

Testing procedures for stability and efficacy of natural products

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2nd South African Conference on Essential and Vegetable oils
SAEOPA



Southern Africa's

“botanical gold mine”

Immense (**unique**) botanical wealth

‘mega-diversity area’ and ‘hot spots’
(*3 floristic regions and 15 centres of endemism*)

Potential resource-base
for extensive new value-products
(*industrial, pharmaceuticals, crop-plants, agro-chemicals*)



Traditional medicine

A broad definition including:

- Phytomedicines
- Herbal products and teas



Also includes:

- Health foods
- Cosmeceuticals
- Nutraceuticals

...derived from indigenous plants



The myth of herbal medicines- Safety issues



- **Maladministration:**

- toxic plants
- long term effects
- mistaken identity

- **Contamination:**

- herbicides and pesticide
- heavy metals
- microbial load

The rebirth of ideas.....



Quality of products....

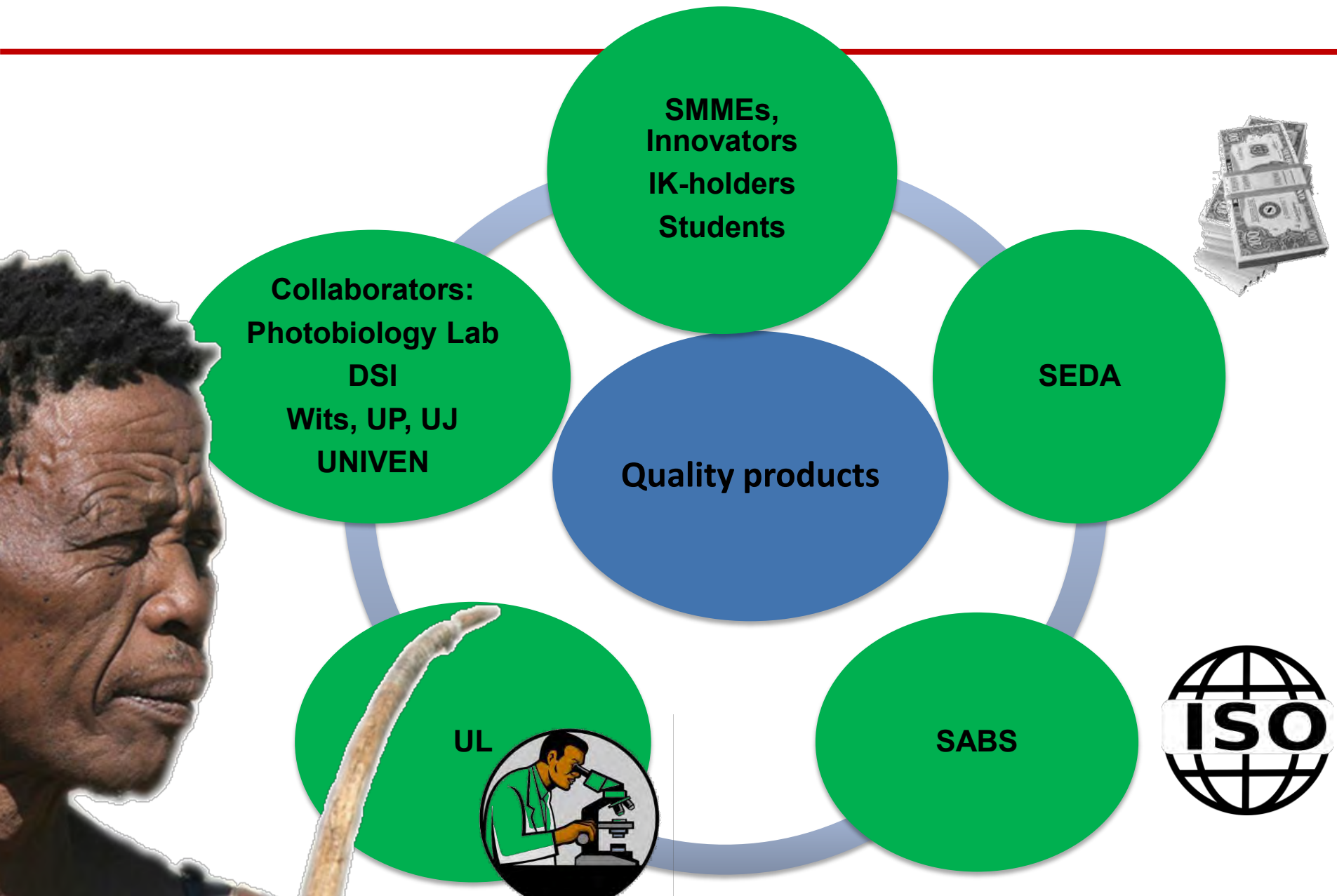
The status of the product is determined by:

