



O ESTADO DA ARTE DA NANOTECNOLOGIA NO BRASIL E O SEU DESENVOLVIMENTO NO SETOR DE COSMÉTICOS

Nanometrologia: painel setorial de cosméticos do Inmetro

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Outline



N&N Brazil



Regulatory concerns



Technical aspects

Outline

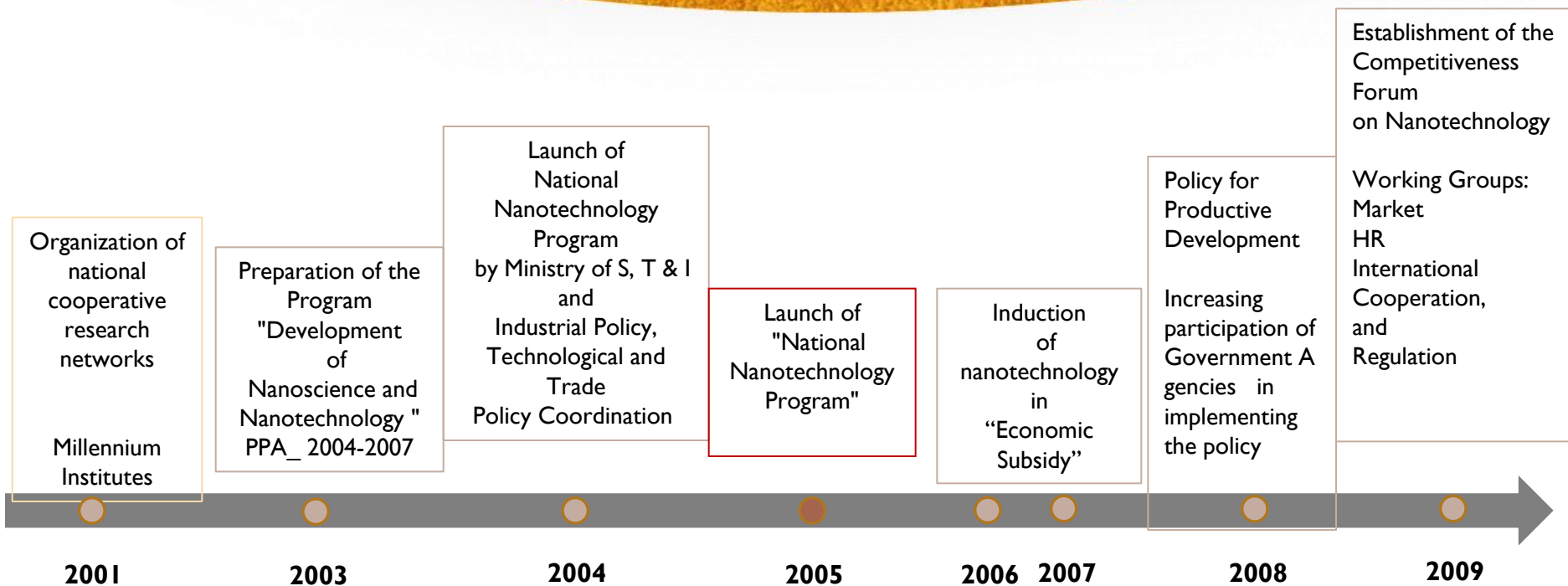


N&N Brazil



Nanotechnology in Brazil:

*delivery systems nanotherapeutics and nanomedicines and cosmetics
(some data)*



Nanotechnology in Brazil – Timeline

Source: MCT



Nanosciences & Nanotechnology Numbers & Facts in Brazil

Cooperative Networks: 24

National S&T Institutes on Nanotechnology:

Researchers > 2000



















Students > 2000

Around 2% of the world Nanosciences papers



Use the checkboxes below to view the records. You can choose to view those selected records, or you can exclude them (and view the others)..

Note: The number of records displayed may be greater than the listed Record Count if the original set contained more records than the number of records analyzed.

 View Records	Field: Country/Territory	Record Count	% of 16409	Bar Chart	 Save Analysis Data to File
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<input type="checkbox"/>	SOUTH KOREA	805	4.9058 %		
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<input type="checkbox"/>	CANADA	526	3.2056 %		
<input type="checkbox"/>	SWITZERLAND	376	2.2914 %		
<input type="checkbox"/>	SINGAPORE	337	2.0538 %		
<input type="checkbox"/>	TAIWAN	317	1.9319 %		
<input type="checkbox"/>	AUSTRALIA	309	1.8831 %		
<input type="checkbox"/>	BRAZIL	266	1.6211 %		

BRIC

NANO* AND DRUG, ano 2011
(Web of Science)

