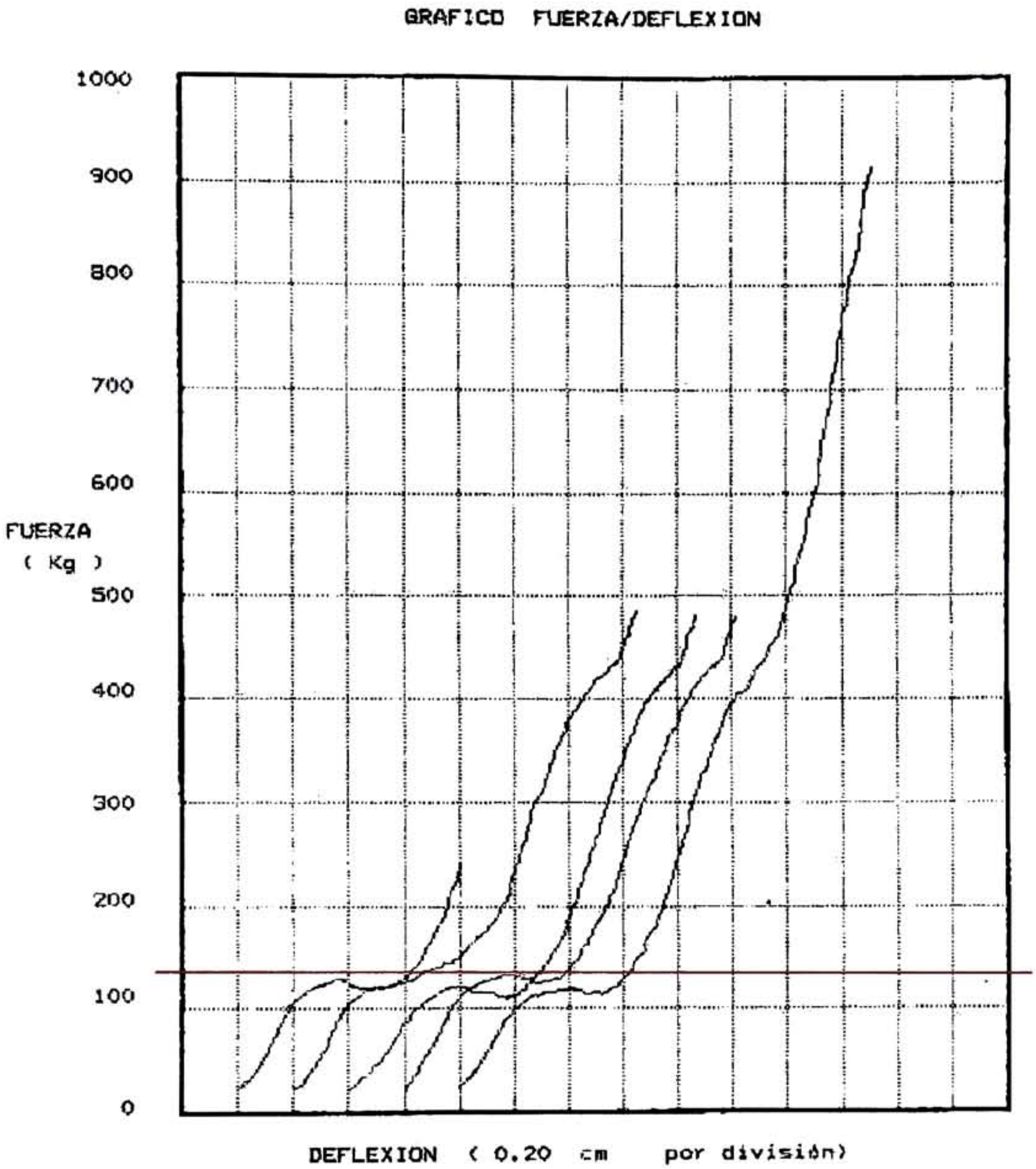


GRAFICO FUERZA/DEFLEXION
1000
900
800
700
600
FUERZA
(Kg)
500
400
300
200
100
0
DEFLEXION (0.20 cm por división)

3.1.1.3. SINUSOIDAL VIBRATION TEST

According to ASTM D 999

Sample Product:	**LUPO**
Instrumentation:	Vertical Vibration Machine Lansmont L-10000-10.
Vibration:	Sinusoidal
Sweep:	3-100-3 Hz
Velocity:	1 oct/min
Acceleration peak:	**0.50 g**

TEST RESULTS

Resonance frequencies:

Resonance frequency Hz	Transmissibility Q
26.99	1.7376
49.45	0.7928

(See enclosed graph)

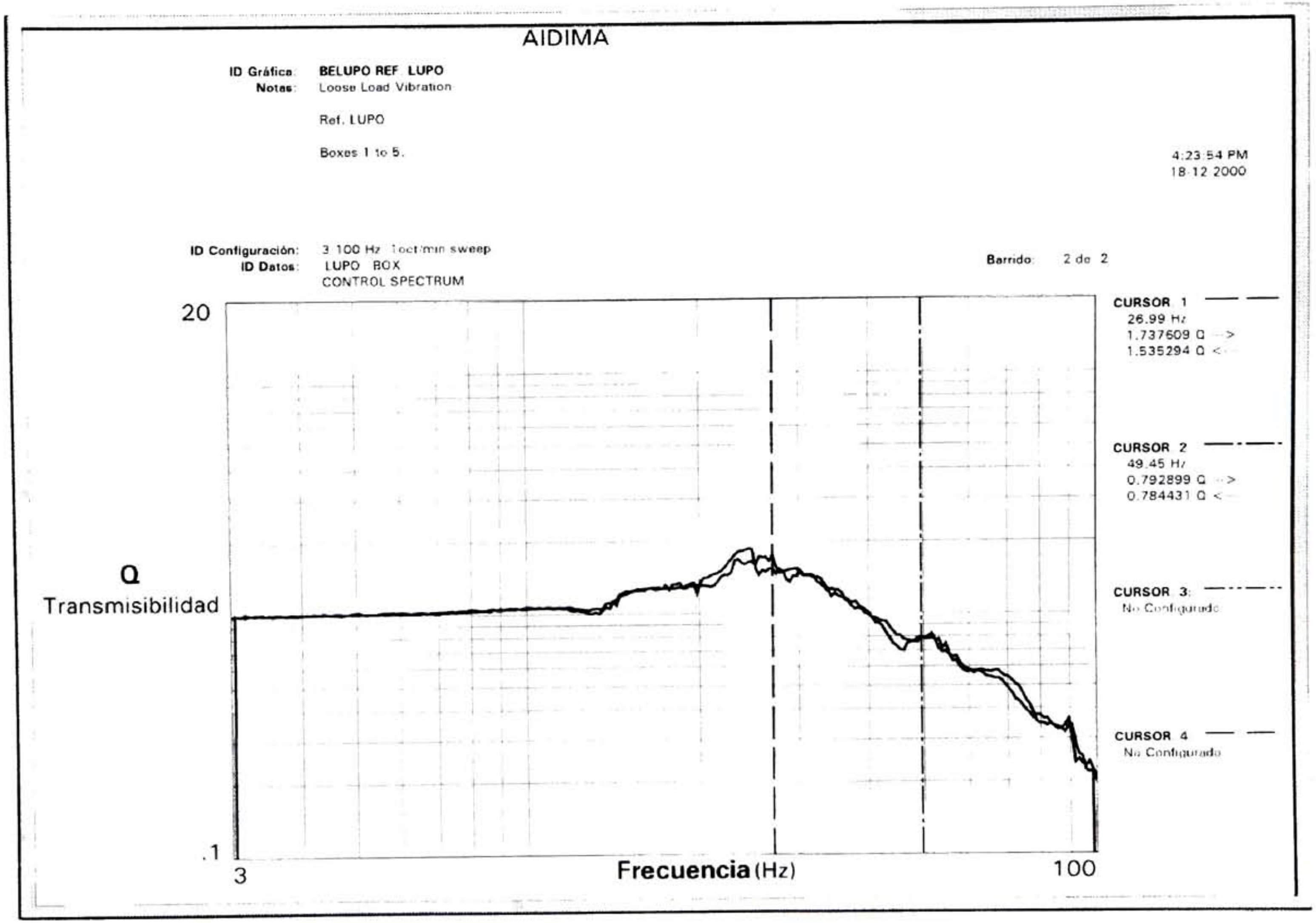
Fatigue test

- Acceleration peak: **0.5 g**

Resonance frequency Hz	Duration minutes	Impact orientation
26.99	20	Bottom
49.45	20	Bottom

<u>Observations after test:</u>

Product is OK.


