Remedica
FOR A HEALTHIER WORLD

Newsletter 36

| December 2016 |

Contents

Welcome note

Welcome to the 36th issue of our Newsletter where we present our associates in Trinidad and Tobago, one of our Area Managers and our products Kivala® and Exatron®.

In our Environmental Issues section we report on "Public transport VS private cars", in Health Matters we report on "The crucial role of the scientific articles for ensuring the efficacy and safety of medicinal products" and in the ABC of Industrial Pharmacy we explain the "Disintegration tests for solid oral dosage forms".

Under Corporate Social Responsibility we have Open Access Week and in Remedica News we report our participation in a chemistry event, Remedica's new exhibition booth, participation in medical conferences and the successful participation in CPhI Worldwide 2016 meeting.

Finally, we explore the Monuments and Archeological Sites of Cyprus which are included in the Catalogue of the World Cultural Heritage of UNESCO.

Charalambos Pattihis
Group CEO

Remedica Worldwide

Massy Distribution (Trinidad) Ltd, Trinidad & Tobago

Trinidad and Tobago, or to give it its official name the Republic of Trinidad and Tobago, is a dual-island nation in the southern Caribbean, lying just 11 kilometers off the coast of Venezuela. Covering an area of 5,129 km² (Trinidad 4,828 km² and Tobago 301 km²) the country consists of the two main islands, Trinidad and Tobago, and numerous smaller landforms, including Chacachacare, Monos, Huevos, Gaspar Grande, Little Tobago and St. Giles Island. The total population of the country is 1.3 million people, of which 165,000 live in the capital city of Port of Spain.

Trinidad and Tobago is not only one of the wealthiest and most developed nations in the Caribbean, but is also listed in the top 40 list of high income countries in the world and is the third richest country by GDP (PPP) per capita in the Americas after the United States and Canada. Unlike most of the English-speaking Caribbean, the country's economy is primarily industrial with an emphasis on petroleum and petrochemicals: it is one of the premier suppliers of natural gas and petrochemicals to the world.

Comprising a mix of descendants of people from American Indian, African, East Indian, European, Middle Eastern and Chinese origin, Trinidad and Tobago's rich heritage is reflected in the "energetic" culture through its food, festivals, customs and general way of life. The most famous festival is the annual carnival, which is considered to be the second largest in the World.

Remedica's local representative in the country is Massy Distribution (Trinidad) Ltd, the largest multi-principal distribution company in Trinidad, and specializes in the distribution of pharmaceuticals, personal care products, food products, medical equipment and agricultural & industrial chemicals. It is a subsidiary of the Massy Group, a diversified regional conglomerate which has operated in the English-speaking Caribbean for over 90 yrs. It is a publicly traded company on the Trinidad & Tobago Stock Exchange with annual revenues of US$1.9 billion (2015). Massy operates through its subsidiaries with diversified activities in Trinidad & Tobago, Guyana, Jamaica, Barbados, St. Lucia, Colombia and the USA. The Group is comprised of six main business segments, offering a range of quality products and services and representing several international brands. The Group employs over 10,000 employees most of whom are shareholders.

Massy Distribution (Trinidad) is a division of Massy Integrated Retail Ltd, a subsidiary of the Massy Group. With over 100 years of experience, a strategic link to the Massy Stores retail chain and the incorporation of 5 distribution divisions, Massy Distribution is a modern and efficient full-service distribution company which provides highly effective representation to a wide variety of International, Regional and Local principals with nationwide distribution.

MASSY DISTRIBUTION

Massy Distribution (Trinidad) - Pharmaceutical Division:

This section of the Company operates in the major English speaking markets in the region having Pharmaceutical & Healthcare Distribution Divisions in Trinidad and Tobago, Jamaica, Barbados and Guyana.
The sales team consists of a Sales Manager who supervises a team of eleven representatives who in turn service all retail pharmacies, hospitals, institutional customers, and doctors; they have real time access to ordering systems. Additionally, the company provides its products and services to the Government through the Ministry of Health and, since its inception, have successfully participated in the National Insurance Property Development Company Limited (NIPDEC) Tenders, which supplies pharmaceuticals and non-pharmaceuticals to the public health system.
Massy Distribution is extremely committed its principals, shareholders and the development of the Caribbean Region and continues to promote and protect its long established reputation for integrity and fair-play in all business dealings. ■