- identity,
- purity,
- Content
 - chemical, physical, or biological properties

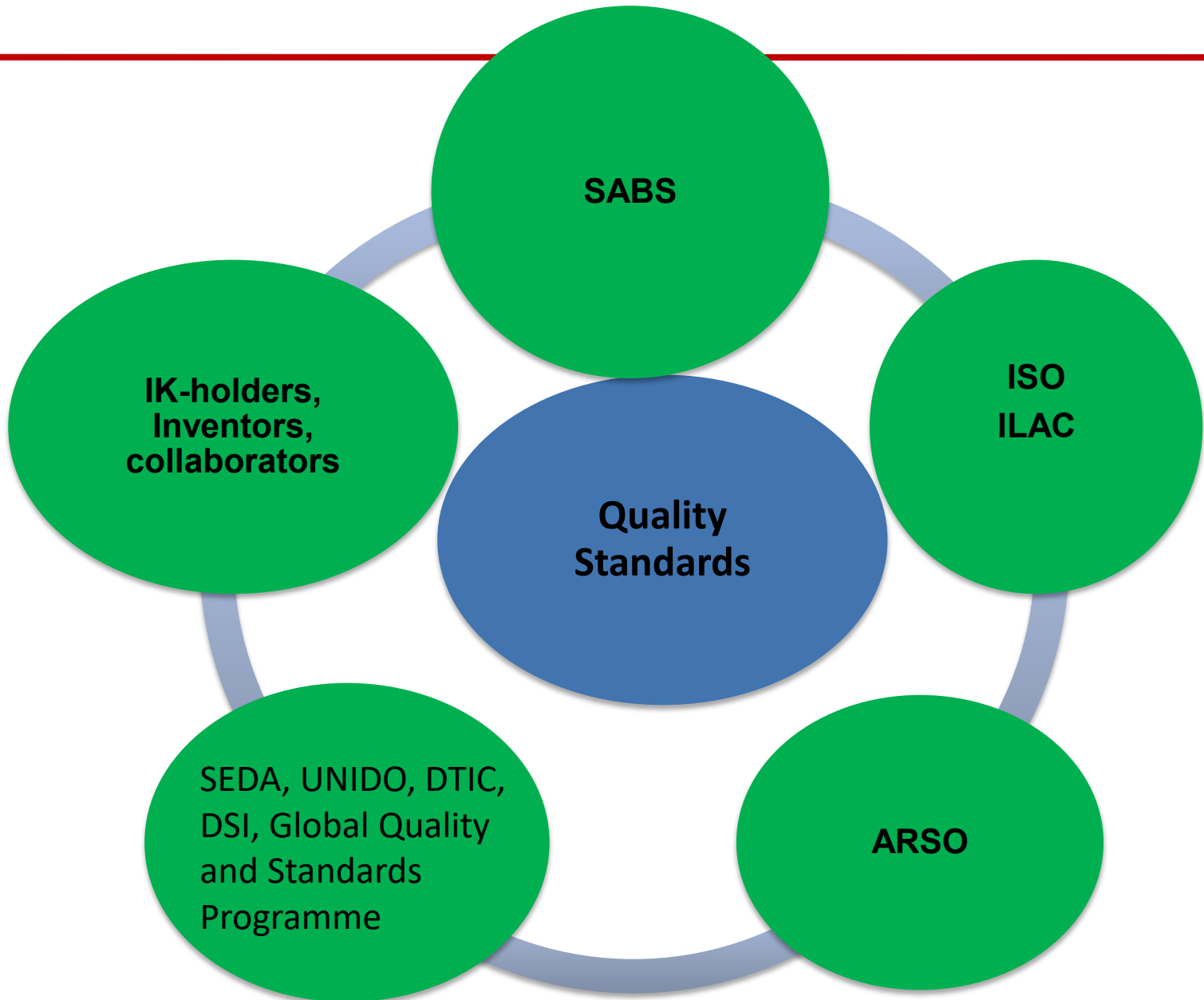
governed by the manufacturing processes



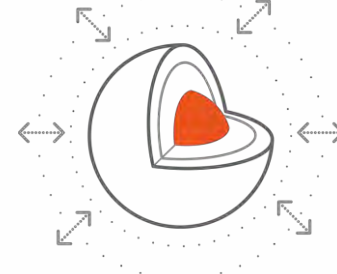
Ubuntu based approach



Ubuntu based approach



Results of the Ubuntu model



More than 10 community development projects supported
DSI/DEFF/UL/ARC/CSIR



Close to 80 SMME supported
SEDA/SABS/UL



More than 10 Agri-entrepreneurs supported
DSI/SABS/UL/ARC/CSIR

Training and Capacity Building

We offer courses on different topics all year round, so one or more of our training courses might be of interest to your closed ones.



Capacity building - BioPack/eKasiLabs/UL

Results of the Ubuntu Model



the dtic

Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Economic Affairs SECO



