



Herbal Extracts and Pure Products for the Pharmaceutical and Nutraceutical Industries

BOTANICAL EXTRACTS | PURE PRODUCTS

sb select botanical



Select Botanical

Producers of Botanical Extracts and Pure Products from Botanical Sources, Since 2001

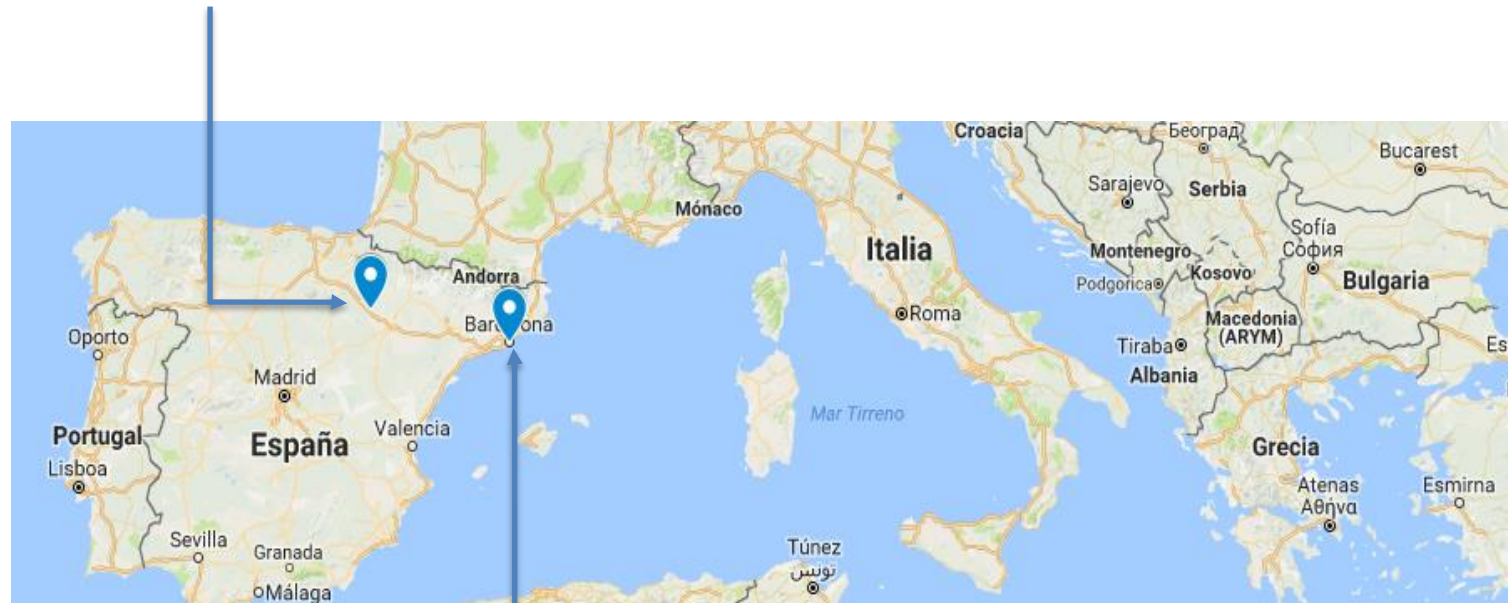


We manufacture conform to strictest EU GMP Part II standards, applying all regulatory aspects by health authorities to produce and market natural products