Remedica News

1. "Chemistry - Pharmaceutical products" One-day event. (photo 1)
During the day-event "Chemistry - Pharmaceutical products," Remedica's Assistant General Manager Dr. Michael Neoptolemou participated as a speaker. With the title "The Role of the Pharmaceutical Industry and the Contribution of Remedica in the Cyprus Economy," Dr. Neoptolemou stressed the importance of Cyprus pharmaceutical manufacturers, especially Remedica and the contribution to the GDP of Cyprus. In addition, he gave essential examples and practices so that the academic community, professional associations (e.g. chemists) and pharmaceutical industry to cooperate for the mutual benefit of stakeholders and society in general.


1

2. New exhibition booth for Remedica. (photo2)
Remedica recently unveiled its new exhibition booth which will be used at various conferences and exhibitions in which the company will participate in Cyprus. Through the new booth visitors will have the opportunity to watch Remedica's corporate film, see its products and to discuss matters with the company's employees in a friendly, yet professional environment.


2

3. Medical conferences. (photo 3)
Remedica's local sales team took part in medical conferences and one-day events where participants (doctors and other healthcare professionals) had the opportunity to be briefed on Remedica's new and existing products. Specifically the team took part in the events organised by the Cyprus Society for the Study of Diabetes, the Mediterranean Orthodontic Congress, the Greece-Cyprus Hypertension Congress, the Pancyprian Genecology conference and the Pancyprian Congress of Internal Medicine.

3

4. Successful participation in CPhI Worldwide 2016. (photo 4)
Remedica successfully participated for the first time as an exhibitor at the International Exhibition CPhI Worldwide 2016 held in Barcelona. During the exhibition, the participants had the opportunity to be briefed on Remedica's new products and to discuss potential cooperation. It is worth noting that CPhI is the leading global gathering of the pharmaceutical industry with more than 2.500 exhibitors and more than 36,000 senior pharma executives attending from more than 150 countries.


4

5. Business Leader of the Year Award for the Group CEO of Remedica, Mr. Charalambos Pattihis. (photo 5)
On the occasion of the 3rd Annual KEBE Business Leader Awards Ceremony, organised by the Cyprus Chamber of Commerce & Industry and IMH, the Group CEO and Chair of the Board of Directors of Remedica, Mr. Charalambos Pattihis, was named Business Leader of the Year in the industrial sector. Mr. Pattihis thanked the organisers for this honour and stated that he is proud and at the same time sad that his father Christakis Pattichis is not with us anymore to share these happy times with him. On his short speech, he devoted the award to his family, whom he has inadvertently neglected somewhat over the years, his colleagues, who have contributed to Remedica's great success, and to his father, whom we lost earlier in the year.
The ÊÅÂÅ Business Leader Awards aim to honour Cyprus business individuals who have expanded their business and contributed to Cyprus entrepreneurship and who, amongst others, have created best practices and innovative strategies. They are individuals who operate with integrity and ethos, have gained the respect of their own employees as well as that of their competitors and the broader business community, and who work on the basis of the key principles that characterise a successful leader: dynamism, innovation, foresight and knowledge. ■


5

Remedica People

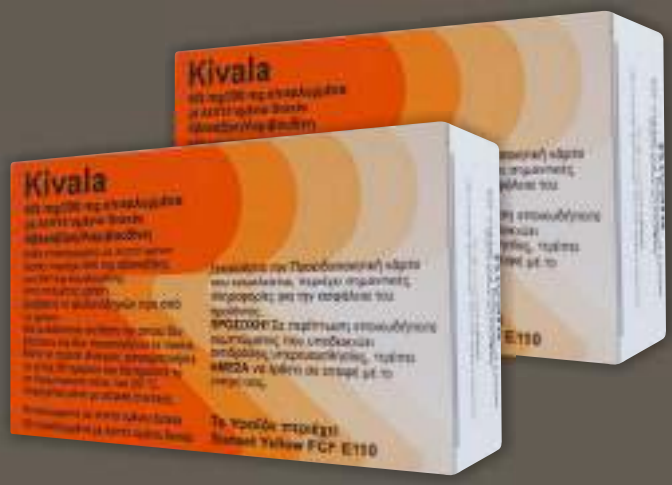
In this issue we present George Manolis, Area Manager

