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Packaging Challenges in Multiplanets

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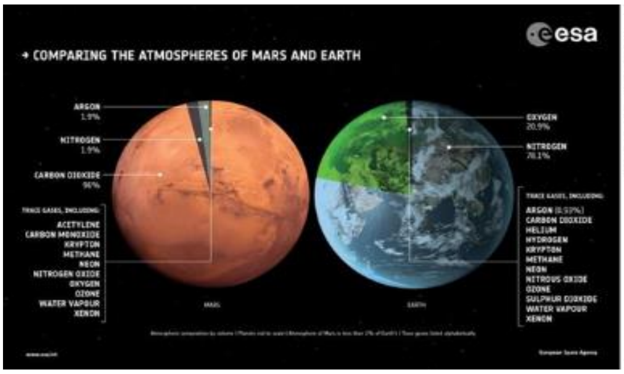
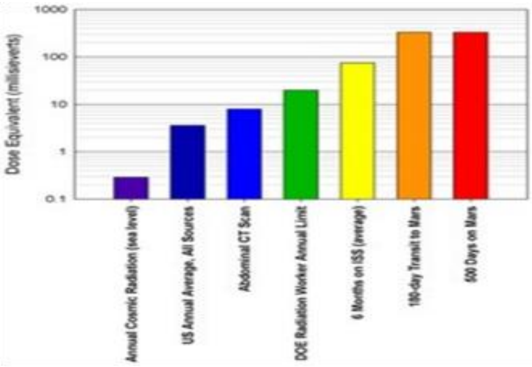
Abstract

I have been involved in basic research for more than 10 years for innovation of wide range of pharmaceutical products New "Packaging design for Drug delivery" like "Solid doses, Injectables (for anti-cancer, HIV, wide range of vaccines, Covid -19 drugs and Biosimilar products) in "Microgravity Environment like MARS mission. Looking at the present ecological imbalance Scientists are thinking for multiplanetary living system in order to survive human species. As we know different planets having critical climatic conditions and Packaging will play a vital role. We as a scientist have clear vision about things are going to happen after 100 years in other planets and from now, we have to keep ready "Packaging designs and delivery systems" for life savings drugs and essential medicines for Astronauts and visitors.

Keywords: *anti-cancer, HIV, wide range of vaccines, Covid -19 drugs and Biosimilar products.*

Mars Vs Earth Comparisons





Earth

Mars

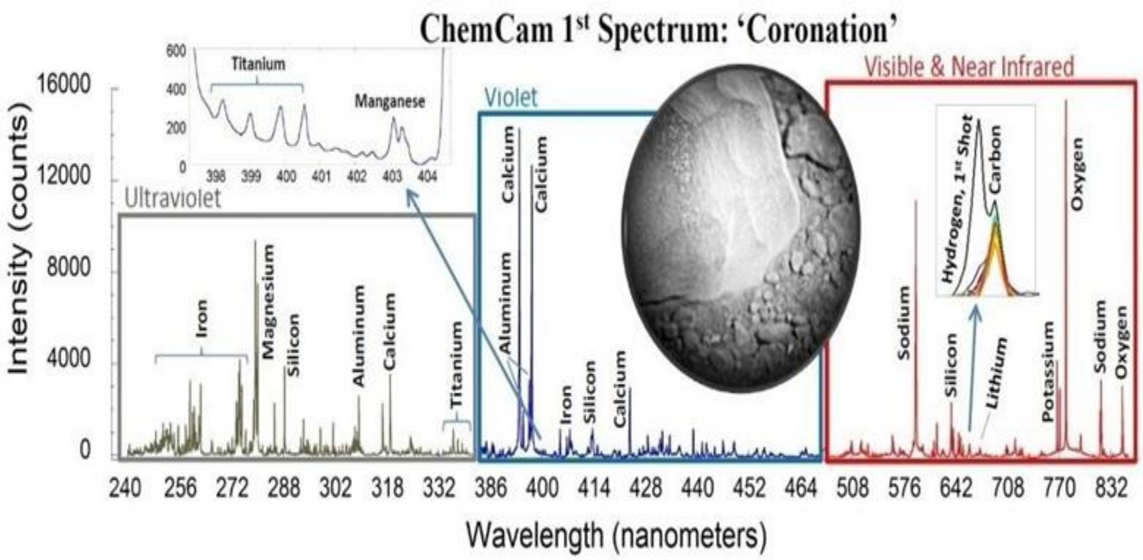
Climatic conditions

Minimum Temp	*-81-degree F*
Maximum Temp	*+70 degree. F (winter)*
Distance from Sun	*141000000 miles*
Diameter at equator	*4222 miles*
CO^2	*95.32 %*
N^2	*2.7%*
O^2	*0.13%*
Argon	*1.6%*
Gravity	*3.72076 ms-2(approx. 38% of Earth)*

Note: Also observed: water, nitrogen oxide, neon, hydrogen-deuterium-oxygen, krypton and xenon.