AIDIMA
ID Gráfica: BELUPO REF LUPO
Notas: Loose Load Vibration
Ref. LUPO
Boxes 1 to 5.
4:23:54 PM
18-12-2000
ID Configuración: 3 100 Hz 1oct/min sweep
ID Datos: LUPO BOX
CONTROL SPECTRUM
Barrido: 2 de 2
CURSOR 1
26.99 Hz
1.737609 Q -->
1.535294 Q <--
CURSOR 2
49.45 Hz
0.792899 Q -->
0.784431 Q <--
CURSOR 3:
No Configurado
CURSOR 4
No Configurado
20
.1
Q
Transmisibilidad
3
100
Frecuencia (Hz)

3.1.1.4. RANDOM VIBRATION TEST

According to ASTM D 4728

Sample Product: **LUPO**
Instrumentation: Vertical Vibration Machine Lansmont L-10000-10.
Vibration: Random
Level: II
Acceleration: 0.52 grms
Duration: 180 minutes

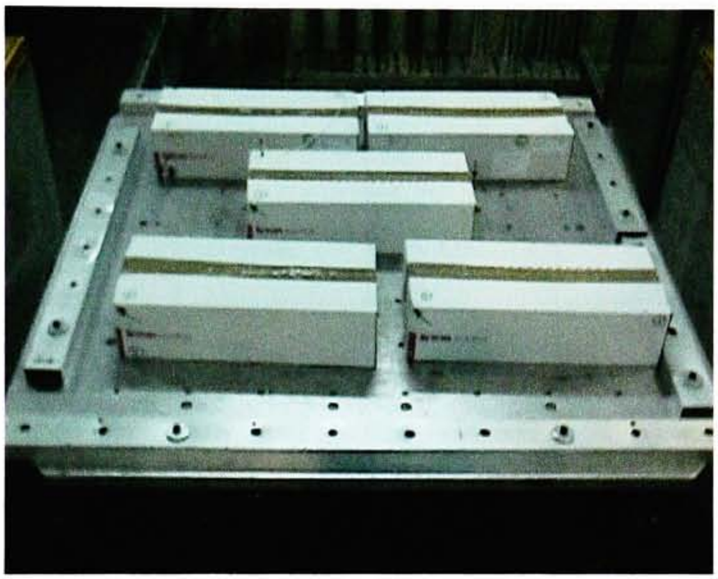


Fig. 9 **Boxes Ref. Lupo in the vertical vibration Machine**

Spectrum of vibration of level II:

Frequency Hz	**PSD g^2/Hz**
1	0.000050
4	0.010000
16	0.010000
40	0.001000
80	0.001000
200	0.000010

Observations after test:

Product is OK.

3.1.1.5. DROP TEST

According to ASTM D 5276

Sample Product: **LUPO**
Instrumentation: Drop Tester Lansmont L-PDT227.
Drop height: 381 mm
Nº of samples: 5

TEST RESULTS

Type of drop	**Box 1**	**Box 2**	**Box 3**	**Box 4**	**Box 5**
Vertical edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge
Lateral face	OK	OK	OK	OK	OK
Adjacent face	OK	OK	OK	OK	OK
Corner of the cover not previously tested	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Cover edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge
Base *	OK	OK	OK	OK	OK

*The height of the base drop is 762 mm.

Observations after test:

After test, 92 of 200 interior packaging remain in good state, that means that **46% of the total is OK**.

After test, 108 of 200 interior packaging have suffered some type of damage that means that **54% of the total is NOT OK**.

Following pages contain some diagrams showing damages occurred on the boxes in relation to the position they occupied in the packaging.

BOX 1

■	✕	●	●	●	OK	●	●	✕	■
OK	OK	■	✕	OK	●	●	■	OK	●
●	●	●	●	●	●	OK	✕	●	OK
✕	●	●	OK	OK	●	OK	OK	OK	●

Boxes OK	12
Boxes Damage	4
Spoon Damage	19
Box + Spoon Damage	5

■ Box Damage
● Spoon Damage
✕ Box + Spoon Damage

BOX 2

OK	OK	OK	OK	●	OK	●	✕	OK	■
OK	OK	OK	OK	OK	OK	OK	■	●	●
OK	●	■	OK	OK	OK	OK	●	■	●
✕	■	✕	●	●	OK	OK	OK	OK	✕

Boxes OK	22
Boxes Damage	5
Spoon Damage	9
Box + Spoon Damage	4

BOX 3

OK	OK	OK	OK	●	OK	●	OK	✕	✕
OK	■	●	●	OK	■	OK	●	●	OK
OK	OK	OK	OK	●	OK	■	■	●	●
✕	■	OK	●	●	OK	●	OK	●	✕

Boxes OK	18
Boxes Damage	5
Spoon Damage	13
Box + Spoon Damage	4

BOX 4

OK	OK	OK	OK	OK	OK	OK	✕	■	■
OK	●	OK	OK	OK	OK	OK	■	●	●
OK	OK	OK	OK	●	●	OK	■	●	OK
■	✕	OK	OK	OK	OK	✕	●	✕	✕

Boxes OK	23
Boxes Damage	5
Spoon Damage	7
Box + Spoon Damage	5

BOX 5

OK	OK	●	OK	●	OK	OK	OK	●	×
OK	OK	OK	●	OK	●	●	OK	×	■
OK	×	OK	●	OK	OK	OK	●	×	●
×	■	×	●	OK	OK	●	●	×	●

Boxes OK	18
Boxes Damage	2
Spoon Damage	13
Box + Spoon Damage	7

Fig. 10 **Lateral edge of a box damage after test**

Fig. 11 **Broken spoon after test**

Fig. 12 **Interior box damaged after test**

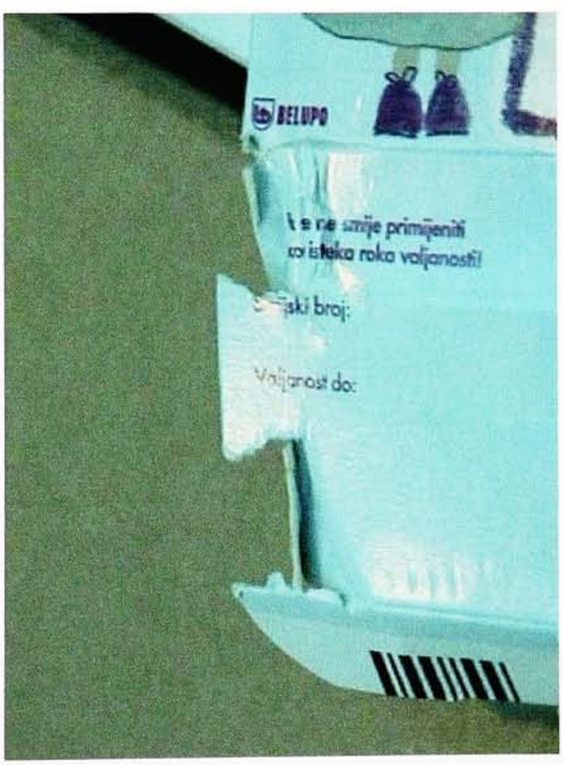


Fig. 12a **Interior box damaged after test**

3.1.2. Product B

3.1.2.1. DROP TEST

According to ASTM D 5276

Sample Product: **BELOS**
Instrumentation: Drop Tester Lansmont PDT-56E
Drop height: 381 mm
N° of samples: 5

TEST RESULTS

Type of drop	**Box 1**	**Box 2**	**Box 3**	**Box 4**	**Box 5**
Top	OK	OK	OK	OK	OK
Bottom edge	OK	OK	OK	OK	OK
Adjacent bottom edge	OK	OK	OK	OK	OK
Bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Diagonally opposite bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Bottom	OK	OK	OK	OK	OK

<u>Observations after the test:</u>

- Corners of boxes are damaged (Fig. 14).
- Boxes do not show other significant damages.