Location

Select Manufacturing Site

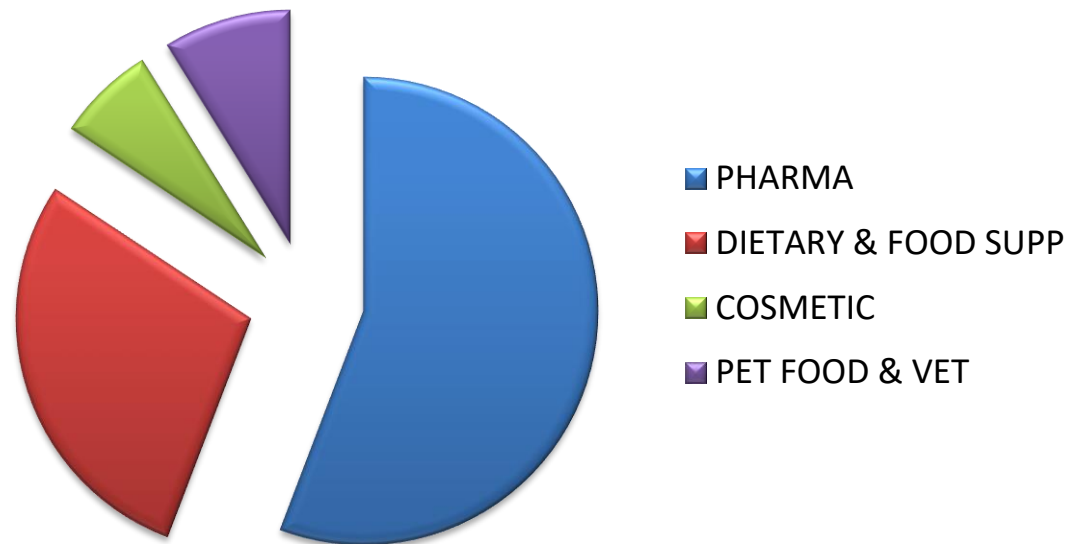
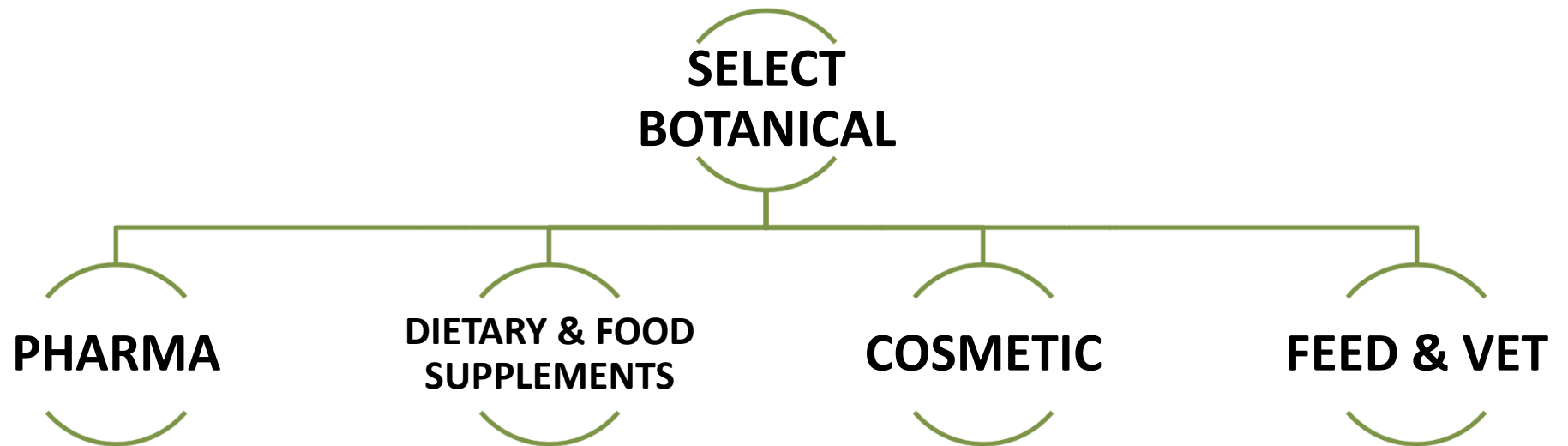
Buñuel - Navarra



Select HQ & Offices

Barcelona

Business Units



Production Site

WAREHOUSE

For Raw Material and Finished Product



PRODUCTION AREA

Extraction → Concentration



CLEAN ROOMS

Purification

Drying → Milling → Homogenization → Packing



Laboratory

QA & QC	
Surface	600 m ²
Staff	10 people
TLC	1
HPLC	3
GC-Head Space	1
UV	2

R&D	
Staff	3 people



Herbal Extracts

Full range of botanical extracts, organic and conventional



Liquid and Solid formulation



Dry Extract
Fluid Extract
Glycolic Extract
Glycerinated Extract
Tinctures
Soft Extract

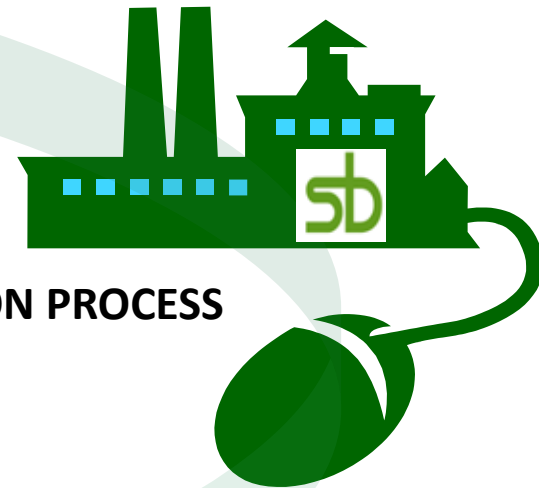
Traceability



**QUESTIONNAIRE / AUDIT:
SELECTION OF PARTNERSHIPS**



**CONTROL AT RECEPTION:
ANALYSE, CONFORMITY
AND VALIDATION**



PRODUCTION PROCESS

**BATCH NUMBER, END
ANALYSIS & PRODUCT
RELEASE**



**DELIVERY TO
CUSTOMERS
WORLDWIDE**



Documentation

FULL SPECIFICATION SHEET & CoA

Description, Physical & Chemical properties, microbial quality, contaminants
(heavy metals, mycotoxins, pesticide residues, etc)

sb select botanical

TECHNICAL DATA SHEET

Product name: **IVY LEAF DRY EXTRACT 10 %** Product Code: **0078-05-P**
Botanical name: *Hedera helix L.* Part Used: Leaf
Storage: Keep container tightly sealed and store in a cool place in closed original container
Shelf life: 3 years