George Manolis originates from the lovely occupied city of Morphou, an area famed for its orange plantations: its inhabitants are renowned for being highly disciplined and for their respect for family values. Despite the difficulties faced due to the Turkish occupation he successfully studied in the UK at the University of Salford, where he received a BSc in Business Studies and an MSc in Marketing. Immediately after completing his studies in 1994 he returned to Cyprus and joined Remedica in the Export & Sales Department; his zeal and competence enabled him at the same time to monitor various other tasks in different departments. His hard work, commitment, experience and knowledge has grown throughout his 22 years' service whilst he was too privileged to witness at first hand the expansion and development of the Company.

Currently, he manages more than 20 countries in the Far East, Europe and the Balkans; he is also accountable for key Non-Profit Organisations. Throughout the years he has participated in various seminars, workshops and training courses all of which have enriched his knowledge in his field. All of his accounts are handled in a hands on manner and are treated assiduously day and night, thus all his business associates recognise him as their GEORGE. As a loyal employee, he is always seeking new ways of fruitful cooperation between Remedica and its associates. George's ethos and professionalism, have helped him to develop reciprocal cooperation within Remedica, between both his colleagues and his supervisors.
Like most men, he loves football and supports AEK Greece. He also enjoys good food and wine with his friends and family.

He is married and blessed with three children.

Our Products:



Kivala® (Abacavir & Lamivudine)

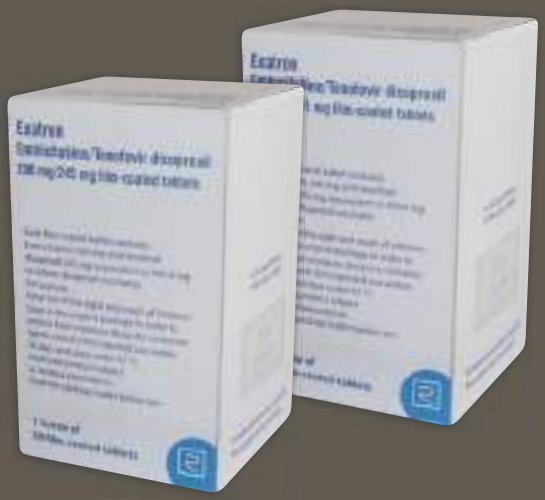
Recently, the medicinal product Kivala® was approved by the pharmaceutical services division of the Ministry of Health of Cyprus. Kivala® contains the active substances Abacavir and Lamivudine and it is indicated as an antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25kg.

Kivala® is available in a strength of 600mg/300mg as film-coated tablets.

Exatron®(Emtricitabine & Tenofovir Disoproxil)

Recently, the medicinal product Exatron® was approved by the pharmaceutical services division of the Ministry of Health of Cyprus. Exatron® contains the active substances Emtricitabine and Tenofovir Disoproxil and it is indicated as an antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus-1 (HIV-1) infected adults aged 18 years and over.

Exatron® is available in a strength of 200mg/245mg as film-coated tablets.

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Environmental Issues:
Public transport VS private cars

The European Commission considers that the relationship between transport and environmental issues is one of the most crucial elements in progress towards sustainable development. The continuous growth in terms of transport services and traffic volume has resulted in environmental issues, such as local air pollution and global climate change. Figures published by the European Commission suggest that transport is responsible for 25% of the total energy related carbon dioxide emissions (CO_2), of which 80% originate from road transport. It should be noted that 45% of the road transport CO_2 emissions arise from private passenger cars, whereas only 33% comes from road freight. Transport as a whole is also responsible for 60% of the carbon monoxide (CO) emissions, a hazardous air pollutant.

In the light of the above, public road transport has been viewed as an alternative solution for tackling the impacts that private cars pose with regard to environmental issues and traffic. As the International Association of Public Transport suggests, for every kilometre travelled, private cars emit 3.5 times more green-house gases per passenger compared with public transport. In addition, the utilisation of trams, metros and electric buses contributes to a reduction of local air pollution. Moreover, the utilisation of electrical means of public transport reduces even more their impact on climate, since a part of that energy originates from renewable resources, incorporated in the EUs energy balance. Walking to the public transport stations is another factor contributing to the tackling of climate change, since no fossil fuels are required for the coverage of the distance between residences and pick-up points.