Developments in Biomedical Nanotechnology in Latin America

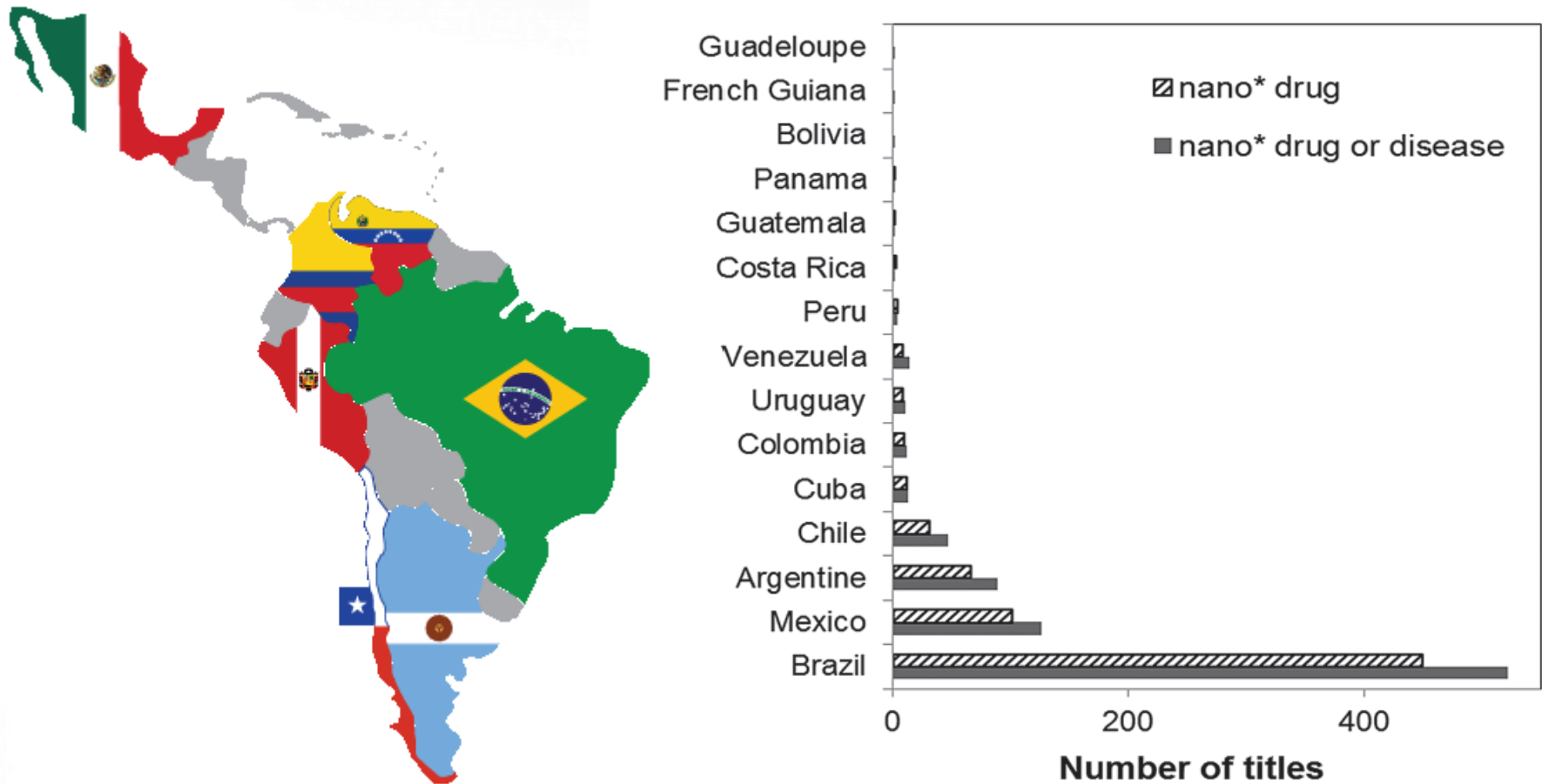


Fig. 1. Number of titles distributed by country in Latin America (Web of Science, Thomson Reuters, Dicember, 1st 2011).

