

# World Class Botanicals extracts from India

Presented by:  
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## The World Health Organization (WHO) estimates

- 4 billion people use herbal medicine.
- Herbal medicine is a major component of all traditional medicine
  - Ayurvedic
  - Homeopathic
  - Naturopathic
  - Native American Indian Medicine

Other forms- Dietary, food, herbal supplements  
etc.,

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## What is a world class herbal Drug?

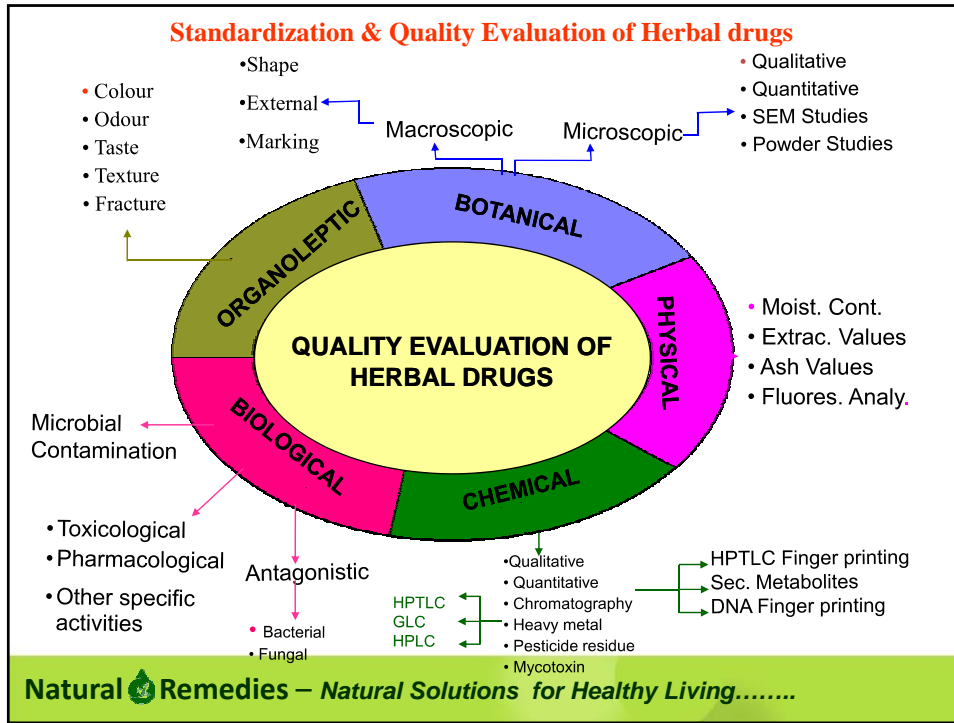
**“A World class standardized herbal extract means that the manufacturer has verified the active ingredient believed to be present in the herb is present in the preparation and that the potency and the amount of the active ingredient is assured in the preparation”**

**The action of the herb may be from a number of constituents and not from just one or two ingredients.**

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## How world class herbal drugs produced ?

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## Services and Contribution to the Herbal Industry

- **Isolated more than 130 reference standard for the industry**
- **Bio-assay standardization for extracts (screened more than 800 Indian plants for various activity)**
- **In house capability to conduct alternatives to animal testing**
- **Contributed 8 monographs to IP, 2 monograph to USP (3 more under developed)**
- **Published more than 70 papers**
- **Capability for New product development as per client requirements**
- **Custom manufacturing to customer specifications**
- **Formulation and development lab for nutraceuticals, drugs and cosmeceutical formulations**
- **Efficient Manufacturing facilities**
- **Operational facilities are certified by ISO 9001, ISO 22000, GMP, ISO 17025 (National Accreditation for Testing Laboratory), DSIR and KOSHER, And now under TGA approval**
- **Pilot plant for scaling up of the work done by R&D**

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## NATURAL REMEDIES

Research and Development Centre is a multi-disciplinary herbal research facility which is recognized by the Department of Scientific and Industrial Research. It also undertakes contractual research and analysis on various aspects of herbal products. The R&D centre is now NABL accredited under ISO/IEC 17025:2005 in the fields of biological and chemical testing of herbs. Our strict adherence to quality standards, well trained staff and advanced instrumentation ensure accuracy and reliability of analytical tests.

**What is NABL accreditation?**

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India and is registered under the Societies Act. NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorized NABL as the sole accreditation body for Testing and Calibration laboratories.



**International Acceptance**

NABL is a signatory to International Laboratory Accreditation Cooperation (ILAC) Agreements as well as Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Agreement (MRA), based on mutual evaluation and acceptance of other MRA Partner laboratory accreditation systems. As a result of these international agreements, our test reports, based on the ISO/IEC 17025:2005 standard for test / calibration results, are accepted in countries which are MRA partners.

**Benefits of testing and getting results from Natural Remedies Pvt. Ltd.**

- Assures the client that the laboratory adopts validated test methods by which they get reliable, repeatable and technically valid test results.
- Endorses that the laboratory operates management systems effectively, matching to international level of competence.
- Ensures continual improvement in quality, efficiency and effectiveness with compliance to ISO 17025 requirements.