In addition, the utilisation of public transport contributes to the improvement of wellbeing of inhabitants in urban areas. This is due to the fact that public transport utilizes far less space per passenger compared with private cars. This not only produces a reduction in the volume of traffic and the space it occupies, which in turn leaves more urban space that can be used to provide parks, cycling routes and facilities for other social activities. In addition, a potential reduction in private car movement due to the potential use of widespread public transport could lead to the reduction of the noise level in urban areas. It is worth mentioning that, according to the European Environment Agency almost 100 million people were exposed to damaging long-term average levels of noise from road vehicles on major roads.

Furthermore a potential increase of the number of private cars could pose an additional detrimental impact on local ecosystems and wildlife. As the European Environment Agency suggests, local ecosystems are fragmented and disturbed by the expansion and overcrowding of road infrastructure, resulting in significant impacts on biodiversity.

According to the European Environment Agency the white paper on transport requires EU Member States to reduce greenhouse gas emissions from transport by 60% by 2050, compared with 1990 levels. However, since emissions have increased by 27% between 1990 and 2009, the EU needs to achieve a 68% reduction between 2009 and 2050 in order to meet its targets. Consequently the further development, promotion and wider usage of public transport on a pan-European scale, is expected to play a vital role in the attempts to meet the greenhouse gases emission targets for transport. ■


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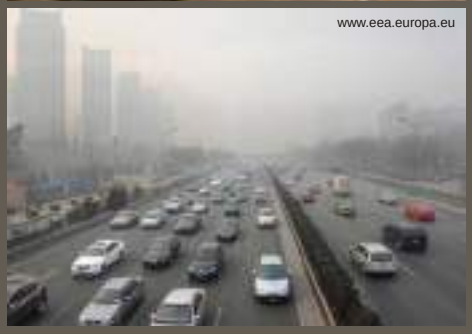

www.eea.europa.eu


www.dailymail.co.uk

Health Matters:

The crucial role of the scientific articles for ensuring the efficacy and safety of medicinal products

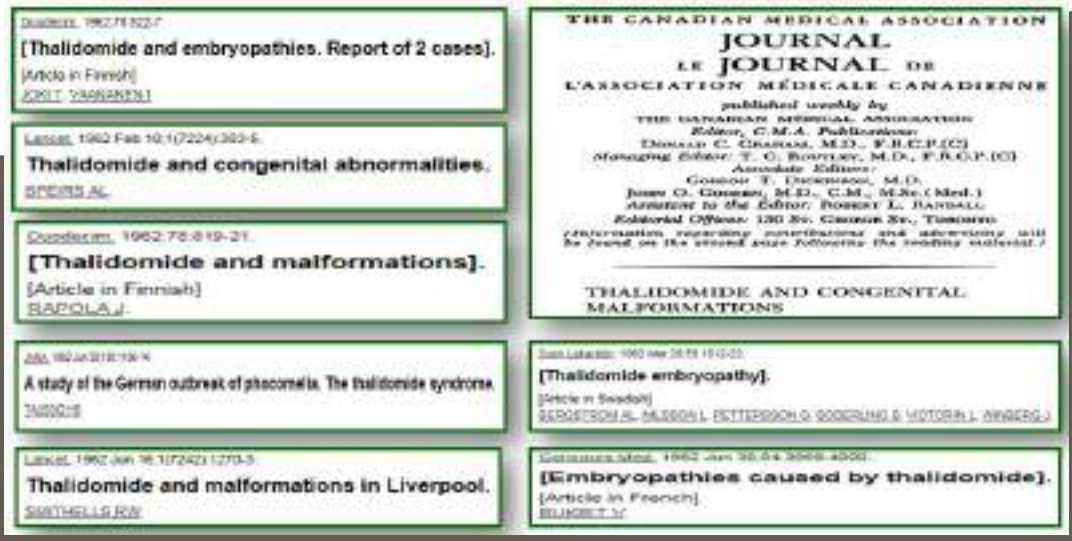
A huge number of scientific articles that concern the efficacy and safety of the active substances that are contained in the medicinal products marketed worldwide, are published every year in scientific journals.
In some cases, the scientific data included in the published articles were so significant that they changed the course of pharmaceutical history. Perhaps the most well-known and tragic example was provided by the drug Thalidomide. Thalidomide was first introduced for human use in 1956 and it was indicated for nausea and as a sedative and hypnotic: it was recommended for the treatment of morning sickness in pregnant women although at the time the company had no evidence that it was effective.