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

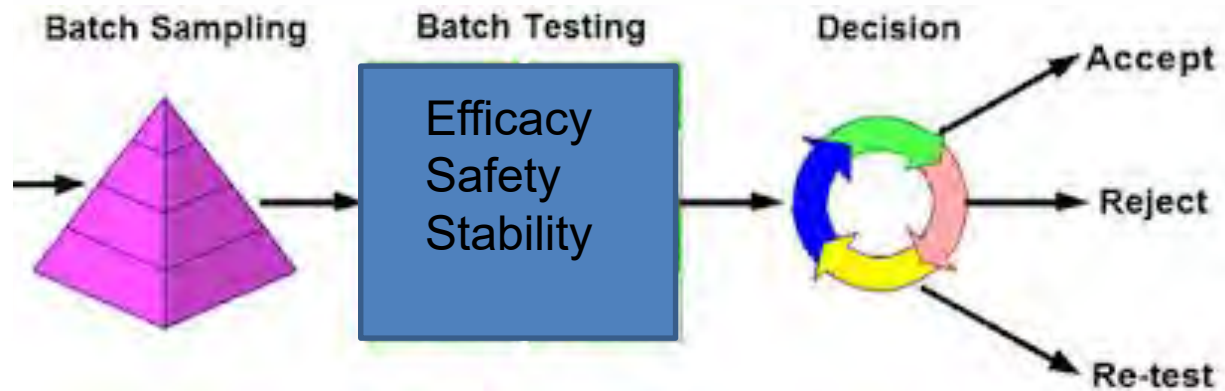


**University of Limpopo Equipment
Training
Accreditation (ISO/EC17025)**



Product testing

Application
For
Funding
etc.....



Stability, shelf life and contaminants – Microbial, pollen etc....



During storage:

- Reduction in odor
- Changes in colour
- Smooth texture
- Changes in pH

Concept of stability

Capability of a specific formulation in a particular container/closure system to remain within its prescribed limits (state)

Physical

Chemical

Microbiological

Efficacy



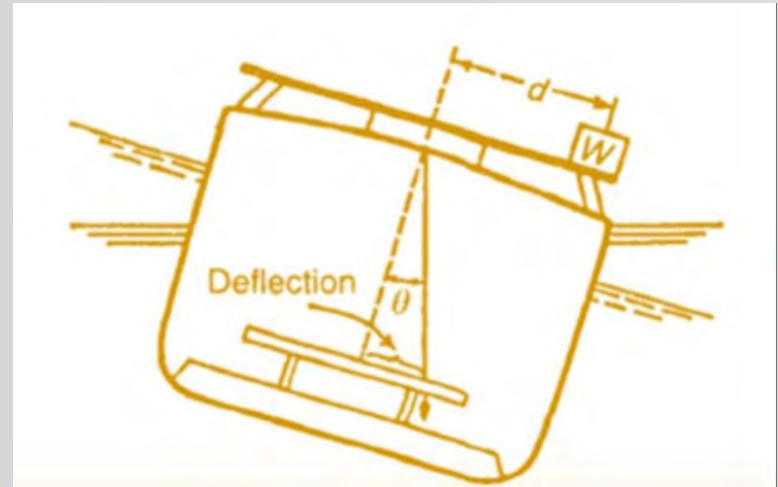
Stability testing methods

Real time testing

Accelerated testing

Intermediate testing

Forced degradation testing



Products testing...