NRPL is also one of the largest developers of primary phytochemical reference substances essential for phytochemical analysis and compliance to pharmacopoeial procedures.






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## Facilities:

### Photochemistry Lab: Areas of cores competence

- Identification of crude drugs using pharmacognostic Techniques
- Isolation of markers for standardisation of herbal Products
- Bioactivity guided fractionations for isolation of bio-active compounds (s)





- Development of optimal extraction procedure for medicinal plants
- Isolation of phytochemicals of high purity for use as chromatographic reference standards

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## Analytical Chemistry: Areas of cores competence

- Standardization of herbal products
- Quantitative determination of over 100 known active principles, biomarkers and marker components in raw materials, extracts and essential oils



- Development of meaningful quality assessment parameters for plants where actives / bioactives are not known
- Development and validation of analytical procedures
- Stability testing of herbal products

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## Microbiology Department: Areas of cores competence

- Analysis of herbal products for microbiological Contamination
- Determination of MIC and Determination of MBC
- Immersion bio-autography assay for Identification of antibacterial compounds
- Preservative efficacy testing
- Development of preservative system
- Testing of plant extracts and their derivatives for combinational effects to determine synergy, additivity and antagonism



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### Bio – assay Department: Areas of cores competence

S.I #	Cell Assays	Pharmacological relevance	
	<b>Lymphocyte proliferation</b>		<ul style="list-style-type: none"> <li>- Bio-activity directed fractionation ( in collaboration with photochemistry dept )</li> <li>- Development of <i>in vitro</i> pharmacological methods For drug evaluation</li> <li>- Biological standardization of herbal products</li> </ul>
	a. Naïve and LPS treated lymphocytes		
	b. Naïve and PHA induced		
	c. Naïve and Con A treated lymphocytes		
	d. Naïve and PWA induced		
1.	e. Naïve and anti-CD3 induced	Immune modulation	<ul style="list-style-type: none"> <li>- Application of bio-assay methods for stability Testing and testing combinational effect of herbal extracts</li> <li>- In-vitro safety evaluation of herbal extracts / combination</li> </ul>
2.	NO release	Immune modulation	
3.	NO scavenging	Inflammation, Arthritis	
4.	Macrophage Phagocytosis	Immune modulation	
5.	LTB4 release	Inflammation, Allergy	
6.	Hepatoprotection	Liver protection	
7.	Histamine release	Inflammation, Allergy	
8.	Chromosomal aberration assay	Safety - Genotoxicity	
9.	Micronucleus assay	Safety - Genotoxicity	
10.	PGE2 release	Inflammation	
11.	Insulin release	Diabetes	
12.	Collagen release	Anti-wrinkle	
13.	TXB2 release	Inflammation, Allergy	
14.	IL-1 beta inhibition assay	Inflammation, arthritis	
15.	TNF Alpha inhibition	Inflammation, Rheumatoid arthritis	
16.	AMES test	Safety - Genotoxicity	
17.	IL-2 release (Con A induced)	Immune modulation	
18.	IL-4 release (Con A induced)	Immune modulation	
19.	IL-6 release (Con A induced)	Immune modulation	
20.	IFN gamma release (Con A induced)	Immune modulation	
21.	Neutral Red Uptake assay	Cytotoxicity	
22.	Cellular antioxidant assay	Cancer, Heart health etc.	

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### Bio - Assay Lab/Cell Culture : Areas of cores competence

## ADME Division

**1. Absorption studies:**

**Ex vivo studies**

1.1. Everted gut sac model

**In vitro studies:**

1.2. PAMPA : Parallel Artificial Membrane Permeability Assay

1.3. Caco-2 model

**2. Herb-drug interactions studies:**

**Cytochrome P450 inhibition studies**

2.1. CYP1A2 inhibition assay

2.2. CYP2A6 inhibition assay

2.3. CYP3A4 inhibition assay

2.4. CYP2D6 inhibition assay

**Phase II enzyme inhibition studies**

2.5. Glutathione S-Transferase (GST) inhibition assay

2.6. UDP-Glucuronosyl Transferase (UGT) inhibition assay


**Transporter inhibition studies**

2.7. P-glycoprotein (P-gp) inhibition assay


**3. Metabolic activation studies**

3.1. Metabolic activation using primary hepatocytes.


3.2. Ex vivo hepatic perfusion



ADME studies are conducted to examine the absorption, distribution, metabolism, and excretion of herbal products.



- Dipeptidyl peptidase IV inhibition assay
- Estrogenic assay using MCF-7 cell line
- Phagocytic index assay
- PTB-IB inhibition assay
- Insulin release assay



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**Extraction facilities**

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**NR-A2**  
Clinically proven dietary supplement blend to support the management of allergic rhinitis

**Preclinical studies**  
Pre-clinical studies on NR-A2 support it to be an effective agent in relieving symptoms of allergy by showing it to be an effective antihistaminic, mast cell stabilizing, anti-inflammatory and anticholinergic in various animal and in-vitro models.