Fig. 13 **Box Ref. Belos in the drop tester**

Fig. 14 **Box corner damage after test.**

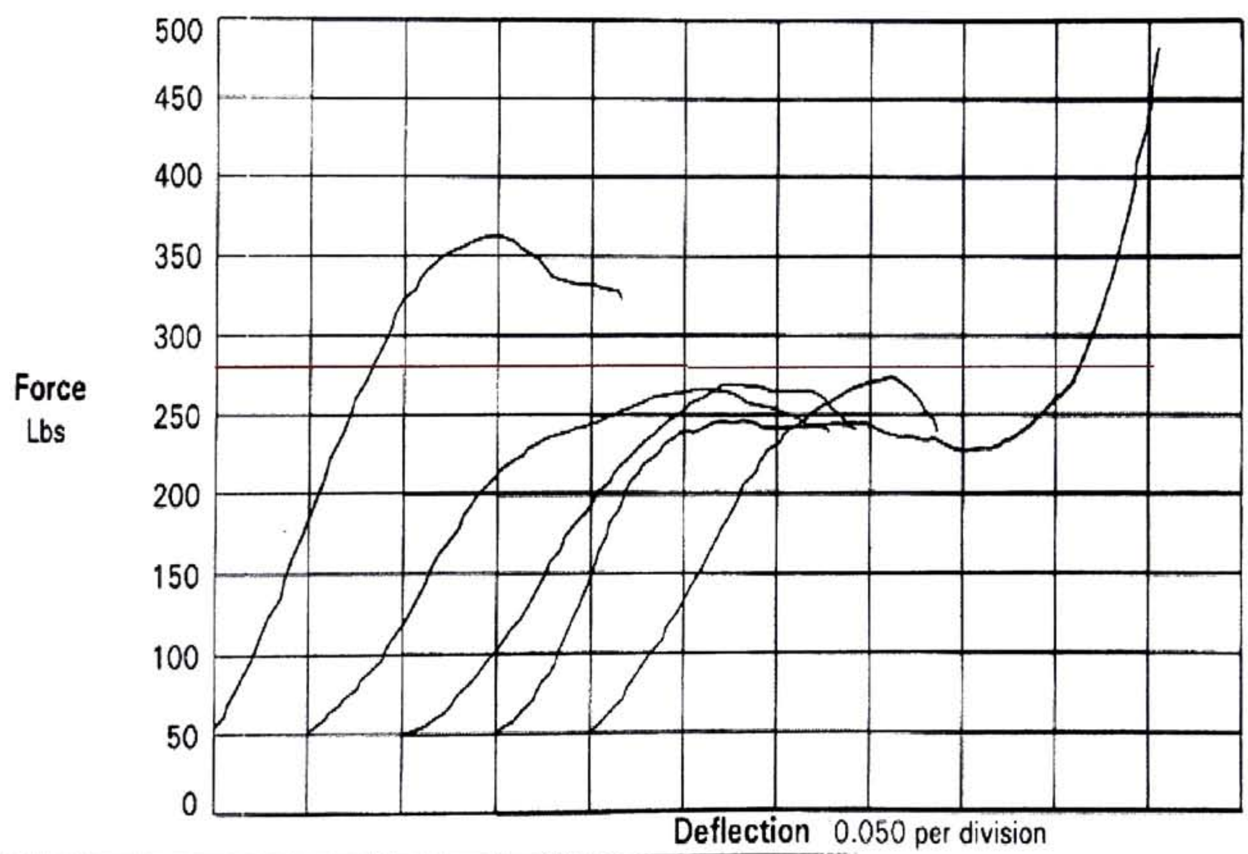
3.1.2.2. DYNAMIC COMPRESSION TEST

According to ASTM D 642

Sample Product: **BELOS**
Instrumentation: Compression Tester Lansmont CCTS 122-15k
Pre-load: 50 kg
Velocity: 10 mm/min
Nº of samples: 5

TEST RESULTS

As the enclosed graph shows, the resistance curves to the compression present a maximum peak around 120-180 kg and a deflection around 0.38 - 0.40 cm. These values correspond to the maximum resistance of transport packaging. From this point, curves keep supporting load. This indicates that in that moment, the contained product begins to support 100% of the load.



Observations after test:

- Lateral face of the boxes is damaged (Fig. 15).
- Boxes do not show other significant damages, except in lateral face.

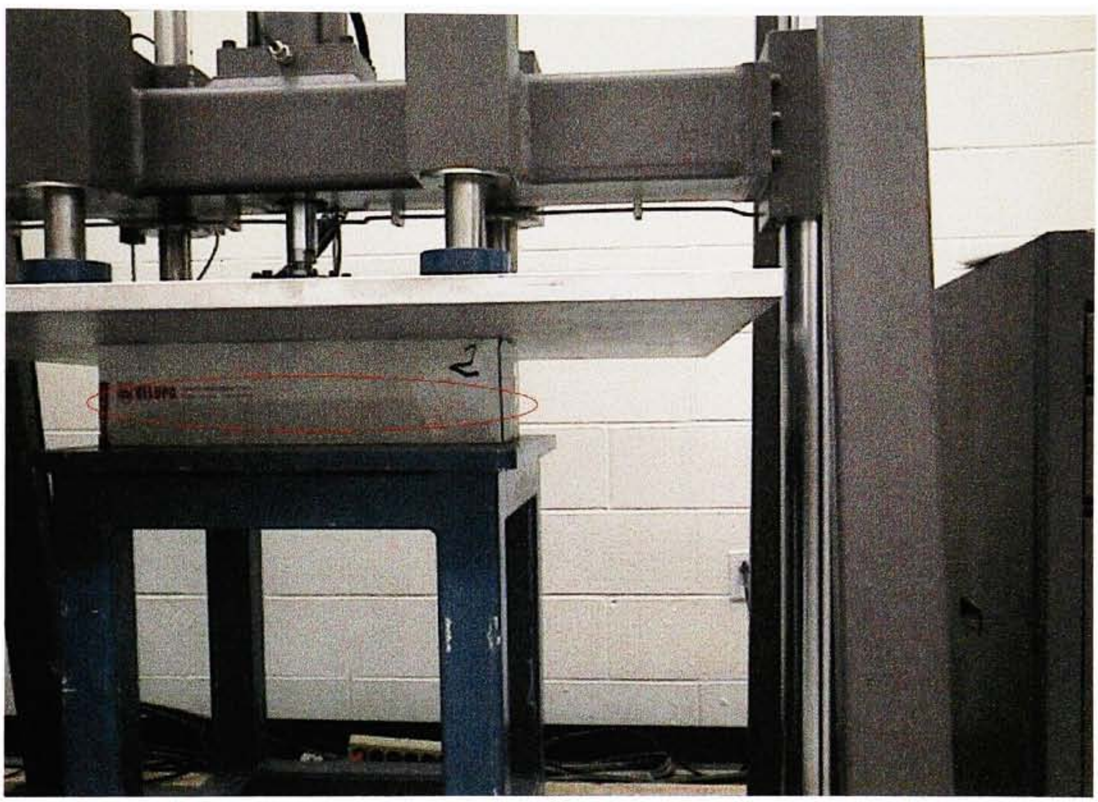


Fig. 15 **Lateral face of a box damaged at compression test**

3.1.2.3. SINUSOIDAL VIBRATION TEST
According to ASTM D 999

Sample Product:	**BELOS**
Instrumentation:	Vertical Vibration Machine Lansmont L-10000-10
Vibration:	Sinusoidal
Sweep:	3-100-3 Hz
Velocity:	1 oct/min
Acceleration peak:	**0.50 g**

TEST RESULTS

Resonance frequencies:

Resonance frequency Hz	Transmissibility Q
19,8	0,2

(See enclosed graph)

Fatigue test

- Acceleration peak: **0.5 g**

Resonance frequency Hz	Duration minutes	Impact orientation
19,8	40	Bottom

Observations after test:

- Product is OK.

Trans / Data

Ortho Clinical
Data has not yet been saved

4:45:10 PM
Jun-26-2000

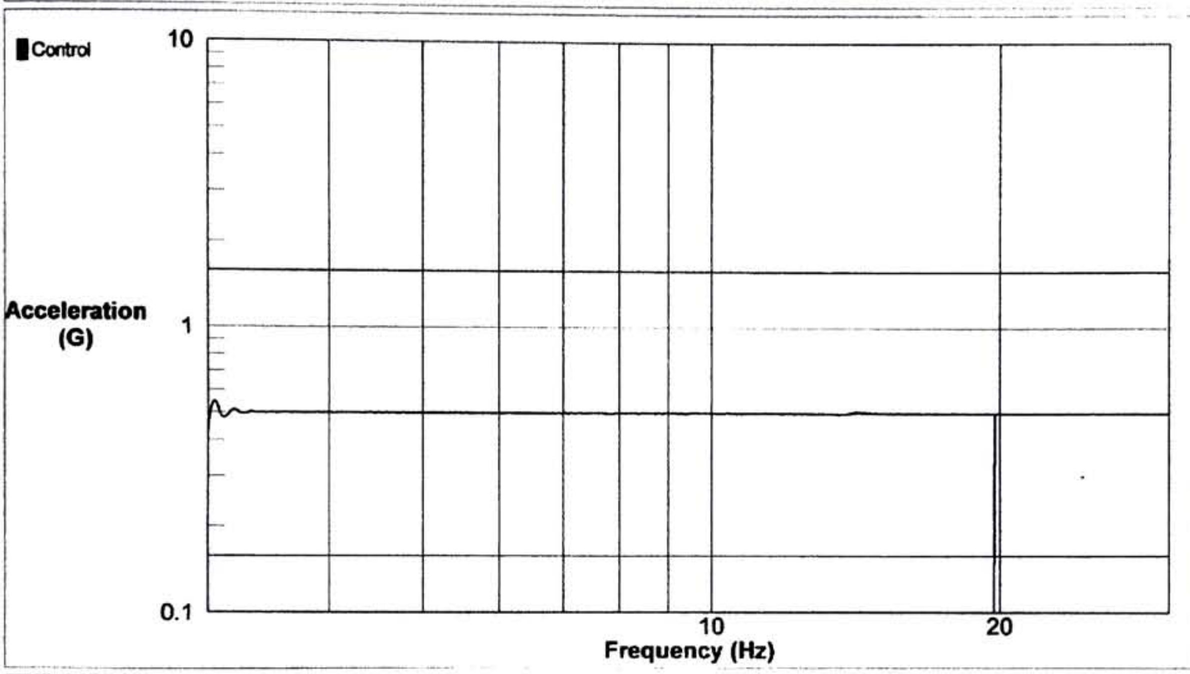
Lansmont Corporation — TouchTest Vibration