NANOBIOTECHNOLOGY FOR DRUG DELIVERY IN BRAZIL

About 50 research groups in Universities
17 Networks on Nanotechnology

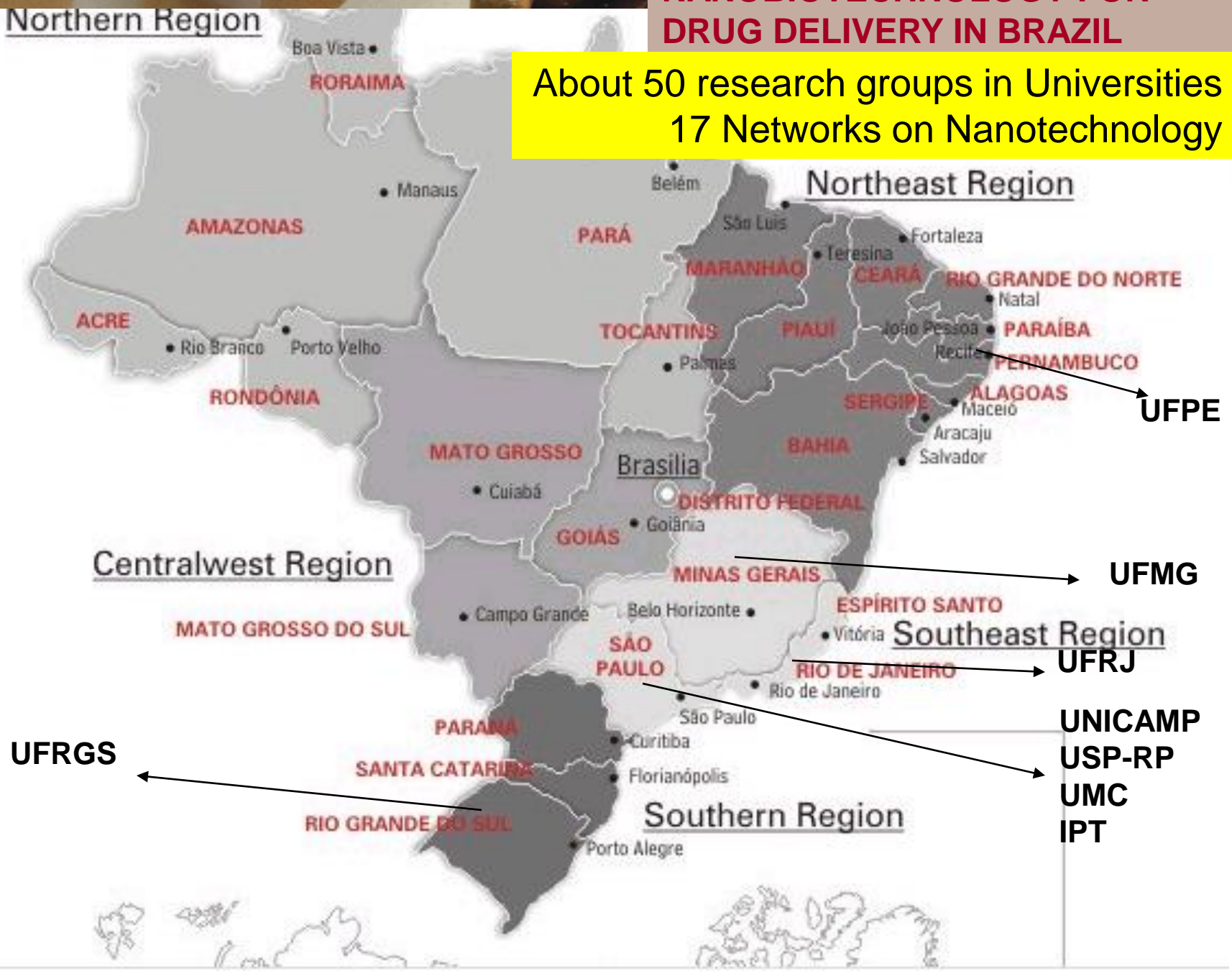
Northern Region

Northeast Region

Centralwest Region

Southeast Region

Southern Region



**Brazil is the third
ranking position in the
world market for
cosmetics.**

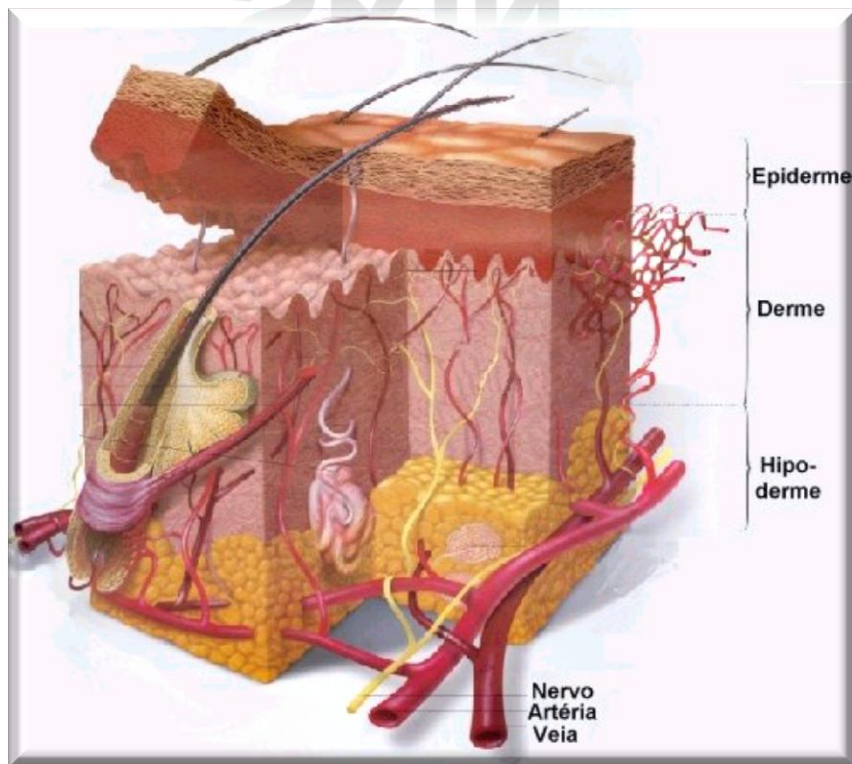
**The opportunity of
working with
nanotech applied
to cosmetics**



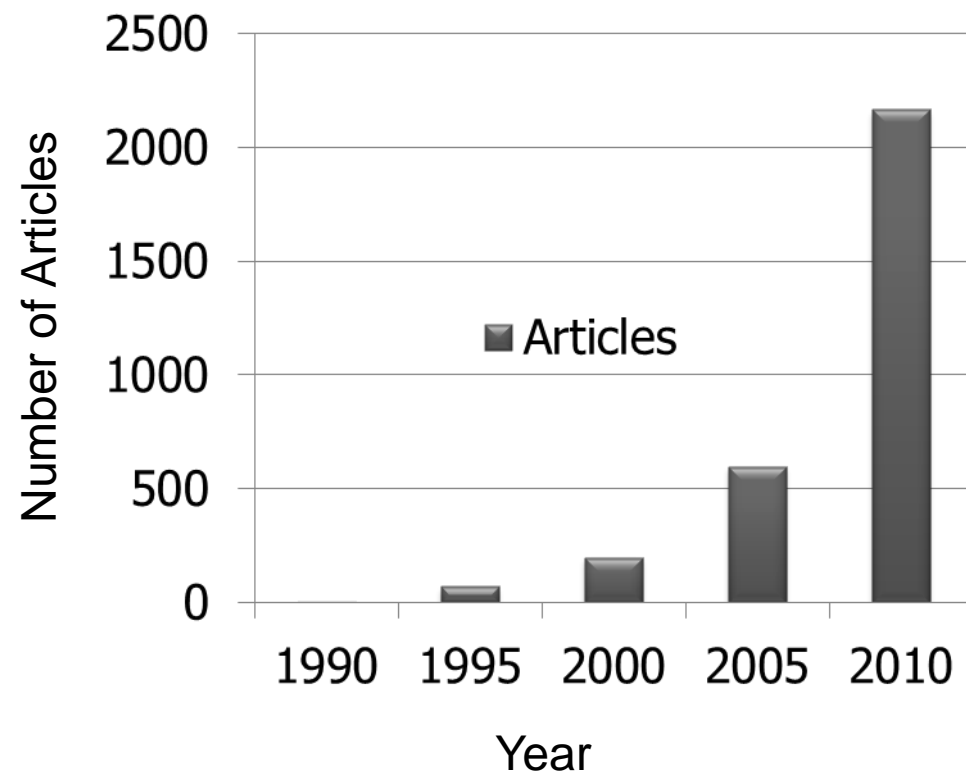
**Scientifically
instigating**

**Technologically
attractive**

SKIN



Evolution of published articles
Nano* *versus* Skin



Web of Science, 2011



2012: Challenges for the development of nanomaterials in Brazil

- Improve facilities to produce nanoformulations in adequate quality for clinical trials
- Validate scaled up processes
- Solve regulatory issues regarding safety, toxicity and environmental impacts



Outline



Regulatory concerns

REGULATORY ISSUES

Innocent until proven guilty



Guilty until proven innocent

(precautionary principle)

RECOMMENDATIONS


COMMISSION RECOMMENDATION

of 18 October 2011

on the definition of nanomaterial

(Text with EEA relevance)

(2011/696/EU)


- 
- (5) The definition of the term 'nanomaterial' should be based on available scientific knowledge.
 - (6) Measuring size and size distributions in nanomaterials is challenging in many cases and different measurement methods may not provide comparable results. Harmonised measurement methods must be developed with a view to ensuring that the application of the definition leads to consistent results across materials and over time. Until harmonised measurement methods are available, best available alternative methods should be applied.