**Clinical studies**

- In phase II, double blind placebo controlled clinical study NR-A2 exhibited a significant improvement in the symptoms like sneezing, nasal congestion and rhinorrhea.
- In a multi-centred, randomised trial NR-A2 showed significant reduction in the scores of total nasal symptoms in 70% of the patients at the end of 4 weeks and 94% of the patients at the end of 12 weeks of study.
- In another double blind placebo controlled study NR-A2 produced a significant reduction in the scores of total nasal symptoms in 92% of the patients.

**Safety**

- Available clinical studies showed NR-A2 to be devoid of clinically significant adverse effects.
- In animal studies LD<sub>50</sub> was found to be 1.5g/kg and 2g/kg body weight/oral and intraperitoneally.
- In sub chronic toxicity study NR-A2 showed no observed adverse effect level (NOAEL) at 1g/kg body weight/oral.
- NR-A2 did not show teratogenicity, reproductive toxicity, mutagenicity or animal studies.

**What makes NR-A2 unique?**

- NR-A2 is derived from herbal origin.
- NR-A2 is a clinically proven.
- NR-A2 is chemically and biologically standardized.
- Quantitative of bio-active molecules corresponds in each batch of NR-A2 across lots to batch consistency.
- Available as a free flowing powder, custom formulated and specifically tailored to meet dietary / nutritional specifications.
- Manufactured in a GMP ISO 9001:2000 and ISO 22000 certified manufacturing facility.
- The product is Kosher certified.

**Recommended dose**  
1320mg/ day in single or divided doses.

**Some of the product with NR-A2**

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**Improves concentration & grasping power**

- ◆ Supports brain performance, attention and memory
- ◆ Assists in mental functioning
- ◆ Supports mental sharpness and working memory
- ◆ Enhances mental alertness and learning performance in children



[www.bacomind.in](http://www.bacomind.in)

**Some of the products with BacoMind**




**Why BacoMind is different from other brain health ingredients?**

- Scientifically proven to help protect memory function both in elderly and children.
- It is proven as safe and non-toxic by successful clinical trials.
- Biologically standardized for assays like Lipoxygenase inhibition, Butyrylcholinesterase inhibition, ABTS radical scavenging, ORAC and DPPH.
- A patent on is being filed to strengthen the intellectual property generated.

**BacoMind designed for various applications:**

Dietary supplements, Health drink, Food supplement, candy and chewing gum





**GutGard™**  
Natural Support to Gut Health

- ◆ Calms the stomach
- ◆ Supports and promotes a healthy stomach lining
- ◆ Helps to soothe heartburn
- ◆ Helps to maintain normal digestive function
- ◆ Provides antioxidant support to digestive tract


Patent pending

Designed as dietary ingredient  
Also suitable for food and confectionaries

**What makes GutGard™ unique?**

- Deglycyrrhizinated extract.
- Rich in flavonoids.
- Effective and safe.
- Biologically standardized.
- Chemically standardized.
- Available as a free flowing powder, custom formulated and specifically tailored to meet dietary/ nutraceutical specifications.

	Conventional DGL	GutGard™
Flavonoids content	Negligible	> 10%
Antioxidant activity	Negligible	Very high
Anti- <i>H. pylori</i> activity	Poor	Good
<i>In vivo</i> animal studies	Effective at high dose	Effective at low dose
Human dose	1500 – 3000 mg/day	150 – 300 mg/day

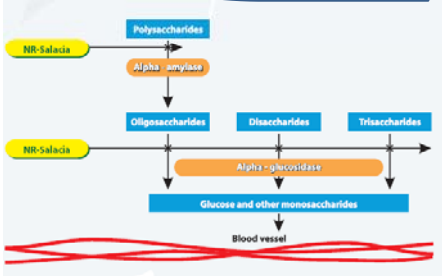


**NR-Salacia**  
A Potent Carbohydrate Blocker

- Blocks absorption of surplus carbohydrates (both sugar & starch) associated with overeating
- Helps to reduce extra calories contributed by carbohydrates
- Blocks both alpha-amylase and alpha-glucosidase enzymes

Patent pending

How it works?



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graph TD; Polysaccharides --> Amylase[Alpha-amylase]; Amylase --> Oligosaccharides; Amylase --> Disaccharides; Amylase --> Trisaccharides; Oligosaccharides --> Glucosidase[Alpha-glucosidase]; Disaccharides --> Glucosidase; Trisaccharides --> Glucosidase; Glucosidase --> Monosaccharides[Glucose and other monosaccharides]; Monosaccharides --> BloodVessel[Blood vessel]; NR-Salacia --> Amylase; NR-Salacia --> Glucosidase;
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**NR Salacia designed for various applications:**  
Dietary supplements, Health drink, Food supplement, candy and chewing gum

**Thank you**

If any support need, please reach us to  
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