- Package leakage tests
- Package compatibility
- Preservative challenge tests
- Package shock tests



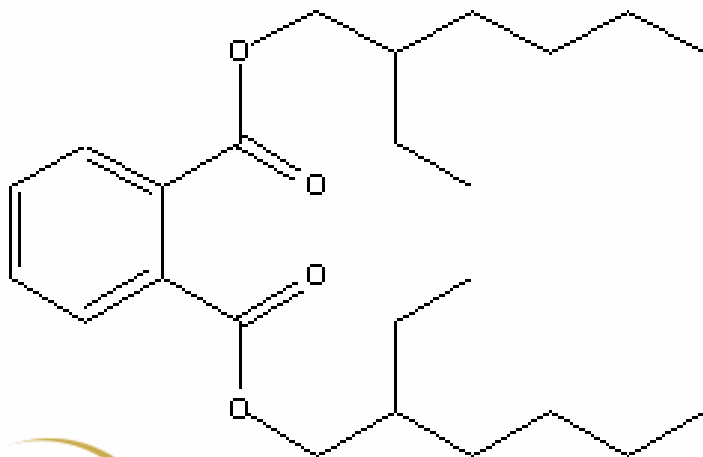
Product packaging.....

Marketing team: sex sells.
Designer: say no more.



Di(2-ethylhexyl) phthalate (DEHP)

- 43.3 mg/L isolated
- Patients consume 7.8 mg DEHP per day



Nair, J.J., Ndhlala, A.R., et al., 2012, South African Journal of Botany 80,

Microbial contamination

E. coli

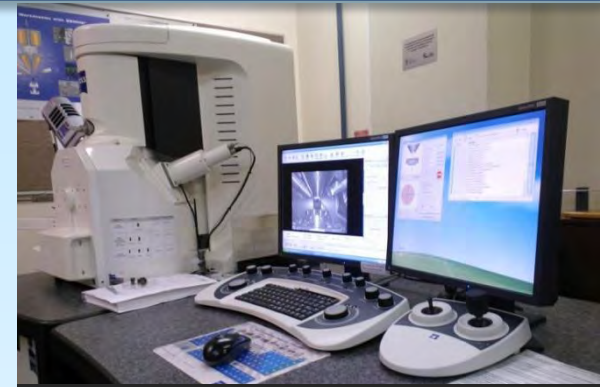
- Lactose broth at 37 °C for 5 hr to revive bacteria
- Transferred into MacConkey broth at 45 °C for 24 hr
- Subcultured on MacConkey agar at 45 °C for 24 hr

S. aureus

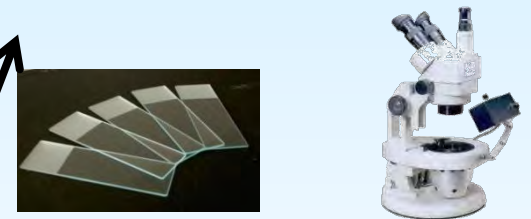
- Lactose broth at 37 °C for 24 hr to revive bacteria
- Subcultured on Baird-Parker agar at 37 °C for 24 hr

Clostridium spp.