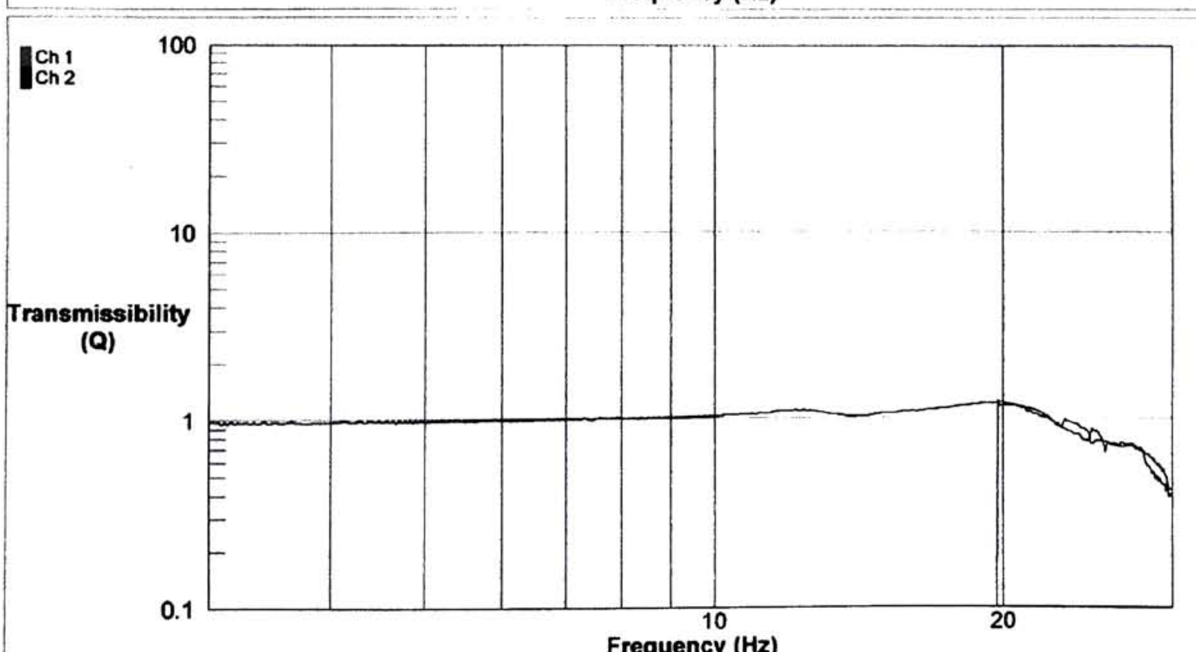
TestQ ID: Default
Profile ID: 3 to 100 Hz 0.5 G 2 oct per min 2

Control: 0.50 G pk
Demand: 19.8 Hz

Elapsed: 0 hr 3 min 55 sec
Remaining: 0 hr 2 min 42 sec

Profile: 1 of 1
Total: 0 hr 6 min 38 sec





3.1.2.4. RANDOM VIBRATION TEST
According to ASTM D 4728

Sample Product: **BELOS**
Instrumentation: Vertical Vibration Machine Lansmont L-7000-10
Vibration: Random
Level: II
Acceleration: 0.52 grms
Duration: 180 minutes

Fig. 16 **Boxes Ref. Belos in the vertical vibration Machine**

Spectrum of vibration of level II:

Frequency Hz	**PSD g^2/Hz**
1	0.000050
4	0.010000
16	0.010000
40	0.001000
80	0.001000
200	0.000010

<u>Observations after test:</u>

- Product is OK.

3.1.2.5. DROP TEST

According to ASTM D 5276

Sample Product: **BELOS**
Instrumentation: Drop Tester Lansmont PDT56 E
Drop height: 381 mm
N° of samples: 5

TEST RESULTS

Type of Drop	Box 1	Box 2	Box 3	Box 4	Box 5
Vertical edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge
Lateral face	OK	OK	OK	OK	OK
Adjacent face	OK	OK	OK	OK	OK
Corner of the cover not previously tested	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Cover edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge	Damaged edge
Base *	OK	OK	OK	OK	OK

* The height of the base drop is 762 mm

Observations after test:

- After test, 217 of 300 interior packaging remain in good state, that means that **72,33 % of the total is OK**.
- After test, 83 of 300 interior packaging have suffered some type of damage that means that **27,67% of the total is NOT OK**.

Following page contain some diagrams showing damages occurred on the boxes, in relation to the position they occupied in the packaging.

■ Box Damage

BOX 1

■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	OK	■	■	OK	OK	OK	OK	OK	OK	OK	■
OK	OK	■	■	OK	OK	OK	OK	OK	OK	OK	OK
■	OK	■	■	OK	OK	OK	OK	OK	OK	OK	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■

Boxes OK 43
Boxes Damage 17

BOX 2

■	■	■	OK	OK	OK	OK	OK	OK	OK	■	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
■	■	OK	■	OK	OK	OK	OK	OK	OK	■	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■

Boxes OK 40
Boxes Damage 20

BOX 3

■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	■
OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	■
■	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■

Boxes OK 48
Boxes Damage 12

BOX 4

■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	OK	■	■	OK	OK	OK	OK	OK	OK	■	■
OK	■	OK	■	OK	OK	OK	OK	OK	OK	OK	OK
■	OK	■	■	OK	OK	OK	OK	OK	OK	OK	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■

Boxes OK 41
Boxes Damage 19

BOX 5

■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■
■	■	OK	OK	OK	OK	OK	OK	OK	OK	■	■

Boxes OK 45
Boxes Damage 15

3.1.3. Product C

3.1.3.1. DROP TEST
According to ASTM D 5276

Sample Product: **GENTA**
Instrumentation: Drop Tester Lansmont L-PDT227
Drop height: 381 mm
N° of samples: 5

TEST RESULTS

Type of drop	Box 1	Box 2	Box 3	Box 4	Box 5
Top	OK	OK	OK	OK	OK
Bottom edge	OK	OK	OK	OK	OK
Adjacent bottom edge	OK	OK	OK	OK	OK
Bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Diagonally opposite bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Bottom	OK	OK	OK	OK	OK

Observations after test:

- Corners of boxes are damaged (Fig. 18).
- Boxes do not show other significant damages.

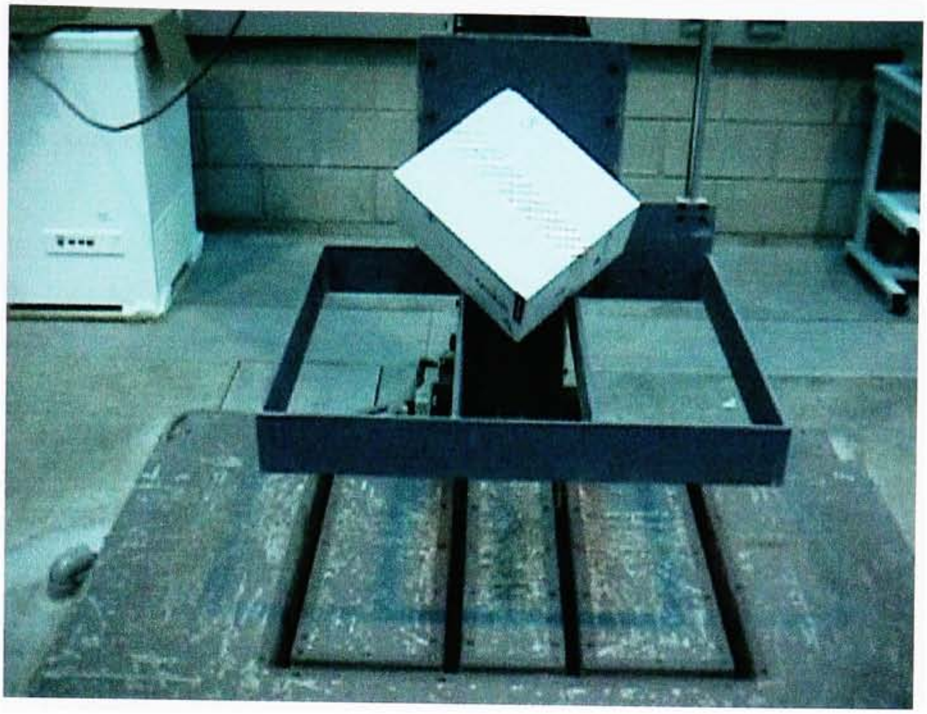


Fig. 17 **Box Ref. Genta in the drop tester**

Fig. 18 **Box corner damaged after test**

3.1.3.2. DYNAMIC COMPRESSION TEST

According to ASTM D 642

Sample Product: **GENTA**
Instrumentation: Compression Tester Lansmont CCTS 122-15k
Pre-load: 20 kg
Velocity: 10 mm/min
N° of samples: 5

TEST RESULTS

Sample	Force kg	Deflection cm
1	132	0.71
2	127	0.29
3	150	1.29
4	129	0.68
5	124	0.43
Average	**132**	**0.68**
Deviation	10	0.38