HAS ADOPTED THIS RECOMMENDATION

1. Member States, the Union agencies and economic operators are invited to use the following definition of the term 'nanomaterial' in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies
2. 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

- 
- (17) Given the special circumstances prevailing in the pharmaceutical sector and the specialised nano-structured systems already in use, the definition in this Recommendation should not prejudice the use of the term 'nano' when defining certain pharmaceuticals and medical devices,



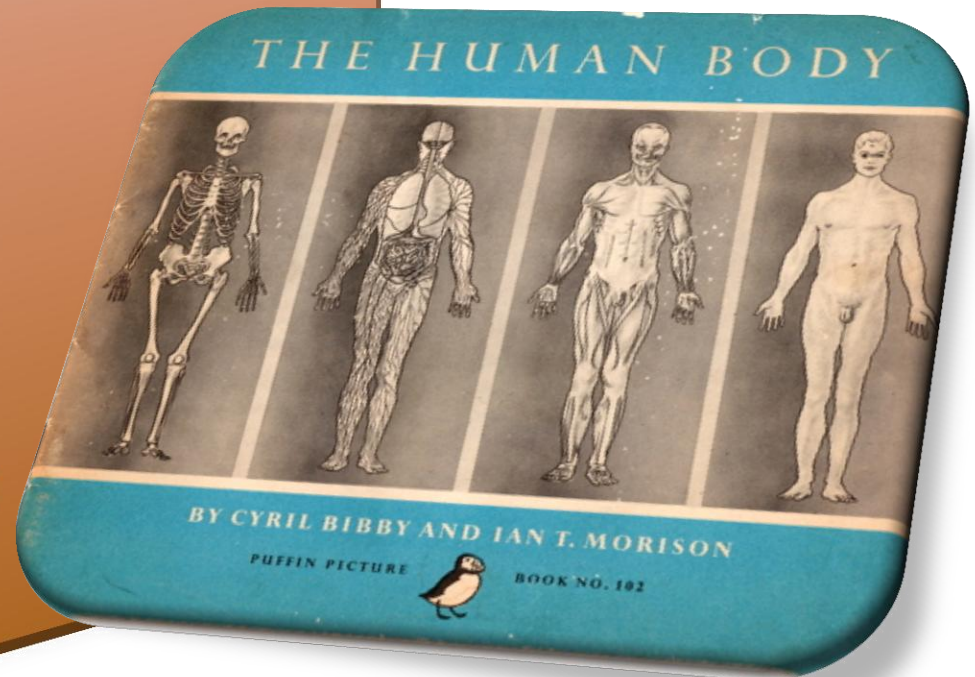
Outline



Technical aspects

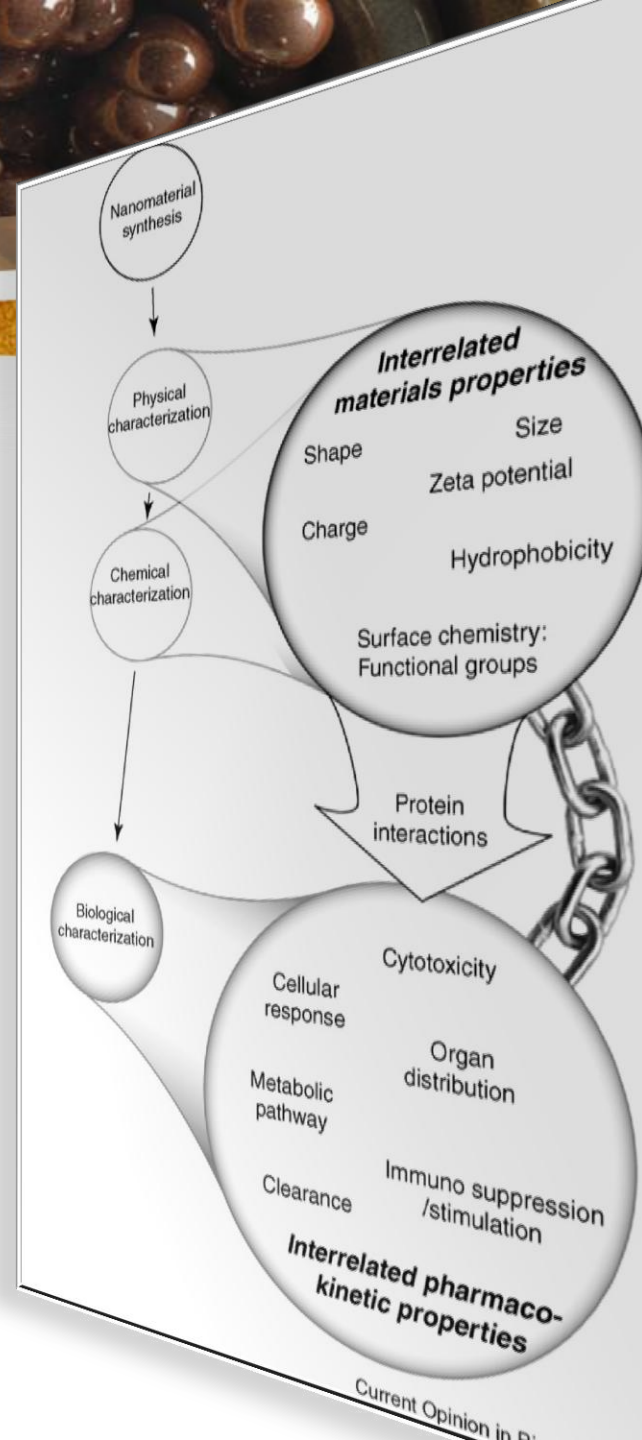
Physico-chemical properties

- Particle size and size distribution;
- Route of administration;
- Lability in biological medium;
- Crystallinity;
- State of aggregation;
- Composition;
- Surface coating;
- Preparation method;
- Purity

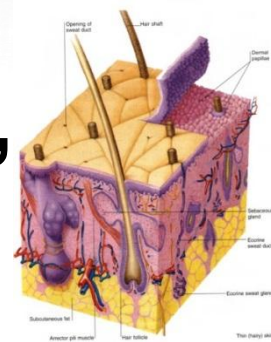


Relationship between physico-chemical properties of nanoparticles and biological responses

Fischer et al., Current Opinion in Biotechnology 2007, 18:565–571.



“NANO-SKIN AND HAIR EFFECTS”