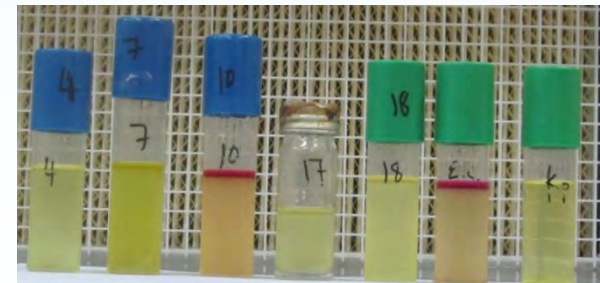
- Extract added to cooked–meat medium
- Medium heated up to 100 °C for a 5 min, cooled to 37 °C
- Examined every 24 hr for up to 4 days



SEM for fungi and bacteria



Light microscopy for fungi



Indole test for *E. coli*





Results for *E. coli* tests

red colonies



Product X



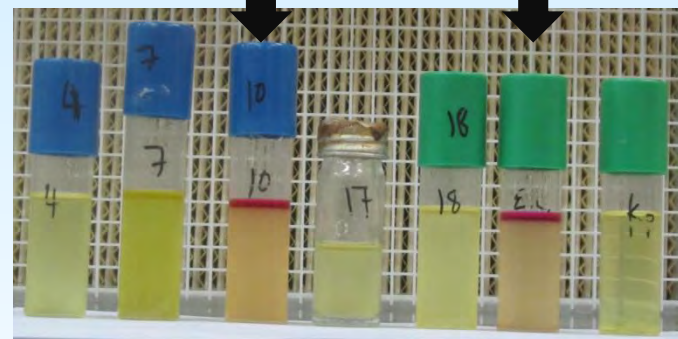
E. Coli
+ve control



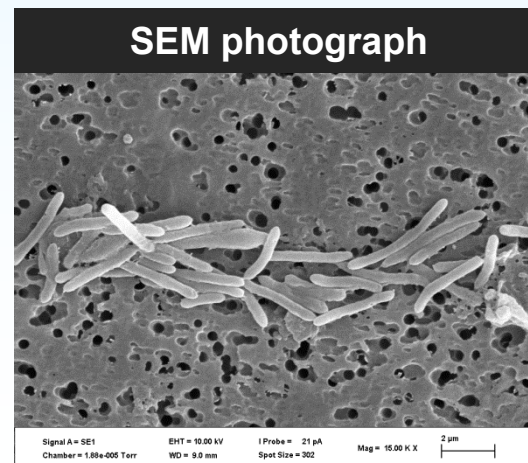
Indole test for *E. coli*

Product X

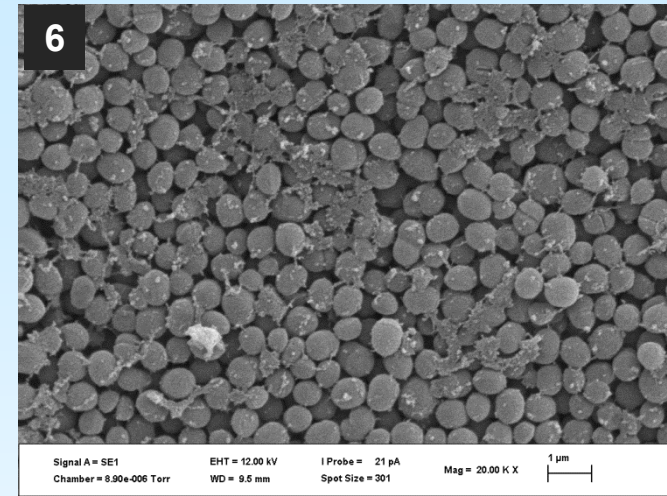
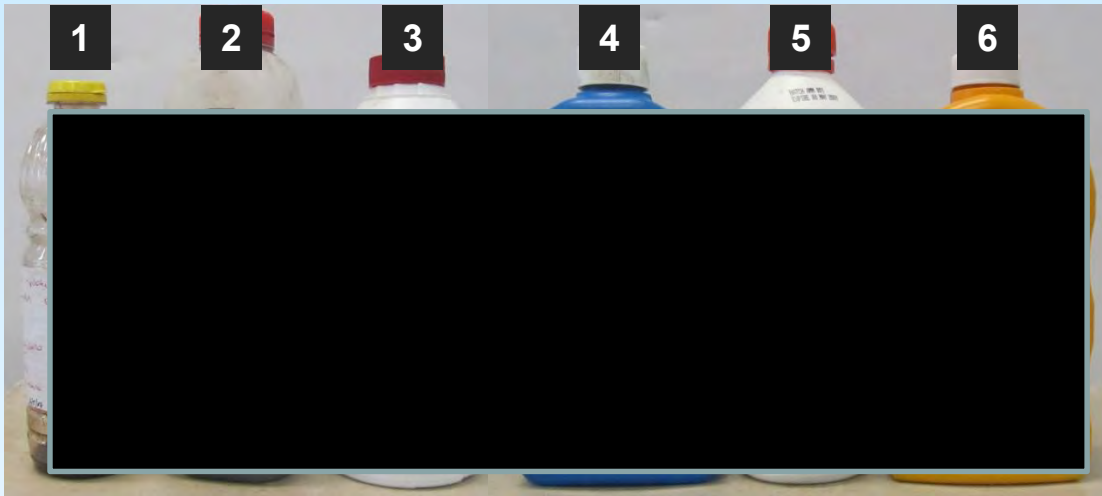
E. Coli
+ve control