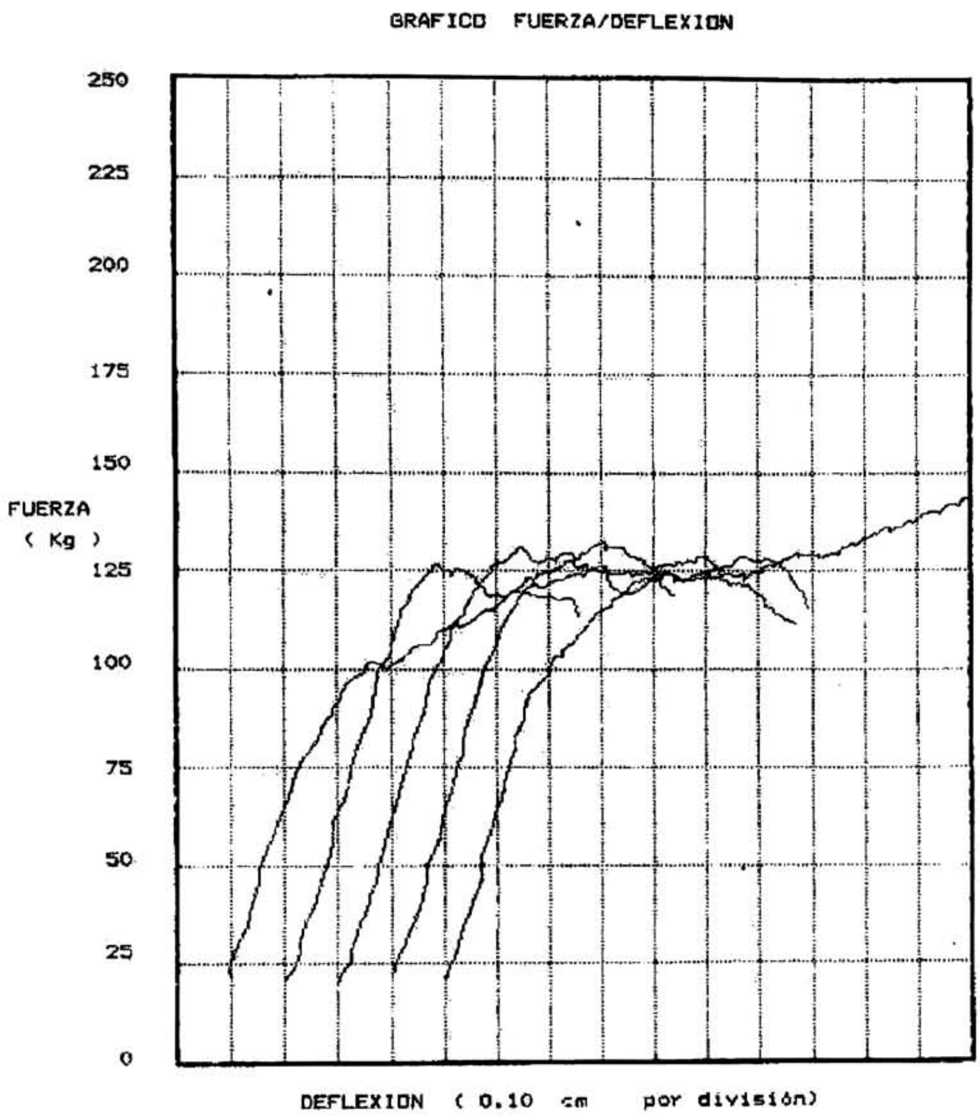


GRAFICO FUERZA/DEFLEXION
250
225
200
175
150
FUERZA
(Kg)
125
100
75
50
25
0
DEFLEXION (0.10 cm por división)

3.1.3.3. SINUSOIDAL VIBRATION TEST

According to ASTM D 999

Sample Product: **GENTA**
Instrumentation: Vertical Vibration Machine Lansmont L-10000-10.
Vibration: Sinusoidal
Sweep: 3-100-3 Hz
Velocity: 1 oct/min
Acceleration peak: **0.50 g**

TEST RESULTS

Resonance frequencies:

Resonance frequency Hz	**Transmissibility Q**
15.81	1.5964
69.34	0.3411

(See enclosed graph)

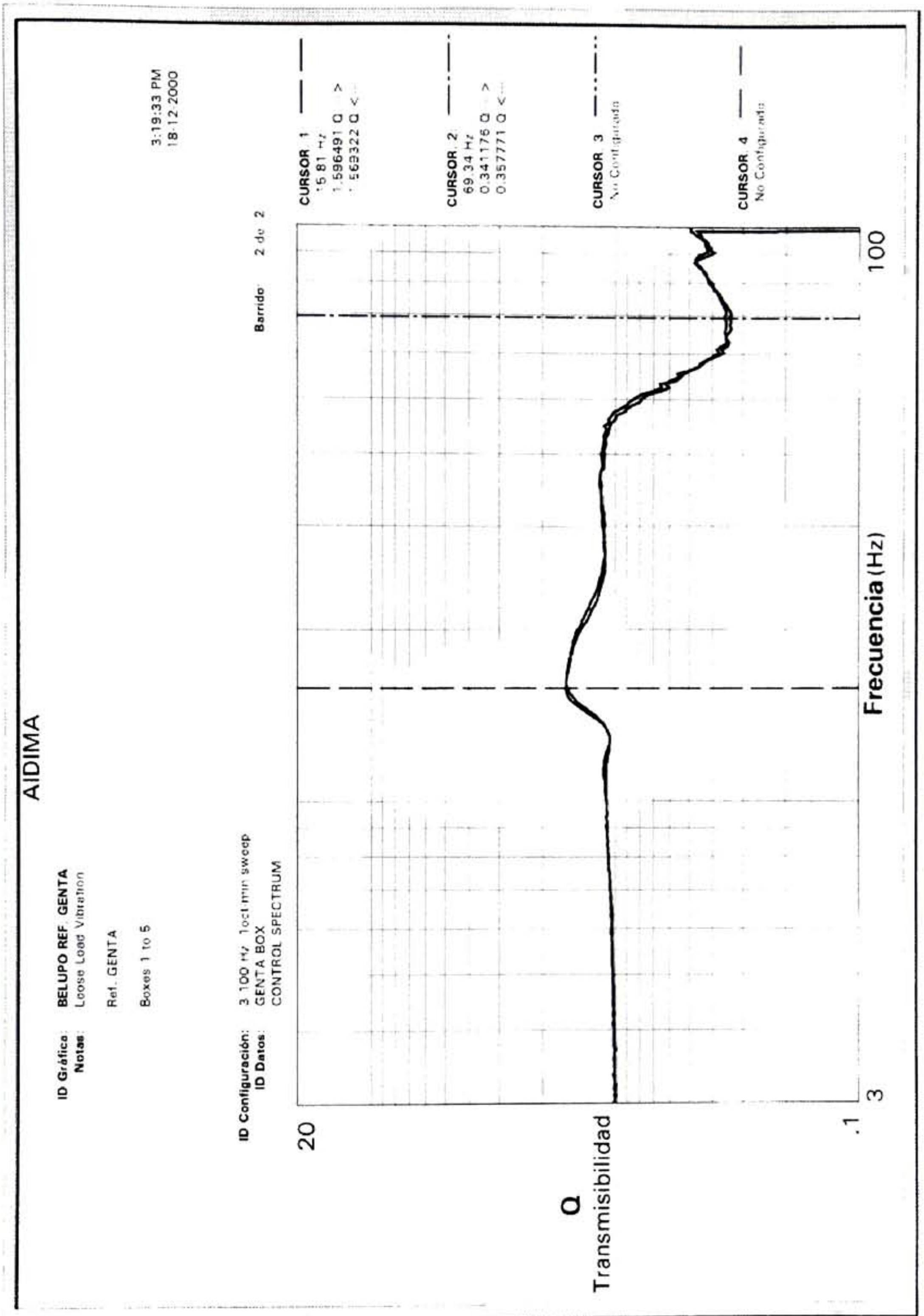
Fatigue test

- Acceleration peak: **0.5 g**

Resonance frequency Hz	**Duration minutes**	**Impact orientation**
15.81	20	Bottom
69.34	20	Bottom

Observations after test:

- Product is OK


AIDIMA
ID Gráfico: BELUPO REF. GENTA
Notas: Loose Load Vibration
Ref. GENTA
Boxes 1 to 5
ID Configuración: 3 100 Hz 1oct/min sweep
ID Datos: GENTA BOX
CONTROL SPECTRUM
Barrido: 2 de 2
3:19:33 PM
18-12-2000
CURSOR 1
15.81 Hz
1.596491 Q --->
1.569322 Q <---
CURSOR 2
69.34 Hz
0.341176 Q --->
0.357771 Q <---
CURSOR 3
No Configurado
CURSOR 4
No Configurado
20
.1
3
100
Q
Transmisibilidad
Frecuencia (Hz)

3.1.3.4. RANDOM VIBRATION TEST
According to ASTM D 4728

Sample Product: **GENTA**
Instrumentation: Vertical Vibration Machine Lansmont L-10000-10
Vibration: Random
Level: II
Acceleration: 0.52 grms
Duration: 180 minutes

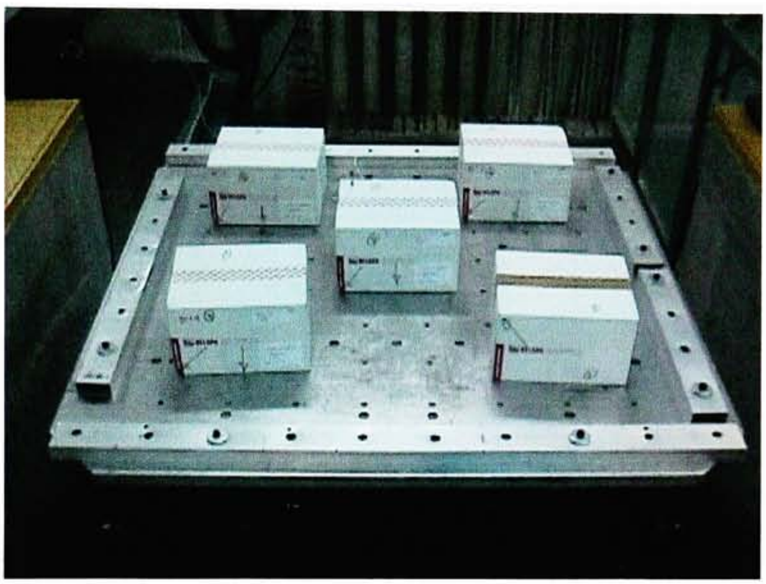


Fig. 19 **Boxes Ref. Genta in the vertical vibration Machine**

Spectrum of vibration of level II:

Frequency Hz	**PSD g^2/Hz**
1	0.000050
4	0.010000
16	0.010000
40	0.001000
80	0.001000
200	0.000010

<u>Observations after test:</u>

- Product is OK.