Sustained and controlled release of substances
nanodevices act as reservoirs

Reduction of cutaneous allergic reactivity
polymeric wall

Increase of cutaneous adhesion
prolonged effect

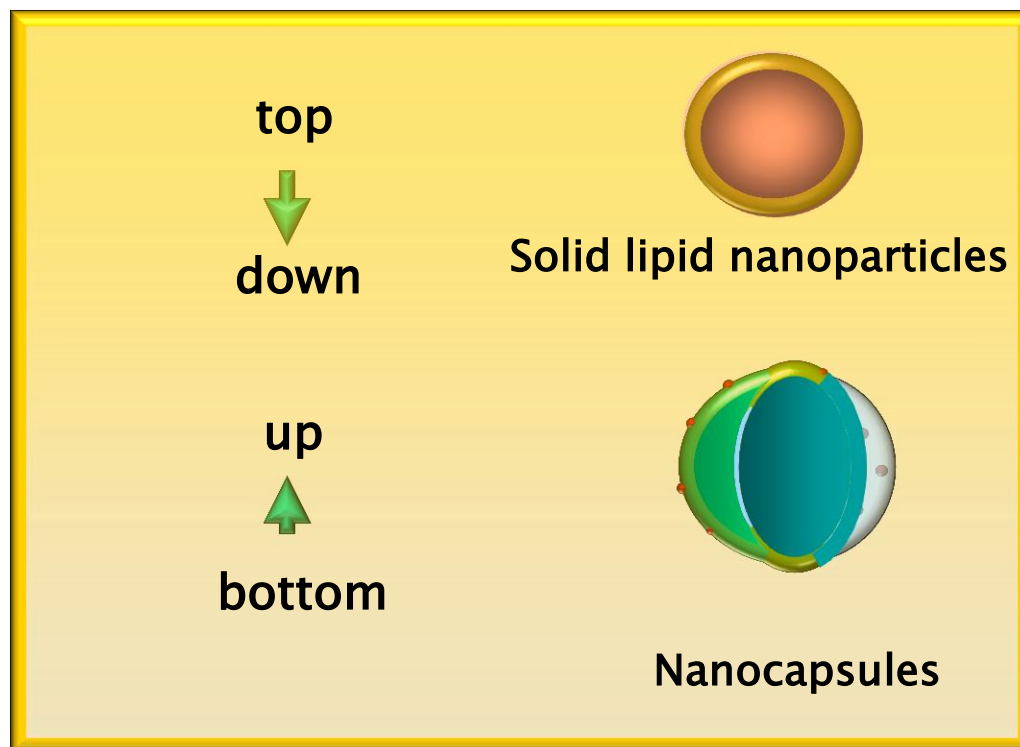
Stabilize labile substances
reservoir effects

Depend on

- shape and molecular organization of nanocarriers
- Size and polydispersity
- Surface coating (hydrophilic or lipophilic)
- surface area

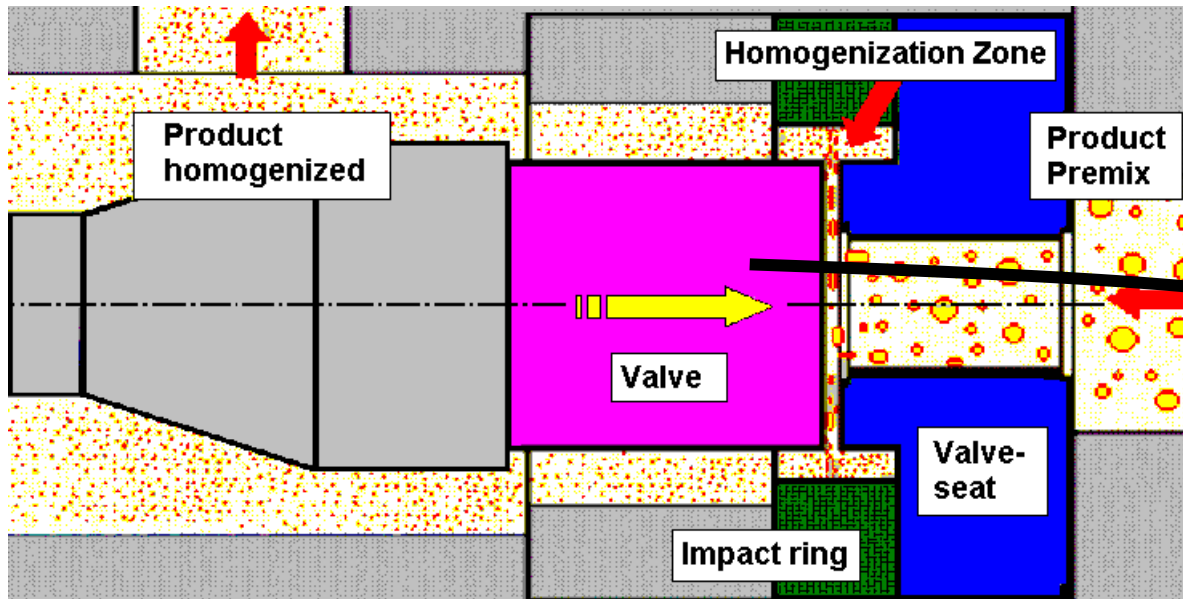


Preparation : strategies



High pressure homogenization

No organic solvent for the preparation: no explosion risks

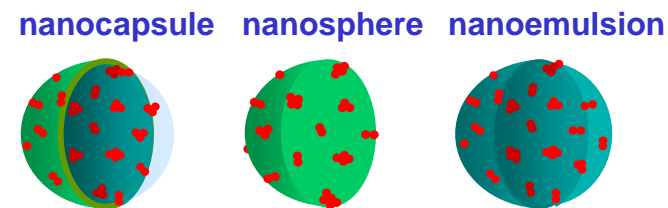
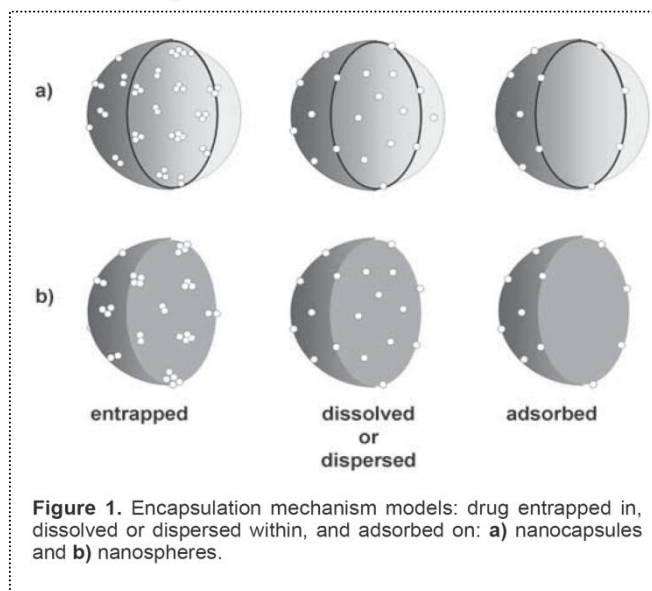
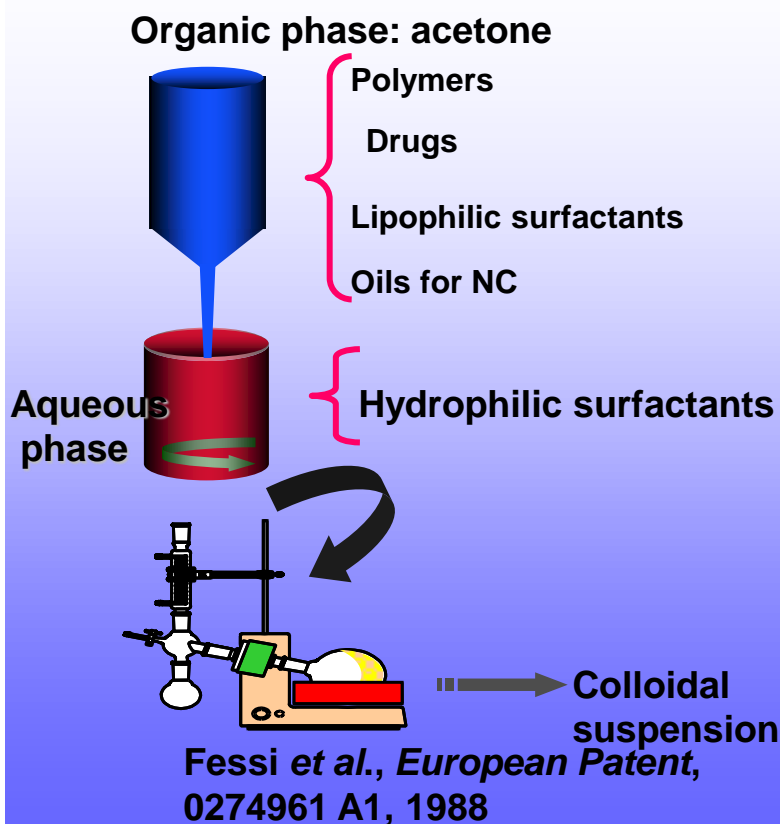