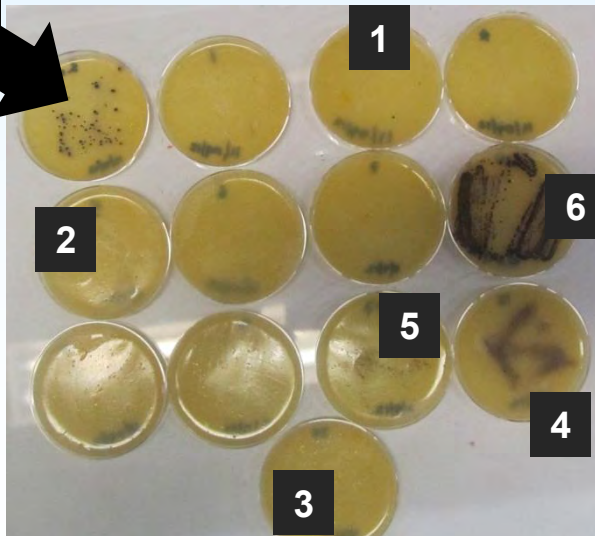
SEM photograph



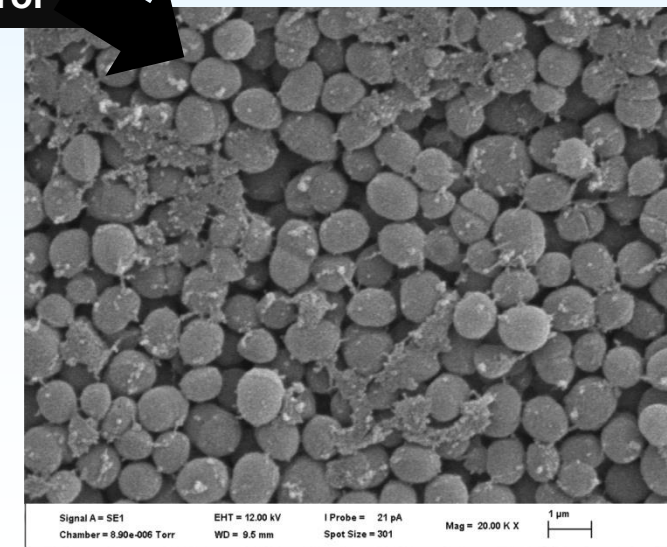
Results for *S. aureus* tests



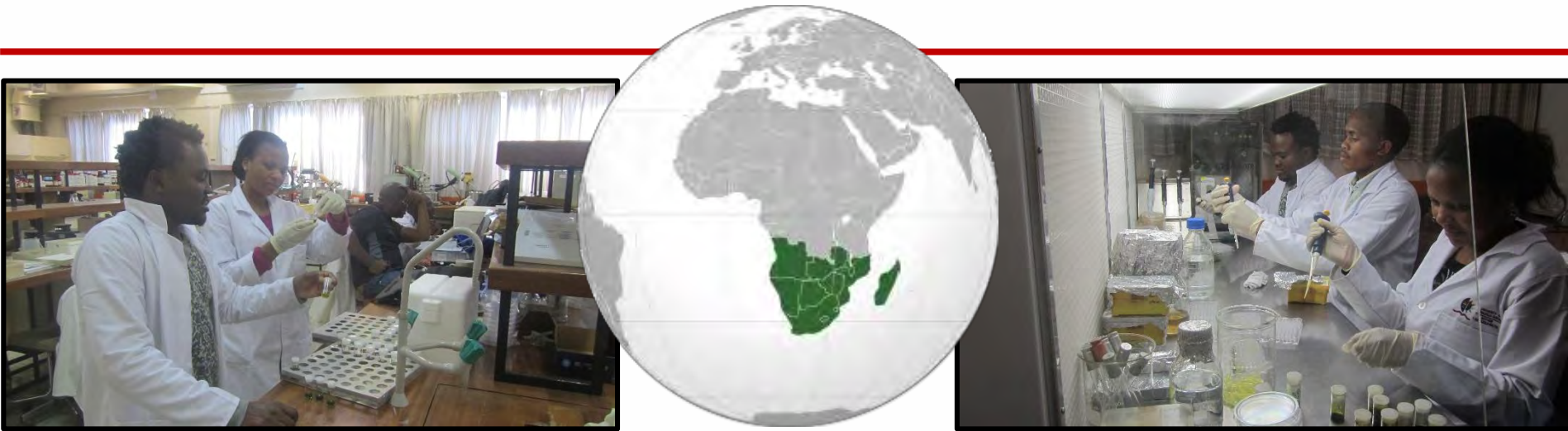
S. aureus
+ve control



S. aureus
+ve control



Product testing.....



Confirming efficacy, safety and stability is therefore critical as it offers direction for product development, and provides scientific rationale for traditional usage

In vitro and *in vivo* assays

Anti- bacterial, fungal,
helminthic, malarial,
inflammatory, oxidant,
depressant



Skin and hair products- Collaboration with Photobiology lab (SMU)



What must be proved about a product?

- Safety – CTFA (DOH), SABS, ARB
- ARB (Code of Practice) <http://www.arb.org.za>

“Any person selling a foodstuff or cosmetic bearing on a label any word, indication or claim that conveys the impression that the foodstuff or cosmetic possesses health-giving properties shall, unless such word, indication or claim can be scientifically substantiated, be guilty of an offence.”