ANALYSIS	METHODS	SPECIFICATIONS
Description		
Appearance Extraction solvent Ratio plant / extract	Visual	Yellowish brown to brown powder Ethanol 24-30 % m/m 4,0-8,0:1
Composition		
Maltodextrin (%) Silicon dioxide (%)		10,0 2,0
Physico-Chemical		
Loss on drying (% w/w) Total ash (% w/w) Particle size (%) Particle size (%) Particle size (%)	Eur.Ph.current ed.2.8.17 Eur.Ph.current ed.2.4.16 through 35 mesh through 80 mesh through 60 mesh	≤5,0 ≤15,0 90-100 % 90-100 % 95-100 %
Assay		
Hederacoside C (dry basis) (%)	HPLC-Internal method	≥10,0
Residual solvents		
Ethanol (ppm)	GC (Acc.CPMP/ICH28355 guidelines)	≤1000
Microbiology		
Total aerobic microbial count (TAMC) (CFU/g) Total combined yeasts/moulds count (TYMC) (CFU/g) Bile-tolerant gram-negative bacteria (CFU/g) Escherichia coli (g) Salmonella (g)	Eur.Ph.current ed.2.8.12 Eur.Ph.current ed.2.8.12 Eur.Ph.current ed.2.8.31 Eur.Ph.current ed.2.8.31 Eur.Ph.current ed.2.8.31	≤10000 ≤100 ≤100 Absence 1 Absence 25
Contaminants		
Pesticides Lead (ppm) Cadmium (ppm) Mercury (ppm)	Eur.Ph.current ed.2.8.13 I.C.P. I.C.P. I.C.P.	Raw material acc.Eur.Ph.current ed. ≤3 ≤1 ≤0,10

sb select botanical

CERTIFICATE OF ANALYSIS

Product name: **IVY LEAF DRY EXTRACT 10 %** Product Code: **0078-05-P**
Botanical name: *Hedera helix L.* Part Used: Leaf
Batch: **00780503327-E** Manufacturing date: **24/11/2015** Exp. date: **23/11/2018**
Storage: Keep container tightly sealed and store in a cool place in closed original container
Comment: 3 years

ANALYSIS	METHODS	SPECIFICATIONS	RESULTS
Description			
Appearance Ratio plant / extract Extraction solvent	Visual	Yellowish brown to brown powder 4,0-8,0:1 Ethanol 24-30 % m/m	Complies Complies Complies
Composition			
Maltodextrin (%) Silicon dioxide (%)		10,0 2,0	Complies Complies
Physico-Chemical			
Total ash (% w/w) Loss on drying (% w/w) Particle size (%) Particle size (%) Particle size (%)	Eur.Ph.current ed.2.4.16 Eur.Ph.current ed.2.8.17 through 35 mesh through 60 mesh through 80 mesh	≤15,0 ≤5,0 90-100 % 95-100 % 90-100 %	10,1 3,8 100 99 96
Assay			
Hederacoside C (dry basis) (%)	HPLC-Internal method	≥10,0	10,1
Residual solvents			
Ethanol (ppm)	GC (Acc.CPMP/ICH28355 guidelines)	≤1000	80
Microbiology			
Total aerobic microbial count (TAMC) (CFU/g) Total combined yeasts/moulds count (TYMC) (CFU/g) Bile-tolerant gram-negative bacteria (CFU/g) Escherichia coli (g) Salmonella (g)	Eur.Ph.current ed.2.8.12 Eur.Ph.current ed.2.8.12 Eur.Ph.current ed.2.8.31 Eur.Ph.current ed.2.8.31 Eur.Ph.current ed.2.8.31	≤10000 ≤100 ≤100 Absence 1 Absence 25	<10 <10 <10 Absence Absence
Contaminants			
Pesticides Lead (ppm) Cadmium (ppm) Mercury (ppm)	Eur.Ph.current ed.2.8.13 I.C.P. I.C.P. I.C.P.	Raw material acc.Eur.Ph.current ed. ≤3 ≤1 ≤0,10	Complies Complies Complies Complies

Documentation

TECHNICAL DATA BOOK

Specification Sheet, Allergens, GMO, Kosher, Organic, Process Description,
Flow Chart and all other relevant information