special homogenizing valve

Different scale equipments

mechanical process that involves the subdivision of particles or droplets into micron sizes

Polymer interfacial deposition

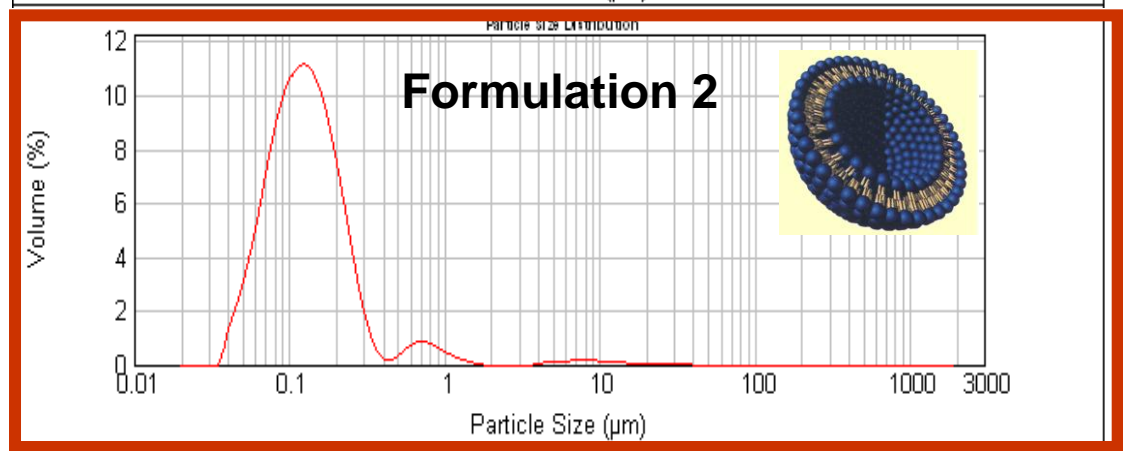
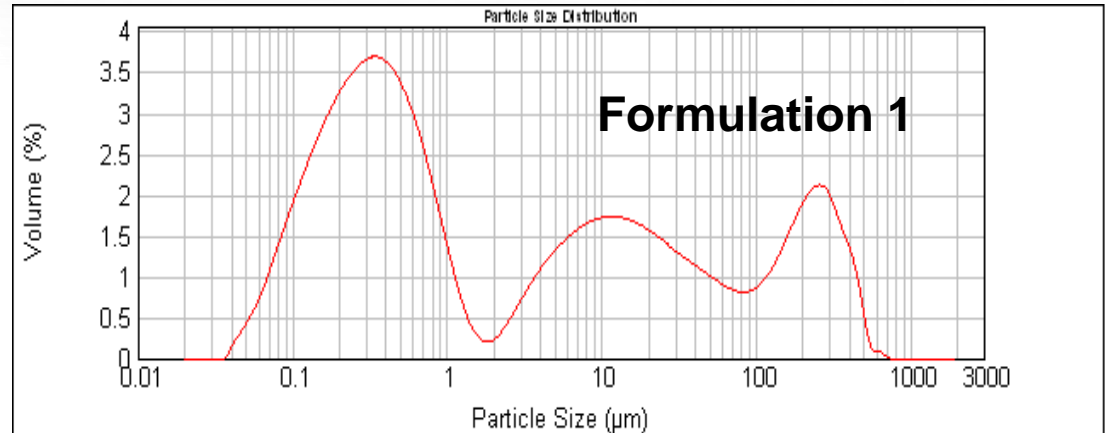
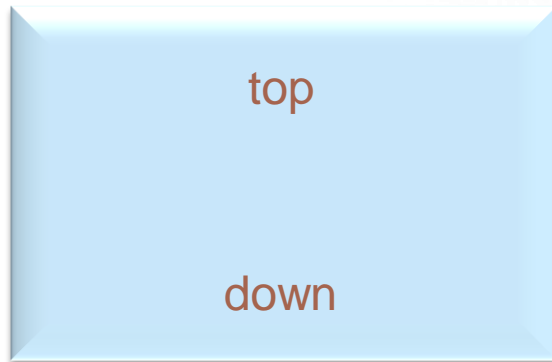