- Efficacy – all claims require proof

Definition: *“Scientific substantiation: means substantiation based on statistically valid data, employing a validated, proven, scientific method and applicable to the claim being made”*

Photobiology Laboratory Registered Protocols

- Sun protection factor *in vivo* and *in vitro* tests
- Irritancy Patch Tests
- Pigmentation studies (PIH, lentigenes, skin lightening, melasma)
- Pseudofolliculitis barbae (razor rash)
- Moisturiser efficacy testing /antiwrinkle assessment/ barrier integrity
- Personal wash-product drying potential
- Oil control
- Scars and striae
- Hair product studies (includes 'Relaxers' and *antidandruff)
- Ophthalmic irritancy
- Deodorant/antiperspirant

ALSO Clinical Departments Specialists:
Depts of Dermatology, Ophthalmology and Paediatrics

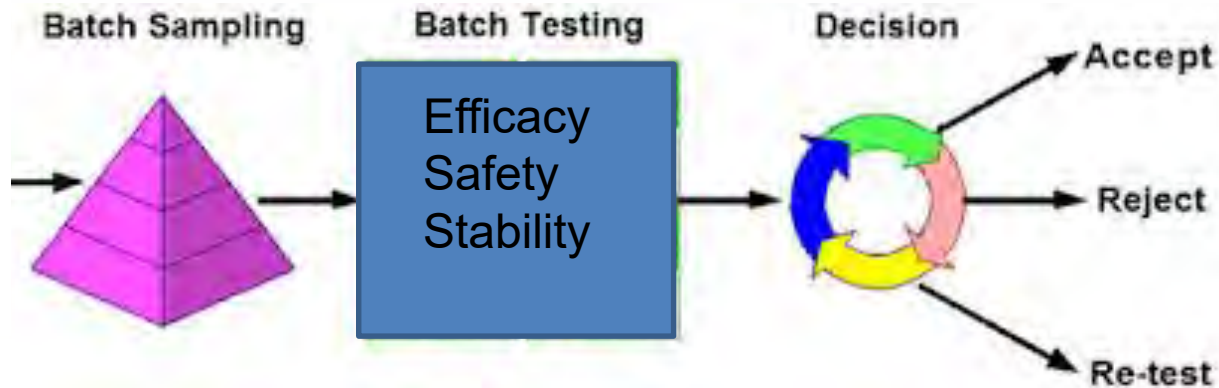
* *Note – provisional approval subject to product submission*

What is a clinical study or trial?