Between 1961 and 1962, more than 100 scientific articles were published in scientific journals, on the association between the usage of Thalidomide during pregnancy and of phocomelia in newborn children [Figure 1] and finally thalidomide was withdrawn from the worldwide market (unfortunately, more than 10.000 children were born with phocomelia). [1] This case led to sweeping changes, especially in the procedures relating to the conduct of research and development of new medicinal products, and stricter protocols for the conduct of clinical trials were introduced. Also, the Competent Authorities now request more safety and efficacy data, before they will approve new medicinal products.
Furthermore, the important findings published in scientific journals over the past few decades, led the European Medicines Agency (EMA) to add to the Pharmacovigilance Legislation, the following:

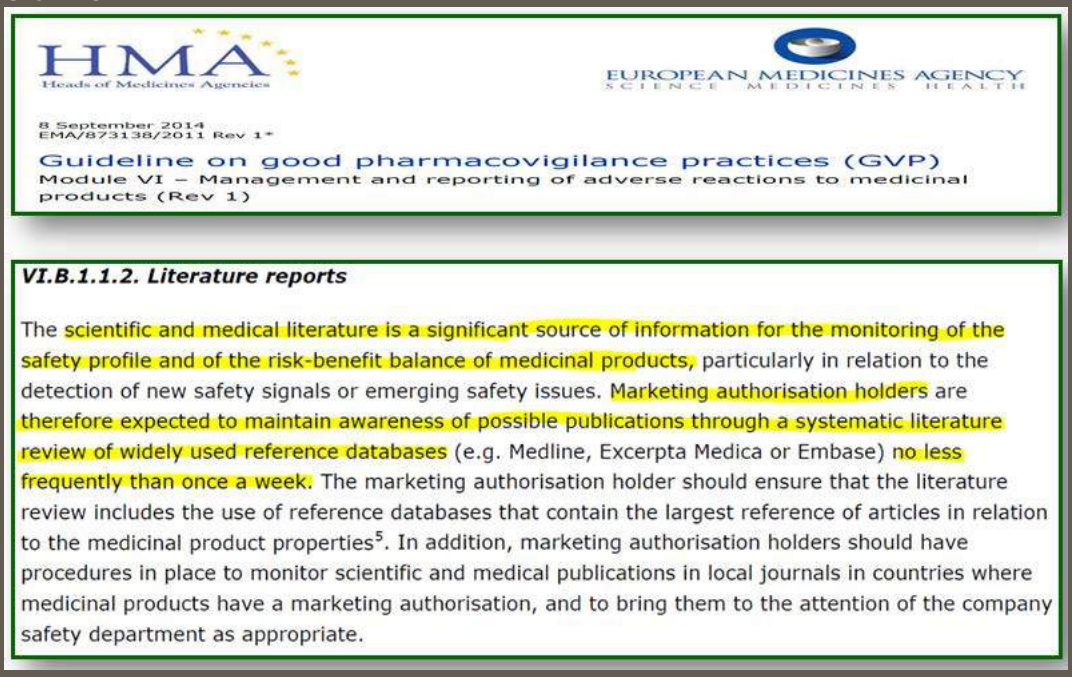
- the worldwide literature must be reviewed on a weekly basis by the Marketing Authorisation Holders
- all the important scientific data that concerns the safety and efficacy of their medicinal products must be recorded in their databases and must be reported to the EMA (if the criteria set by EMA are met). [2] [Figure 2]

As a result of the above, scientific articles have become an integral part of the process for ensuring the efficacy and safety of the medicinal products and the healthcare professionals must therefore be encouraged to publish their findings. This process enhances the quality of the safety databases and should lead to the early detection of any serious adverse reactions of medicinal products.