Guterres, 2012

Pre-formulation studies

liposomes

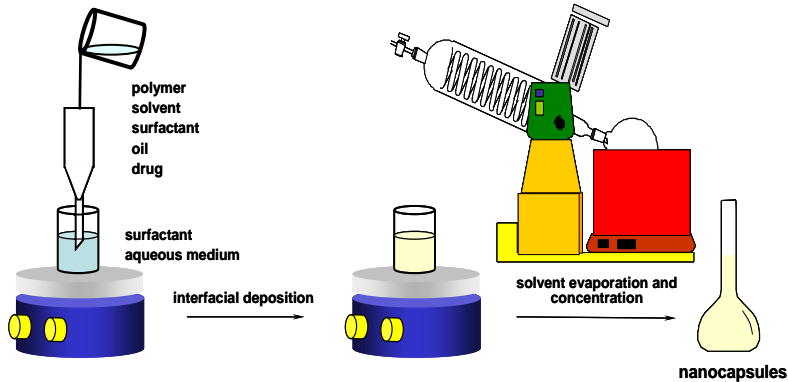
High pressure homogenization



Selection of formulations by
laser diffractometry

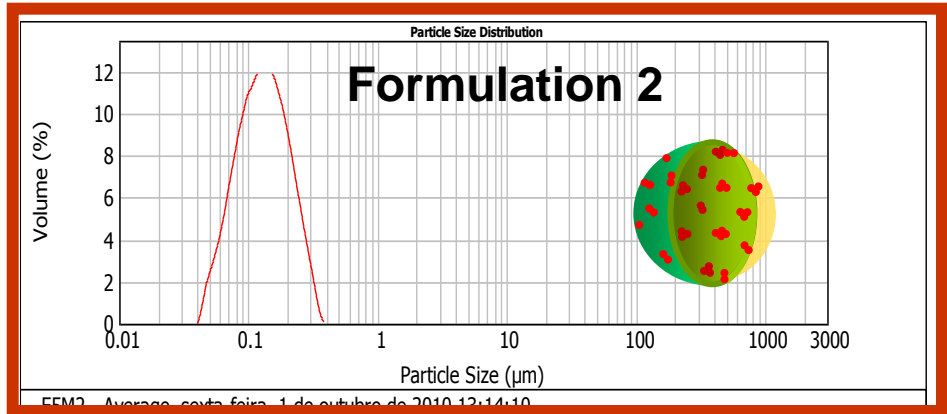
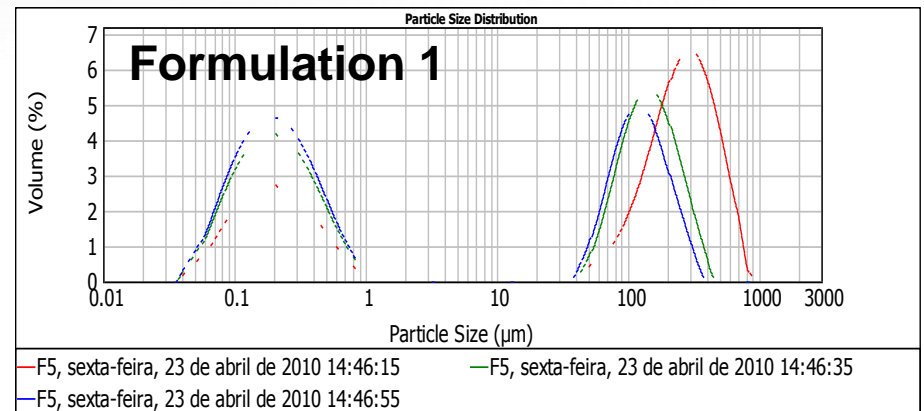
Pre-formulation studies

Interfacial deposition of polymer



Different raw materials give different profiles

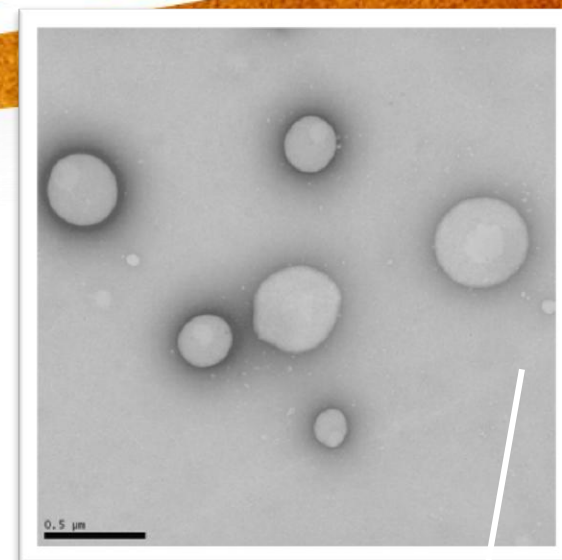
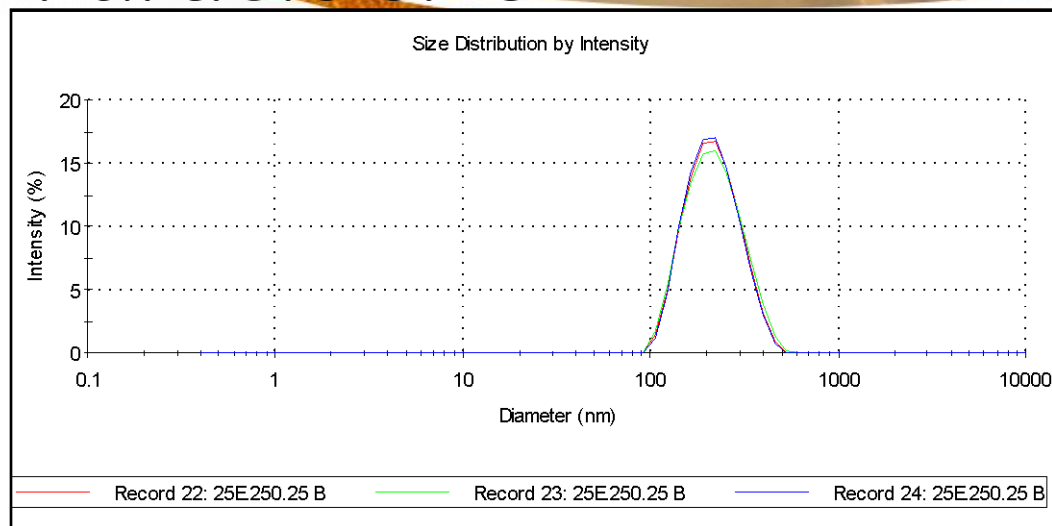
Lipid-core nanocapsules