3.1.3.5. DROP TEST
According to ASTM D 5276

Sample Product: **GENTA**
Instrumentation: Drop Tester Lansmont L-PDT227.
Drop height: 381 mm
Nº of samples: 5

TEST RESULTS

Type of drop	Box 1	Box 2	Box 3	Box 4	Box 5
Vertical edge	OK	OK	OK	OK	OK
Lateral face	OK	OK	OK	OK	OK
Adjacent face	OK	OK	OK	OK	OK
Corner of the cover not previously tested	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Cover edge	OK	OK	OK	OK	OK
Base *	OK	OK	OK	OK	OK

* The height of the base drop is 762 mm

<u>Observations after test:</u>

- An average of four of sixty interior boxes are damaged, therefore, **6.6% of the interior packaging shows some damage.**
- Corners of the boxes are ruined after the test, damaging the interior packaging (Fig. 20 and 21).
- Neither boxes nor interior packaging show other significant damages, but the corners.

Fig. 20 **Box corner damage after test**

Fig. 21 **Interior box corner damage after test**

3.1.4. Product D

3.1.4.1. DROP TEST

According to ASTM D 5276

Sample Product: **LORSI**
Instrumentation: Drop Tester Lansmont L-PDT227
Drop height: 381 mm
N° of samples: 5

TEST RESULTS

Type of drop	**Box 1**	**Box 2**	**Box 3**	**Box 4**	**Box 5**
Top	OK	OK	OK	OK	OK
Bottom edge	OK	OK	OK	OK	OK
Adjacent bottom edge	OK	OK	OK	OK	OK
Bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Diagonally opposite bottom corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Bottom	OK	OK	OK	OK	OK

Observations after the test:

- Corners of boxes are damaged (Fig. 23).
- Boxes do not show other significant damages.

3.1.4.2. DYNAMIC COMPRESSION TEST

According to ASTM D 642

Sample Product: **LORSI**
Instrumentation: Compression Tester Lansmont CCTS 122-15k
Pre-load: 20 kg
Velocity: 10 mm/min
N° of samples: 5

TEST RESULTS

Sample	**Force kg**	**Deflection cm**
1	174	0.48
2	165	0.36
3	147	0.33
4	156	0.32
5	135	0.31
Average	**155**	**0.36**
Deviation	15	0.07

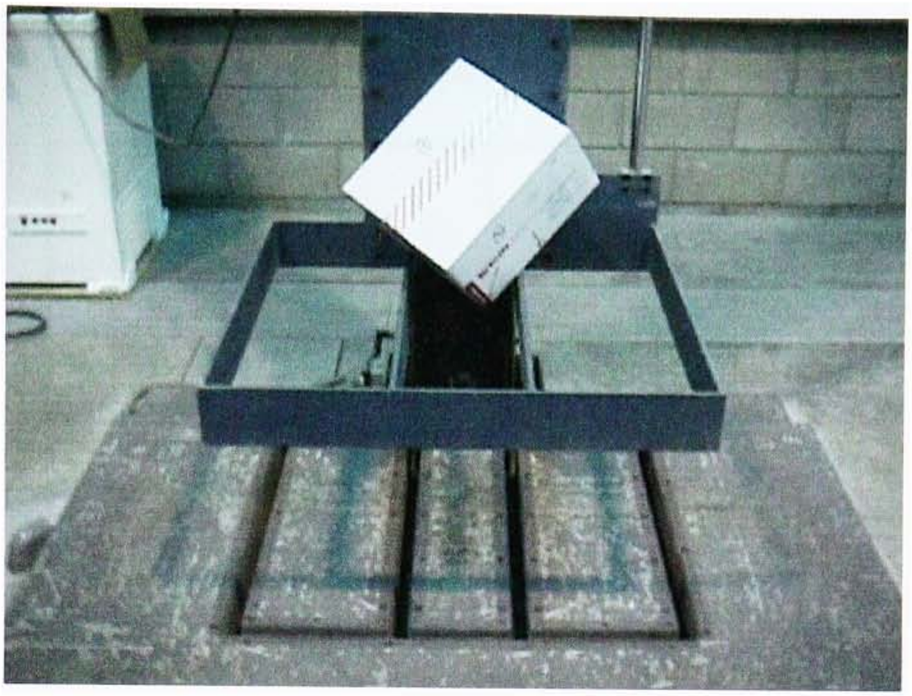
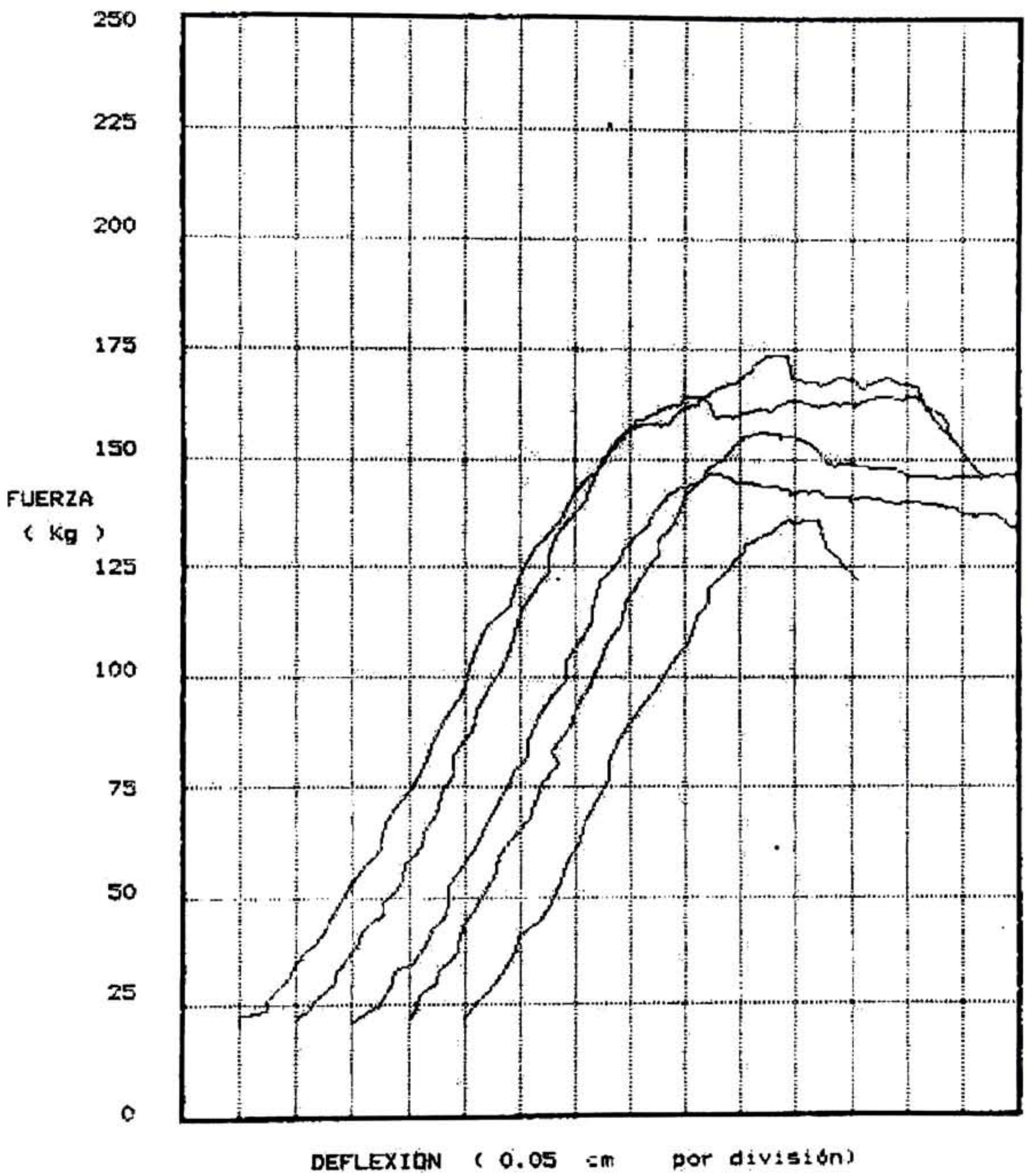