Radiation: 24-30 rads or 240-300 mSv per year. This is about 40-50 times the average on Earth.	**EARTH**	**MARS**
Weight	*5.972 × 10^24 kg*	*6.39 × 10^23 kg*
Gravitational force	*9.8m/s2*	*3.711 m/s2*
Minerals		
Max /Min Tp	*Max 58 Deg.C / (-88 Deg.C)*	*Max 30 Deg.C /-153 Deg.C)*
Rh	*30 % Average*	*80- 100 %*
Ice/water	*yes*	*yes*
Gases	*Contains 78% nitrogen and 20% oxygen. There are also small amounts of other gases, including carbon dioxide (0.04%)*	*96% carbon dioxide and only 0.145% oxygen. The Martian atmosphere is also "thin", because it is 100 times less dense than Earth's atmosphere*
Hydrogen		*Source of energy*
Wind strength	*60 miles an hour*	*60 miles an hour*

Soil on earth and mars

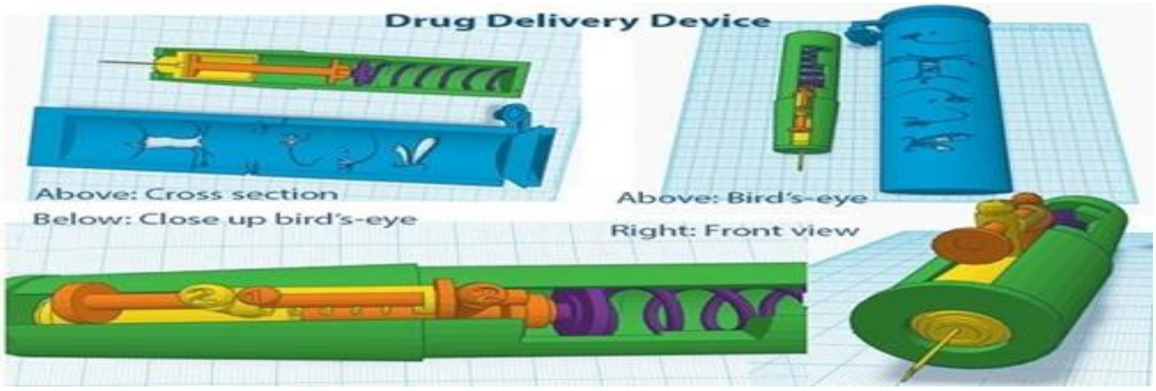


Wave length

Critical Parameters: Surface temperature Atmospheric pressure Atmospheric composition Carbon/oxygen cycles Nitrogen cycles Magnetic fields achieve temperatures and pressures similar to standard atmospheric temperature and pressure here on Earth.