[Figure 1]



[Figure 2]



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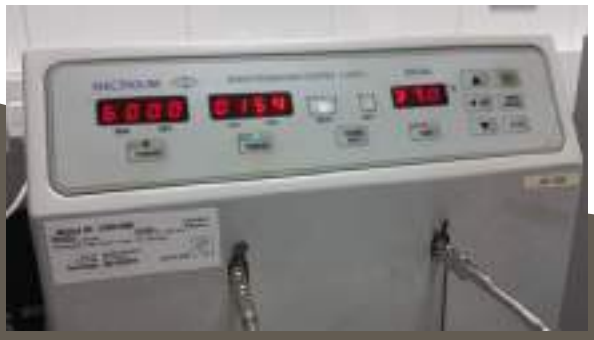
The ABC of Pharmacy:
Disintegration Tests For Solid Oral Dosage Forms

The preferred route of administration of most drugs that are intended to exert an effect following absorption from the gastrointestinal tract is via the mouth. This means that after the dosage form has been swallowed it will need to release the drug into the fluid in the stomach or the small intestine so that it can dissolve and then be absorbed. Consequently it will be initially necessary for the tablet or capsule to break up, a process which is usually referred to as disintegration. This will not be necessary for a drug which is swallowed as a solution from which absorption may begin as soon as the mixture reaches the stomach. Historically, solid dosage forms may not have passed the test which is used nowadays. For example, in Medieval times a lump of the metal antimony was swallowed as a purgative and as the effect was almost explosive then the device could be extracted from the faeces, washed and saved for future use. Since only a very small amount of antimony would dissolve with each passage through the intestine it was common, if not necessarily hygienic, practice for the devices to be handed down from one generation to another. In more recent times medicines were presented as pills which were solid spheres of excipients in which the drug was suspended and it was always considered doubtful whether these broke up (disintegrated) in the stomach especially when they were coated with silver or gold. In an attempt to ensure that this did not happen with the more modern tablets, a disintegration test was introduced in the 1945 British Pharmacopoeia and was followed by the United States Pharmacopoeia in 1950. The same test was adopted for use with capsules in the 1968 British Pharmacopoeia: in 2008 the International Committee on Harmonisation issued a method which had been approved by the European, United States and Japanese Pharmacopoeias, in all of which it is now included.

The test apparatus consists of a rack of six open-ended transparent tubes 77.5 mm long and 21.8 mm in diameter (internal) mounted between two plates and the whole arrangement is hung below a shaft which is used to attach it to a device which can raise and lower the baskets at a frequency of 29 - 32 cycles per minute with a stroke of between 50 and 60 mm. The lower ends of the tubes are covered with wire gauze which is woven in such a way as to produce a mesh of 2 mm dimension. Each tube is also provided with a plastic disc 9.5 mm in diameter which has five 2 mm holes and 4 peripheral tapered grooves. These discs are inserted into the tubes, if this is stipulated in the relevant monograph, once a single tablet or capsule has been placed in each tube. The apparatus is then positioned in a 1 litre beaker containing the prescribed liquid (distilled water or buffer solution) which is maintained at 37±2°C and run for the time set indicated in the relevant monograph by the end of which all parts of the each tablet or capsule must have passed through the mesh although bits of the tablet coating or



capsule shell are permitted to remain. For a tablet or capsule that is intended to release the drug as soon as possible after administration the dosage form must disintegrate with 15 minutes in the case of tablets and 30 minutes for both hard and soft gelatin capsules. For some tablets and capsules these times are different and are specified in the individual monographs. If any of the dosage forms do not satisfy this requirement then the whole batch of the product has failed the test.

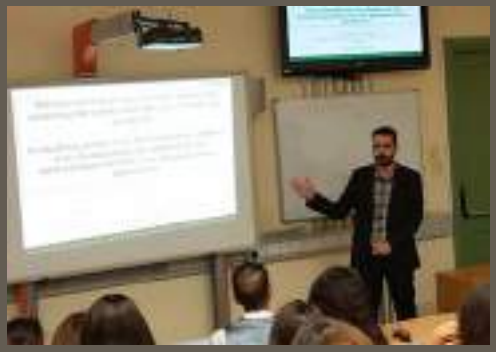
The apparatus described above is for use with unit doses that are up to 18 mm in their longest dimension. For units larger than this the apparatus differs but only in that there are only 3 tubes with an internal diameter of about 31.5 mm. In all other respects, the system is the same as the one described above both in terms of construction and use.