Fig. 22 **Box Ref. Lorsi in the drop tester**

Fig. 23 **Box corner damage**

GRAFICO FUERZA/DEFLEXION



3.1.4.3. SINUSOIDAL VIBRATION TEST

According to ASTM D 999

Sample Product:	**LORSI**
Instrumentation:	Vertical Vibration Machine Lansmont L-10000-10
Vibration:	Sinusoidal
Sweep:	3-100-3 Hz
Velocity:	1 oct/min
Acceleration peak:	**0.50 g**

<u>TEST RESULTS</u>

Resonance frequencies:

Resonance frequency Hz	Transmissibility Q
16.26	1.2609
44.81	1.4127

(See enclosed graph)

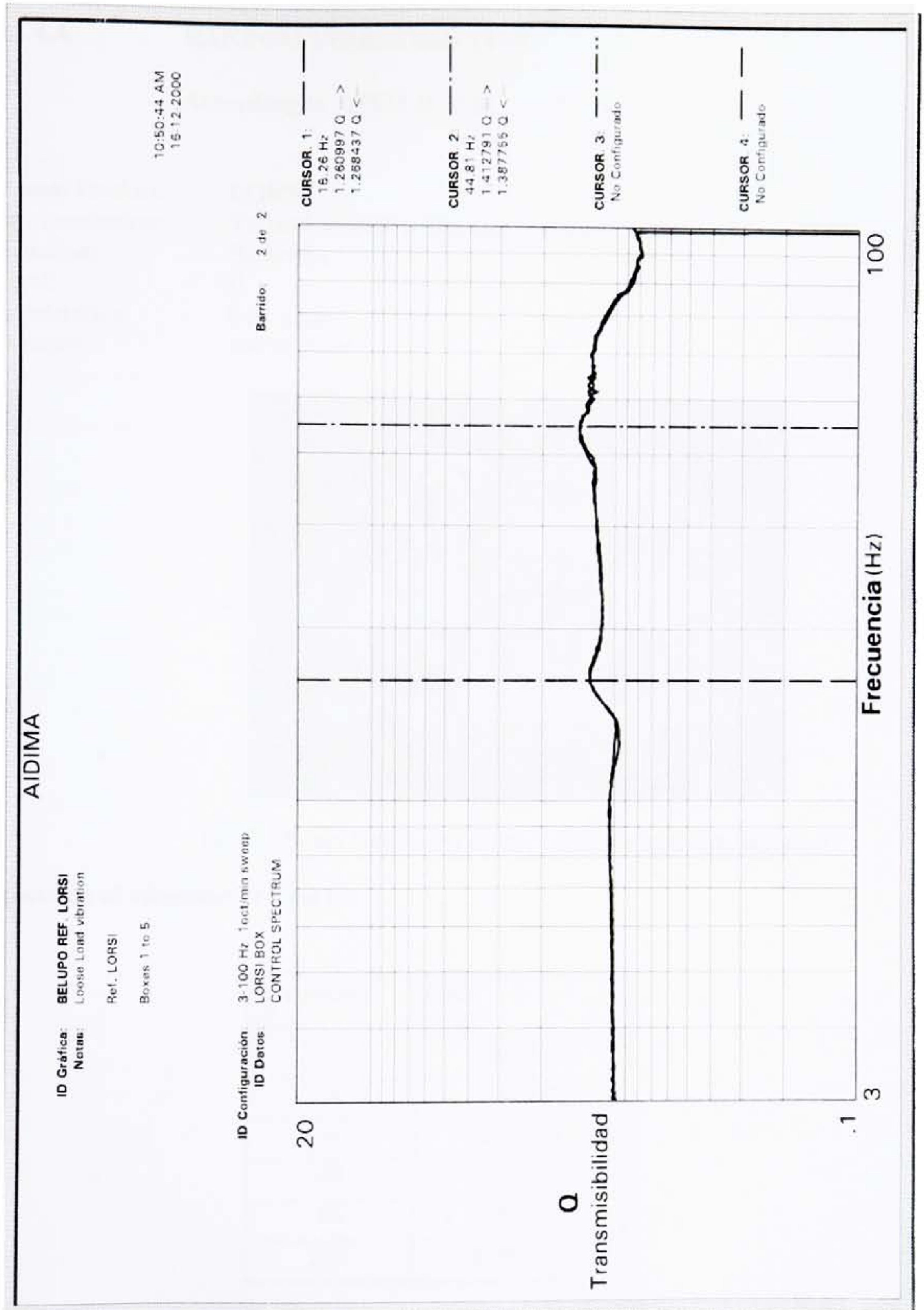
<u>Fatigue test</u>

- Acceleration peak: **0.5 g**

Resonance frequency Hz	Duration minutes	Impact orientation
16.26	20	Bottom
44.81	20	Bottom

<u>Observations after test:</u>

- Product is OK.


AIDIMA
ID Gráfica: BELUPO REF. LORSI
Notas: Loose Load vibration
Ref. LORSI
Boxes 1 to 5
ID Configuración: 3-100 Hz 1oct/min sweep
ID Datos: LORSI BOX
CONTROL SPECTRUM
Barrido 2 de 2
10:50:44 AM
16-12-2000
CURSOR 1: 16.26 Hz
1.260997 Q -->
1.268437 Q <--
CURSOR 2: 44.81 Hz
1.412791 Q -->
1.387756 Q <--
CURSOR 3: No Configurado
CURSOR 4: No Configurado
20
.1
3
100
Q
Transmisibilidad
Frecuencia (Hz)

3.1.4.4. RANDOM VIBRATION TEST

According to ASTM D 4728

Sample Product: **LORSI**
Instrumentation: Vertical Vibration Machine Lansmont L-10000-10
Vibration: Random
Level: II
Acceleration: 0.52 grms
Duration: 180 minutes

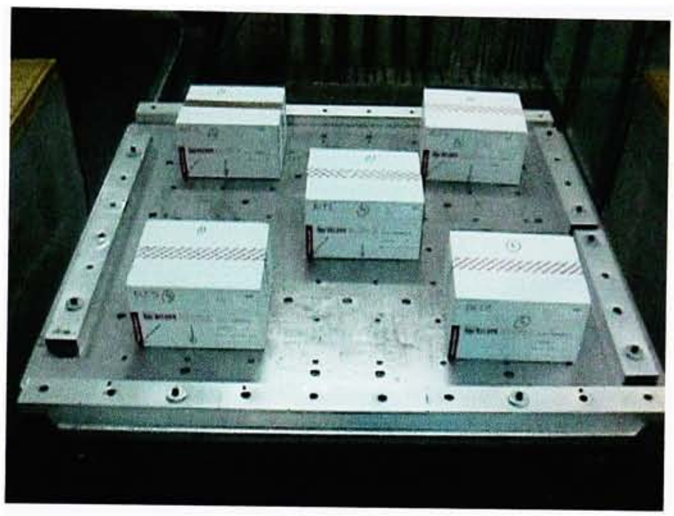


Fig. 24 **Boxes Ref. Lorsi in the vertical vibration Machine**

Spectrum of vibration of level II:

Frequency Hz	**PSD g^2/Hz**
1	0.000050
4	0.010000
16	0.010000
40	0.001000
80	0.001000
200	0.000010

Observations after test:

- Product is OK.

3.1.4.5. DROP TEST

According to ASTM D 5276

Sample Product: **LORSI**
Instrumentation: Drop Tester Lansmont L-PDT227
Drop height: 381 mm
Nº of samples: 5

TEST RESULTS

Type of drop	**Box 1**	**Box 2**	**Box 3**	**Box 4**	**Box 5**
Vertical edge	OK	OK	OK	OK	OK
Lateral face	OK	OK	OK	OK	OK
Adjacent face	OK	OK	OK	OK	OK
Corner of the cover not previously tested	Damaged corner	Damaged corner	Damaged corner	Damaged corner	Damaged corner
Cover edge	OK	OK	OK	OK	OK
Base *	OK	OK	OK	OK	OK

* The height of the base drop is 762 mm

Observations after the test:

- After the test, three of a hundred interior boxes are damaged, therefore, **3% of the interior packaging shows some damage**.
- Corners of boxes are ruined after test, damaging the interior packaging (Fig. 25 and 26).
- Neither boxes nor interior packaging show other significant damages, but the corners.