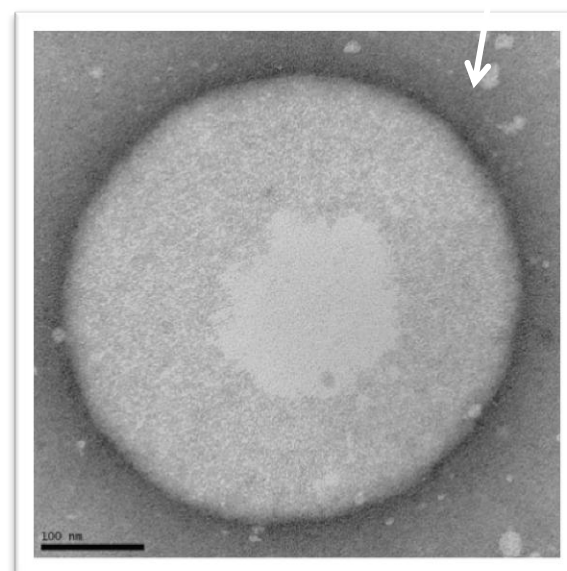
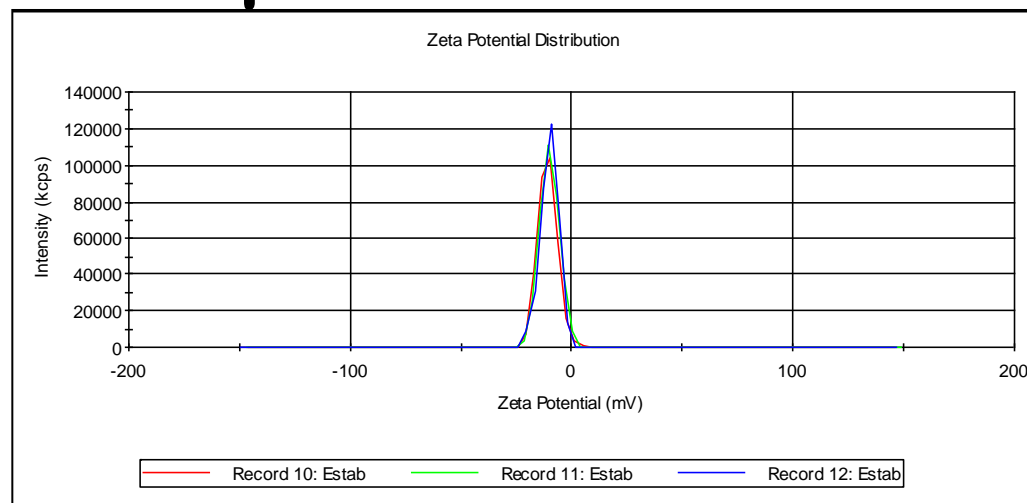
Selection of formulations by
laser diffractometry

TEM

Particle size

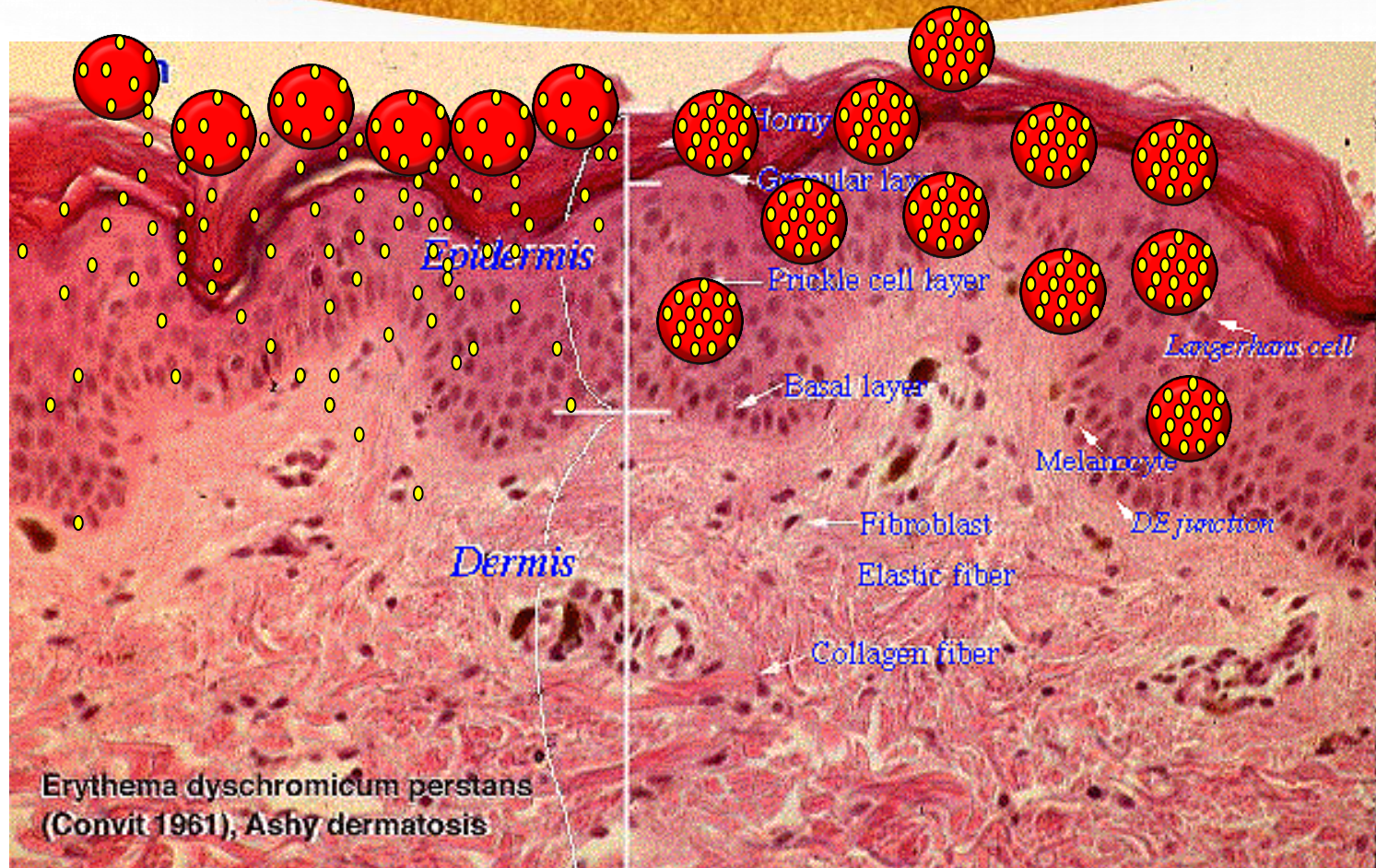


Zeta potential



Which entity permutes?

Drug vs Particle





Summarizing...

TO EVALUATE TOXICITY/SAFETY OF A NAMOMATERIAL

- i. Dose metric: mass/ g or mL not applicable
- ii. Translocation: aerosol for example, systemic distribution
- iii. Physico chemical properties — shape, size and surface area, surface activity.
- iv. Solubility
- v. Reliable/ validated methods of analyses

THANK YOU

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