Pharmaceutical Plant Design for MARS

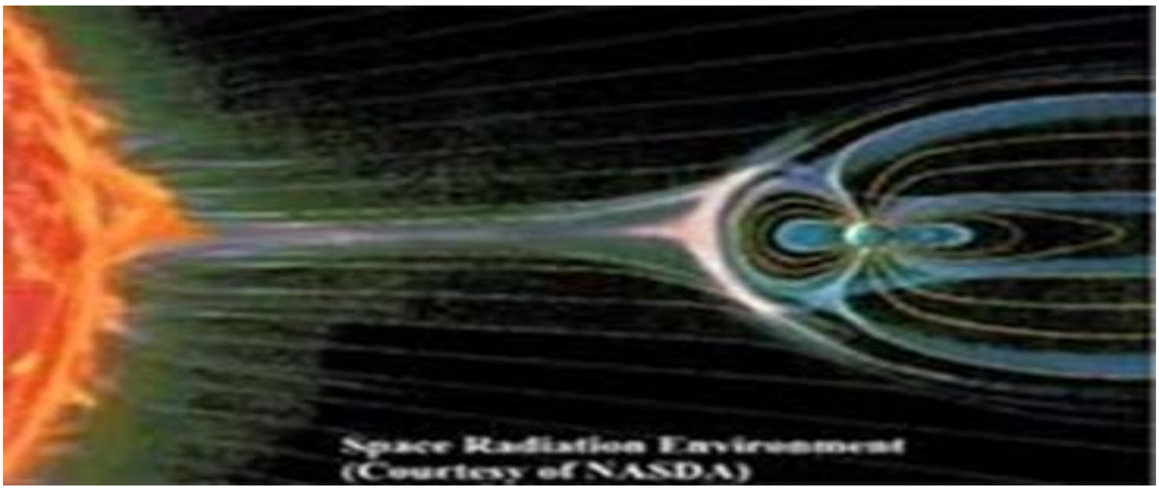
How Injectable device will work in MARS



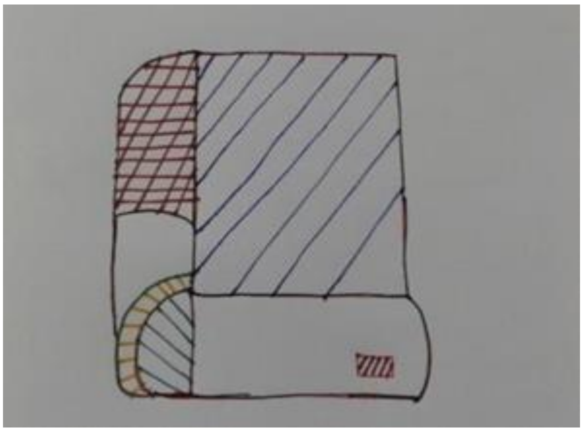
Drug Delivery Device

Application Methods

1. Draw up the drug by the needle from the vial with the piece labeled “1” and lock it in place by rotating it to the side.
2. Load the spring by pulling both bars labeled “2” into the slots at the end.
3. Before administrate the drug, press the device against your leg or arm and release the bars from the slots. This will release the spring and simultaneously push the needle into the body and inject the medication. The device and the container should be printed out of plastic, and the needle should be printed from stainless steel. It is designed for both the microgravity trip and the one-third gravity of Mars.



High radiation In Microgravity and Packaging solutions



Tablet/capsule Dispensing (Manual operation)

Packaging for Solid Doses products (Microgravity)

Recommendations:

1. In order to avoid extremeheat and radiationbetter t o use “Multilayer bottles (black coating inside)
2. Outside and inside “Black ink (food grade) layer need to use.

Packaging for “Injectables” (Microgravity)

Recommendations:

1. Outer surface of the “Vial, PFS and cartridges” should be “Lacquer with gold ink”
2. You can go for “black /gold lacquering

1 2

Bubble Free Injection Syringein Space a Big Challenge

- During or before administration on Earth we are ra rely facing “Air bubble “formationinside the syringe. Whereas on MARS i t’s common due to low gravity
- A single air bubble into a crewmember is harmful.

Air bubble

Recommendation

Applied "Electromagnetic field" inside the "Auto inject or" to infuse the Air bubbles.
We can avoid delamination inside the syringe if we use following:

1. Plunger inner surface can be coated with "Silicon oil"
2. Change of "Sterilization process"
3. Can be use COC/COP syringes.
4. Possible to use "Fluoropolymer coating" inside the syringe surface.
5. Rectification of product formulation i.e reduce Ph o f the product if possible.

Extractable and leachable are most important for inh alers and catheters. For an extractables from a device component the AET (µg/g) can be determine d using Equation 1: Equation 1

AET = SCT. Dt

Dd m

Dd- Doses per day

Dt- Total Labelle doses

m - mass of component

The AET (µg/device) for a drug delivery device (*e.g.,* an MDI) can be determined from Equati on 2: *AET = SCT. Dt*

Dd

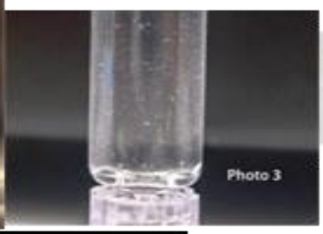
Dd- Doses per day

Dt- Total Labelle doses

Delamination of Glass, inhaler and catheters

There are many cases we observed Astronauts are facing breathing problems, so this is advisable they should carry sufficient numbers of "Inhalers". Packaging technologists are playing major role for selection of primary packing m aterials, designing and final packing.