- An investigation in human subjects intended to discover or verify clinical or other ...effects...with the object of ascertaining safety and/or efficacy
- In SA the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants* set out the requirements for Good Clinical Practice.

Pass or fail.....

Application
For
Funding
etc.....



☒ **Pass**

☐ **Fail**

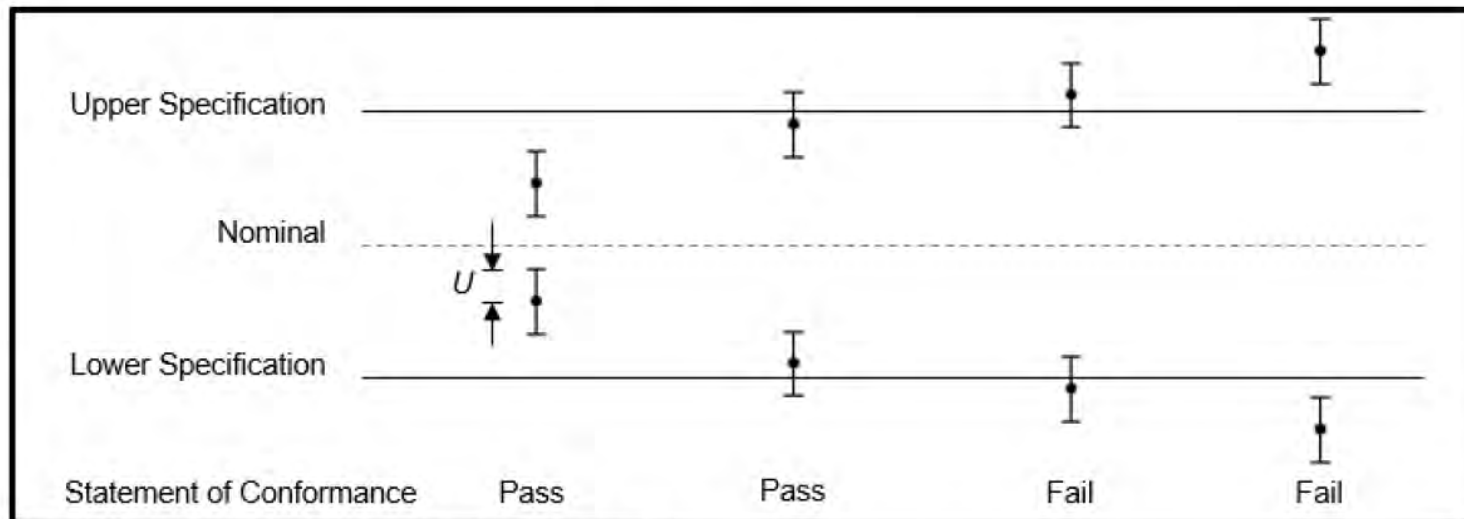
How do we decide

Decision Rules and Statements of Conformity

Binary Statement for Simple Acceptance Rule ($w = 0$)

Statements of conformity are reported as:

- Pass - the measured value is below the acceptance limit, $AL = TL$.
- Fail - the measured value is above the acceptance limit, $AL = TL$.



$U = 95\%$ expanded measurement uncertainty



Report submission

- **Internal verification – to produce a draft report**
- **Draft report submitted to an independent lab/colleague for verification**
- **Apply any recommendations**
- **Submit to client**



Conclusions



What must be done

What tools are available

What are the risks

Resources (biodiversity) must be used as parsimoniously as possible (biotechnology) to meet current needs without compromising the same ability of future generations



politics

emotion

economics



Conclusions

- **The idea of quality control is to promote the responsible use of herbal medicines so that they are used with the highest degree in product development and safe products is achievable.**
- **Our primary way to accomplish this is through the development of standards of identity, purity, and analysis for botanicals, as well as to critically review of some traditional and scientific data regarding their efficacy and safety.**



Thank you
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