Fig. 25 **Corner of a box damaged after test**

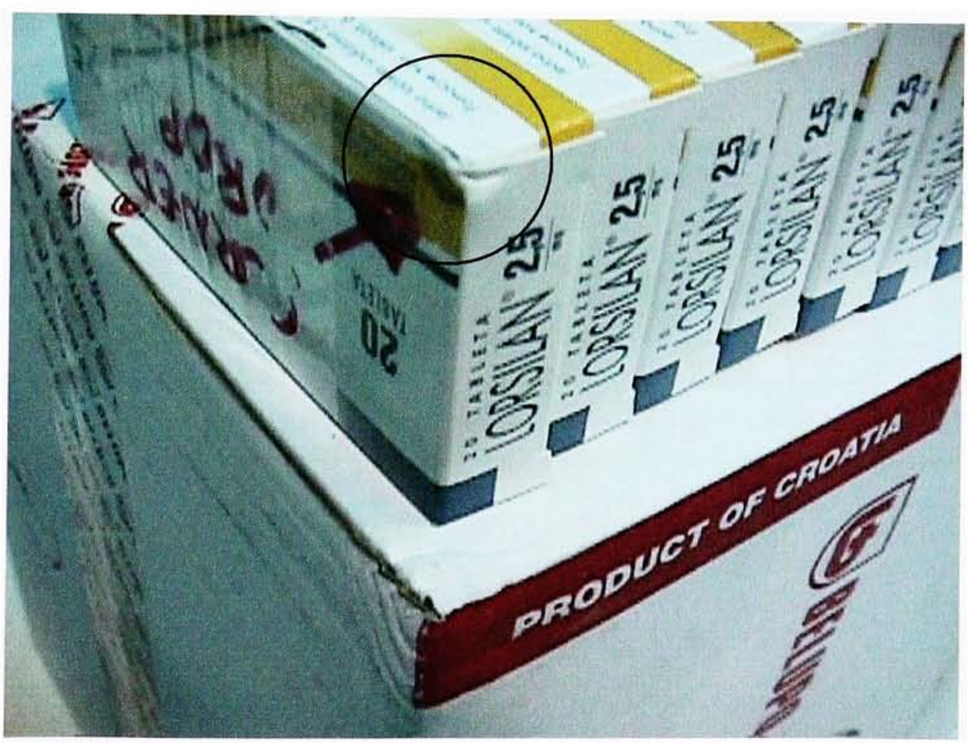


Fig. 26 **Corner of an interior box damage after test**

3.2. RESULTS FROM TRANSPORTATION

3.2.1. Transportation I

Truck loaded in Belupo on July 18th 2000 at 18:00.
Truck returned to Belupo on July 21st 2000 at 8:00.
Summer weather
Temperature 15 – 35 ° C
Relative Humidity 60 – 85 %
Driver 1

Product A

Shipper	No. items in shipper	No of damaged items	% of damage
A	40	0	0
B	40	0	0
C	40	0	0
D	40	0	0
E	40	0	0
TOTAL	200	0	0

Product B

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product C

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product D

Shipper	No. items in shipper	No of damaged items	% of damage
A	100	0	0
B	100	0	0
C	100	0	0
D	100	0	0
E	100	0	0
TOTAL	500	0	0

3.2.2. Transportation II

Truck loaded in Belupo on November 28th 2000 at 16:00.
Truck returned to Belupo on December 01st 2000 at 8:00.
Autumn weather, fogy days
Temperature 0 -15 ° C
Relative Humidity 40 – 90 %
Driver 2

Product A

Shipper	No. items in shipper	No of damaged items	% of damage
A	40	0	0
B	40	0	0
C	40	0	0
D	40	0	0
E	40	0	0
TOTAL	200	0	0

Product B

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product C

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product D

Shipper	No. items in shipper	No of damaged items	% of damage
A	100	0	0
B	100	0	0
C	100	0	0
D	100	0	0
E	100	0	0
TOTAL	500	0	0

3.2.3. Transportation III

Truck loaded in Belupo on January 9th 2000 at 16:00.
Truck returned to Belupo on January 12th 2000 at 8:00.
Winter weather, foggy days with snow
Temperature -8° C to 10 ° C
Relative Humidity 30 – 70 %
Driver 3

Product A

Shipper	No. items in shipper	No of damaged items	% of damage
A	40	0	0
B	40	0	0
C	40	0	0
D	40	0	0
E	40	0	0
TOTAL	200	0	0

Product B

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product C

Shipper	No. items in shipper	No of damaged items	% of damage
A	60	0	0
B	60	0	0
C	60	0	0
D	60	0	0
E	60	0	0
TOTAL	300	0	0

Product D

Shipper	No. items in shipper	No of damaged items	% of damage
A	100	0	0
B	100	0	0
C	100	0	0
D	100	0	0
E	100	0	0
TOTAL	500	0	0

3.3. DATA BASE ANALYSIS TRANSPORTATION LOSSES AND DAMAGES

Pharmaceutical industry in normal operation applies many regulations and rules. One of those is to record all events in distribution. At the end of a year it is necessary to analyze losses and damages in warehousing and in distribution. Database of damages shows the protection and security measures in distribution cycles for our products, and financial losses caused within distribution can be calculated from those data.

This type of data can show to packaging engineer what happens with products in reality and can suggest where is it necessary to provide other investigation or changes in the packaging design.

Dispatch data base shows that 85 % of goods go out from a warehouse as single shippers and only 15 % as a whole pallet. For dispatch 85 % of goods we usually use smaller trucks and for the rest 15 % bigger ones.

In the table (Table 4. Data Base analysis of transportation losses and damages) of losses and damages there are following data: date of event, customer who detected the damages, name of product, quantities of damaged goods, type of damages, product price and value of damaged goods.

On the bottom of the table shows the data about percentage of damages in dependence turnover and dispatched quantities.

Date	Customer	Product	Quantity	Type of damage	Product price kn	Value of damaged product kn
14.06.2000.	Oktal Pharma, Zagreb	Lubor cps 20x20 mg	1	Damaged box	4,27	4,27
06.06.2000.	Medical Intertrade d.o.o. Sveta Nedjelja	Ibuprofen drag. 30 x 400mg	5	Damaged box	4,20	21,00
01.06.2000.	Oktal Pharma, Zagreb	Afloderm krema 40 g	1	Box and product damaged	10,17	10,17
09.05.2000.	Medical Intertrade d.o.o. Osijek	Lidokain-Adrenalin 2ml 2%	1	Broken 10 ampoules	62,98	62,98
23.03.2000.	Medika Zagreb	Instrudes 1 l	2	Cap broken	61,91	123,82
29.03.2000.	Medika Zagreb	Retafilin amp. 50x10 ml	1	One ampoule broken	90,75	90,75
23.03.2000.	MAICO d.o.o. Varaždin	Lidokain 2ml 2% ample	1	Two ampoules broken	58,32	58,32
06.03.2000.	Arnika, Zagreb	Silapen sirup	2	Bottle broken	5,00	10,00
03.03.2000.	Medika Zagreb	Instrudes 1 l	1	Cap broken	61,91	61,91
14.02.2000.	Kondor , Zagreb	Indusan 1 l	2	Bottle damaged	58,39	116,78
26.01.2000.	Farmacija, Zagreb	Sirup protiv kašlja	20	Boxes damaged	10,40	208,00
25.11.1999.	Cro-dens, Zagreb	Moldano 4,5 kg	1	Box damaged	47,07	47,07
22.11.1999	Ljekarna "Dr. Gaj Varaždin"	Lidokain-Adrenalin 2ml 2%	1	One ampoule broken	62,98	62,98
20.10.1999.	Cro-dens, Zagreb	Lidokain-Adrenalin 2ml 2%	3	Five ampoules broken	62,98	188,94
13.07.1999.	Arnika, Zagreb	Lumidol kapi	1	Product like out	10,04	10,04
		Lupocet kapsule 100x300 mg	1	Box damaged from Lidokain	18,61	18,61
		Amoksicilin kapsule 16x500mg	1	Box damaged from Lidokain	5,36	5,36
		Lubor kapsule	1	Box damaged from Lidokain	4,27	4,27
		Normabel 30x5 mg	1	Box damaged from Lidokain	1,53	1,53
23.06.1999.	Medika, Zagreb	Instrudes 1 l	1	Cap broken	61,91	61,91
28.05.1999.	Oktal Pharma, Zagreb	Fitolax prašak	5	Boxes damaged	13,94	69,70
Total			**53**			**1.238,41**
Net turnover (from 01.06.1999. to 31.05.2000.)						**468.583.860 kn**
Percentage of damage (from 01.06.1999. to 31.05.2000.)						**0.00026 %**
The goods output from warehouses (from 01.06.1999. to 31.05.2000.)						**18 573 496 items**
Percentage of damage in dependence of output the goods from warehouse (from 01.06.1999. to 31.05.2000.)						**0.00029 %**

Table 4. Data Base analysis transportation losses and damages

4. CONCLUSION

During our testing in the lab we reached certain conclusions:

- percentage of damages is increased with the increase of a masse of shippers
- damages of the products are usually caused by the drop of the shippers

When compared,-results from lab and those from the real transportation and data base losses and damages are not compatible.

Results from the lab show 3.0; 6.6; 27.67 and 54.0 % but in test transportation we had 0 % damages.

Data from test transportation and database show almost equal statement of damages, 0 % from test transportation and 0.00029 % from database.

In a situation when we have different results from general simulation (ASTM 4169) and test transportation, it is necessary to collect dynamic data from real transportation using special electronic device like SEVER®. The data collected in transport have to be analyzed by a PC, and the results converted to laboratory test levels. After providing test with test level collected from real distribution cycles we can judge the fragility of distribution pack with pharmaceutical products of Belupo Company.

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