We should be very much carefulto avoid corrotion, le akage, extractable & leachables. Better not to use a ny coloured lacquersinside surface of the "Inhalercyli nder. Design has to be validated.



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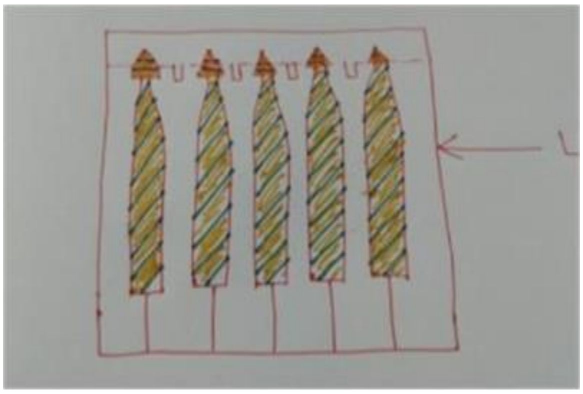
Eye ointments Packaging

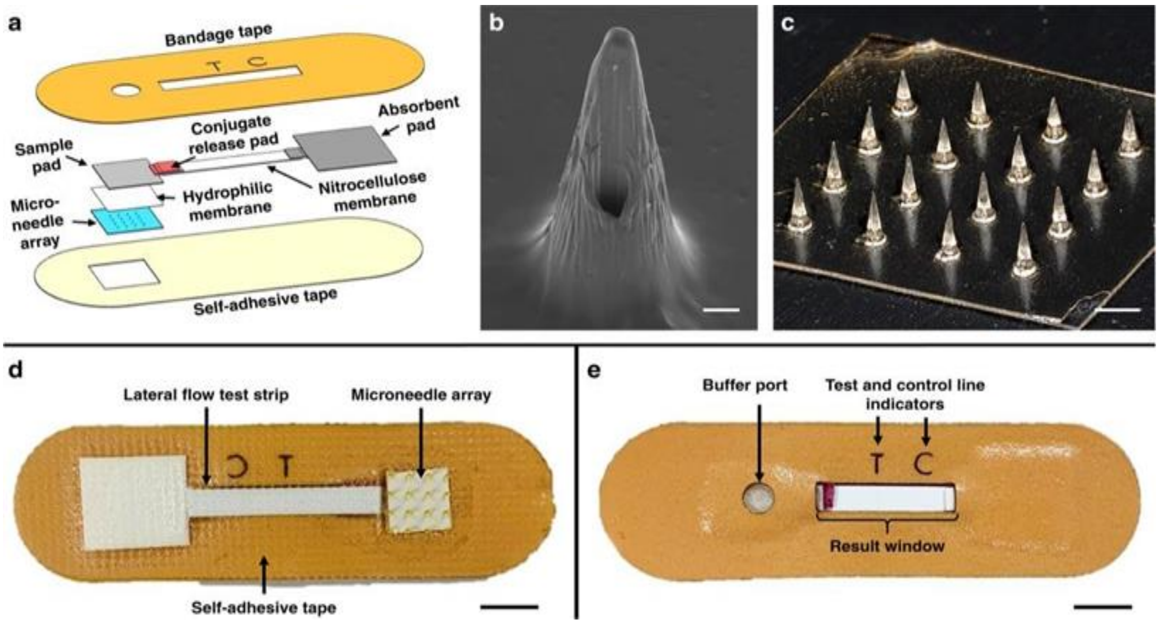
As you know due to extreme heat and radiation "Fluid of eyes" get dries, so Astronauts need to carry "eye ointments" those should have single dose" and make sure 100% product will come out in one press. Recommend to use "LDPE or LLDPE" for primary packaging materials. One strip should contain 5 tubes and should be vacuum-packed.



Fluid of eyes

Nitrocellulose patches Packaging

Burning skin is the most common thing in Microgravity environment. So, Astronauts and visitors have to carry sufficient numbers of this item. This has to keep in a cool place and packed in a "Gold lacquered" Tin or Aluminum box.