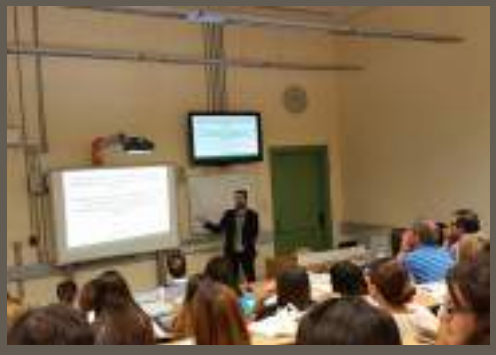
The use of both sizes of disintegration apparatus has been extended to the testing of other solid dosage forms for oral administration such as soluble tablets, dispersible tablets (both of which added to water before swallowing) and orodispersible tablets (which disintegrate in the mouth). The design of the test is altered only in terms of the length of time over which it is run since these dosage forms must disintegrate very rapidly. A much bigger change is made for tablets or capsules to which a coat that is resistant to acid had been applied. Here, the test is comprised of 2 phases: the first involves the use of 0.1M hydrochloric acid as the liquid medium and the test is run for 2 hours after which the dosage form should still be intact, although it may be deemed to have passed this phase of the test if it maintains its integrity for 1 hour. The medium is then replaced with a buffer of pH 6.8 (almost neutral) in which the dosage form should disintegrate in 1 hour. In the table below these tests are summarized together with their acceptance levels and the former time has been labelled TIME (a) and the latter TIME (n) which is also used for the dosage forms where only the one stage test is used. These are the standard pharmacopoeial times but these can be different for specific products, for example 5 and 30 minutes for Aloxiprin and Cephalexin tablets respectively.

DOSAGE FORM	MEDIUM	TEMPERATURE	TIME (a)	TIME (n)
UNCOATED TABLETS	Water	35 - 39°C		15 min
COATED TABLETS	Water	35 - 39°C		30 min
CAPSULES (HARD & SOFT)	Water	35 - 39°C		30 min
GASTRO-RESISTANT TABLETS & CAPSULES	0.1M HCl, pH 6.8 buffer	35 - 39°C	> 60 min	60 min
SOLUBLE TABLETS	Water	15 - 29°C	> 60 min	60 min
ORODISPERSIBLE TABLETS	Water	35 - 39°C		3 min
DISPERSIBLE TABLETS	Water	15 - 25°C		3 min

So, what do we learn from disintegration tests? The test is really only intended to show that the dosage form has been properly formulated in that once it comes into contact with water it swells up and breaks up into numerous small pieces (> 2 mm) which will in turn disaggregate to produce particles which are small enough to dissolve. It was a very important test when it was first introduced because the excipients which were used to encourage disintegration of the dosage forms were not as sophisticated as they are today. Consequently if a tablet disintegrated in less than 15 minutes then there was every likelihood that it would produce acceptable blood levels in a reasonable time. However it is not, and was never intended to be, able to predict what blood levels might be achieved after administration. Modern dosage forms disintegrate much more quickly than 15 minutes but this does not indicate that all the contained drug will be rapidly and completely absorbed. The laboratory test which is used to indicate this correlation is the dissolution test which measures the rate at which the active ingredient actually goes into solution (this technique will be dealt with in a future article). To all intents and purposes the dissolution test has superseded the disintegration test although the latter still serves a useful purpose in the design and development and in the monitoring of the quality of the dosage forms during the manufacturing process since it can be carried out relatively quickly. ■

Corporate Social Responsibility:
Remedica Cares





Open Access Week

As part of the International Open Access Week (24 - 30 October 2016) an event was organised by the Cyprus University of Technology (CUT). During the event various lectures were given dealing with open access while the vice dean welcomed the attendees and acknowledged Remedica's financial support for the «Cyprus University of Technology Open Access Author Fund» over a number of years. Among the lectures presented was one given by Remedica's Head of Drug Safety Department/Pharmacovigilance, Andreas Vasiliou, with the title "The crucial role of the scientific articles for ensuring the safety and efficacy of medicinal products"

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A glimpse of Cyprus: Monuments and Archeological Sites of Cyprus included in the Catalogue of the World Cultural Heritage of UNESCO

The rapid and uncontrollable rhythm of financial growth observed over the last few decades has presented an increasing threat to the archaeological sites and cultural monuments identified by UNESCO during its General Conference in 1972 and their adoption under the Convention for the Protection of the World Cultural and Natural Heritage.