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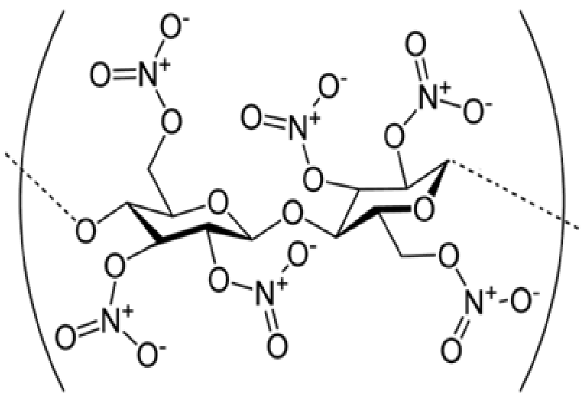
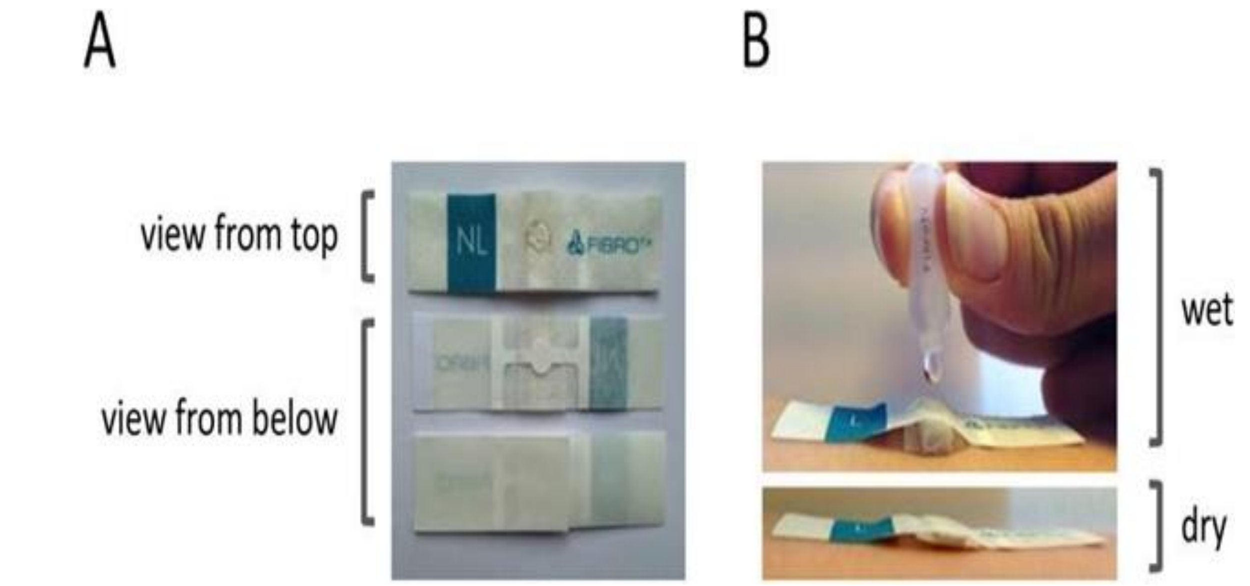


Chemical Structure of Nitrocellulose



A & B

Risk Ratings and Dispositions per Design Reference Mission (DRM) Category

DRM Categories	Mission Duration	Operations		Long Term Health	
		LxC	***Risk Disposition****	***LxC***	***Risk Disposition****
Low Earth Orbit	*Planetary*	*3x2*	*Accepted*	*3X2*	*Accepted*
	Planetary	*3x3*	*Accepted*	*3X2*	*Accepted*
Deep Space Sortie	*Planetary*	*3x2*	*Accepted*	*3X1*	*Accepted*
Lunar Visit/ Habitation	*Planetary*	*3x3*	*Requires Mitigation*	*3X2*	*Requires Mitigation*
Deep Space Journey/Habitation	*Planetary*	*3x4*	*Requires Mitigation*	*3X4*	*Requires Mitigation*
Planetary	*Planetary*	*3x4*	*Requires Mitigation*	*3X4*	*Requires Mitigation*

Medical device Regulations for space (Drafting is going on) Medical device safety

- Medical device safety and risk management
- Effectiveness/performance of medical devices
- Phases in the life span of a medical device
- Participants in ensuring the safety of medical devices
- The role of each participant/stakeholder
- Shared responsibility for medical device safety and performance

Governmental regulation of medical devices

- Critical elements for regulatory attention
- Stages of regulatory control
- A common framework for medical device regulations
- Regulatory tools and general requirements
- Product control
- Vendor establishment control
- Post-market surveillance/vigilance
- Quality system requirements

References

1. Humans in Space, International Space Station (ISS), Space Station Research and Technology.
2. NASA Technology Transfer Program on twitter @NASAsolutions.
3. Handheld Diagnostic Device Delivers Quick Medical Readings.