This convention is of a great importance and value to humanity and promotes the registration, protection and conservation of the cultural and natural heritage. It has as its primary objective the defining and the protection of this global heritage through the creation of a catalogue which includes those sites whose value has to be preserved. Since 1992 this convention has been administered by the Centre of Global Heritage with its head office located in Paris.

In 1975 the Republic of Cyprus validated the Convention jointly with the rest of the EU Member States and thus ensured the protection of global heritage sites. It should be noted that Cyprus, because of its important archeological sites and Byzantine churches that exist within its territory, was one of the first Member States to sign the Convention. It also managed to get sites and monuments that are located on the island included in the Catalogue of Global Heritage.

To date, Cyprus has made three registrations: The first registration took place on 1980 and included the Sanctuary of Aphrodite in Kouklia (Palaipaphos) and Nea Paphos today's Kato Paphos (Paphos' down town) for two main reasons. Firstly, for the role that the area of Paphos played regarding the worship of Aphrodite, the local goddess of fertility and the global goddess of love and beauty. The second reason was that Cyprus and, especially Paphos, played a major role in the expansion of Christianity, because it is the home of Apostolos Pavlos. Some of the registrations on the catalogue are the mosaics of Roman period (Dionysus' Mansion, Theseus Mansion) as well as the "Kings' Tombs" of the Hellenistic period. The most important monuments of Palaipaphos are the Sanctuary of Aphrodite, the Medieval Agrepavlis, the church of Panagia Katholiki, Leda's House, the Fortification Wall and the Palace on the site Hadji Abdoullah, the Necropolis and the Medieval Sugar-mill.

It is important to state that Nea Paphos is one of the most important archeological sites in Cyprus which was established towards the end of 4th century B.C. by the king of Paphos Nikoklis. Until the end of 2nd century B.C. it was the political and financial centre of the area and Ptolemies who had their seat in Alexandria transferred their capital there. In the 4th century B.C. because of the earthquakes that took place on the island the capital was transferred to Salamina but Paphos retains its important position amongst the rest of the cities because of the existence of the Temple of Aphrodite in Palaipaphos. The most important monuments of Nea Paphos are: the Dionysus' Mansion, Orfea's House, the Theseus' Mansion, the Century's Mansion, the Roman Market, the Conservatory and the Asklepion, the Theatre, Vasiliki of Chrysopolitissa, and the Fortress of Saranta Kolones.

The second registration took place on 1985 and included the Byzantine and Meta-Byzantine churches in Troodos. These monuments were added to the catalogue because (a) they represent a testimony to the existence of Byzantine culture on the island, (b) they are important examples of ecclesiastic architecture which are in a very good state of repair and (c) the art in these churches presents evidence of the relation between Eastern and Western Christian art. Some examples of these ecclesiastic monuments are the Holy Monastery of Agios Nikolaos Stegis in Kakopetria, the Holy Monastery of Osios Ioannis Lampadistis in Kalopanagiotis, the Holy Monastery of Panagia Forbiotissa (or Asinou) in Nikitari, the Holy Monastery of Panagia Araka in Lagoudera, the Church of Panagia of Moutoullas in Moutoullas, the Church of Archangelos Michael in Pedoulas and many more.

The third registration took place in 1998 and included the archeological site of Neolithic settlement of Chirokoitia. This settlement is included in the catalogue for three main reasons: because of the fact that it is one of the most important archeological sites of the Neolithic period that is extremely well maintained. It has revealed much valuable scientific data regarding the expansion of the civilization and culture from Asia to the Mediterranean region, and lastly both the artifacts discovered and the parts of the site which have not yet been excavated clearly provide evidence of the creation of a permanent settlement in the Mediterranean.

In conclusion, it is important that as rational thinking citizens and inhabitants of Cyprus that we understand and appreciate the importance of our cultural heritage and to preserve it for future generations to study and enjoy.

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