MELISSA DRY EXTRACT 7%

QUALITY DOSSIER- CHARACTERIZATION OF BOTANCIAL PREPARATIONS

(Confidential information)



DRUG MASTER FILE (ASMF / DMF) CTD FORMAT

DRUG MASTER FILE (DMF)



Strategic products with DMF available:

Valerian, Lemon Balm, Hawthorn, Peppermint, Witch Hazel, Ivy Leaf, Soya Isoflavones, and Enoxolone (18-β-Glycyrrhetic Acid)

New DMF available on request

Quality Management System

Continuous improvement of Quality Management System

Spanish Health Agency Audit

EU GMP Part II (“Good Manufacturing Practice”)

Kosher Certification

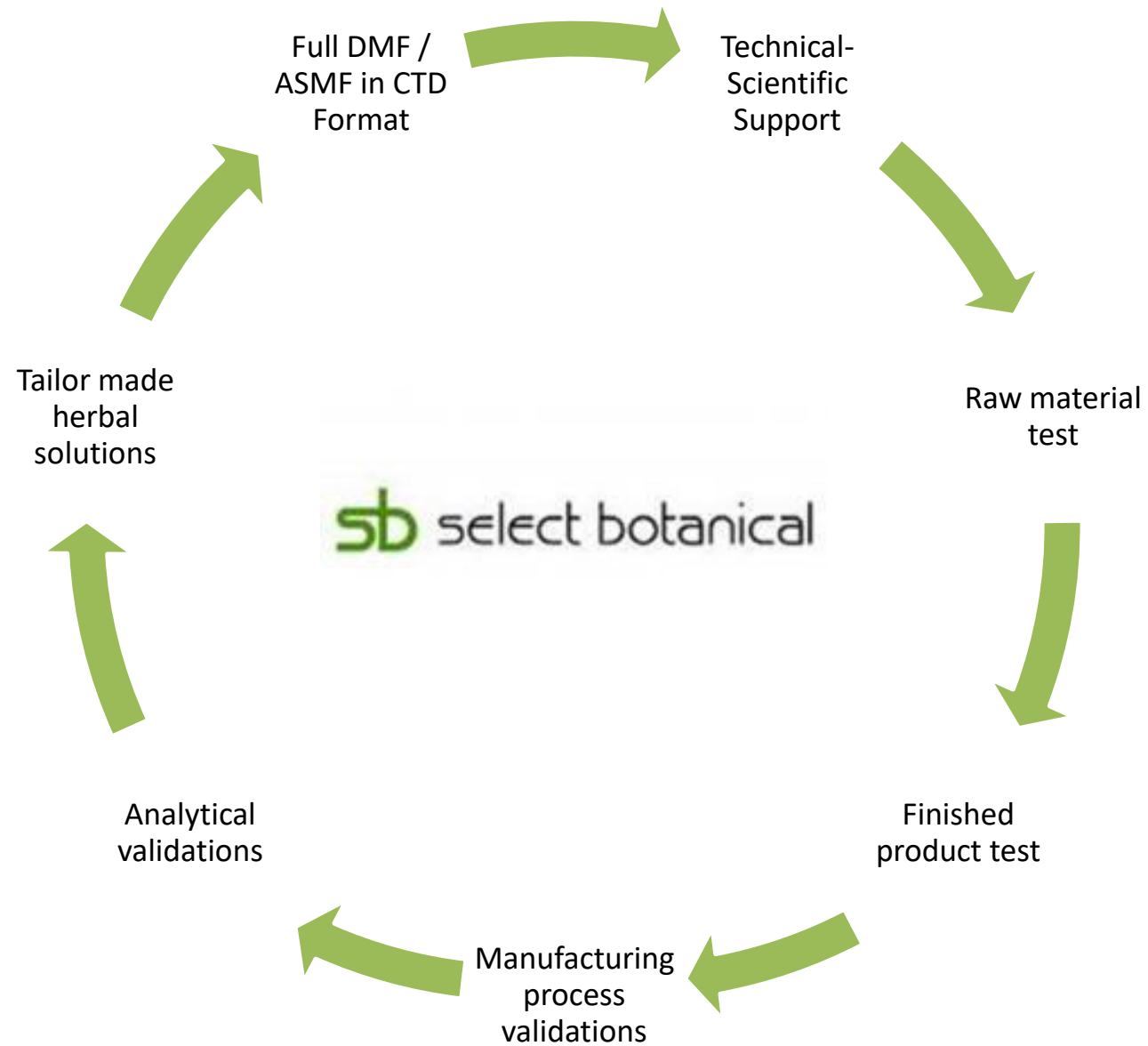
Feed Additive (flavoring) Manufacturer

Organic and conventional production

FDA Manufacturing site audited



Services



Experimental Fields

Our factory is located in a strategic geographical location allowing us to trial and harvest a large variety of medicinal plants



VALERIAN



LICORICE

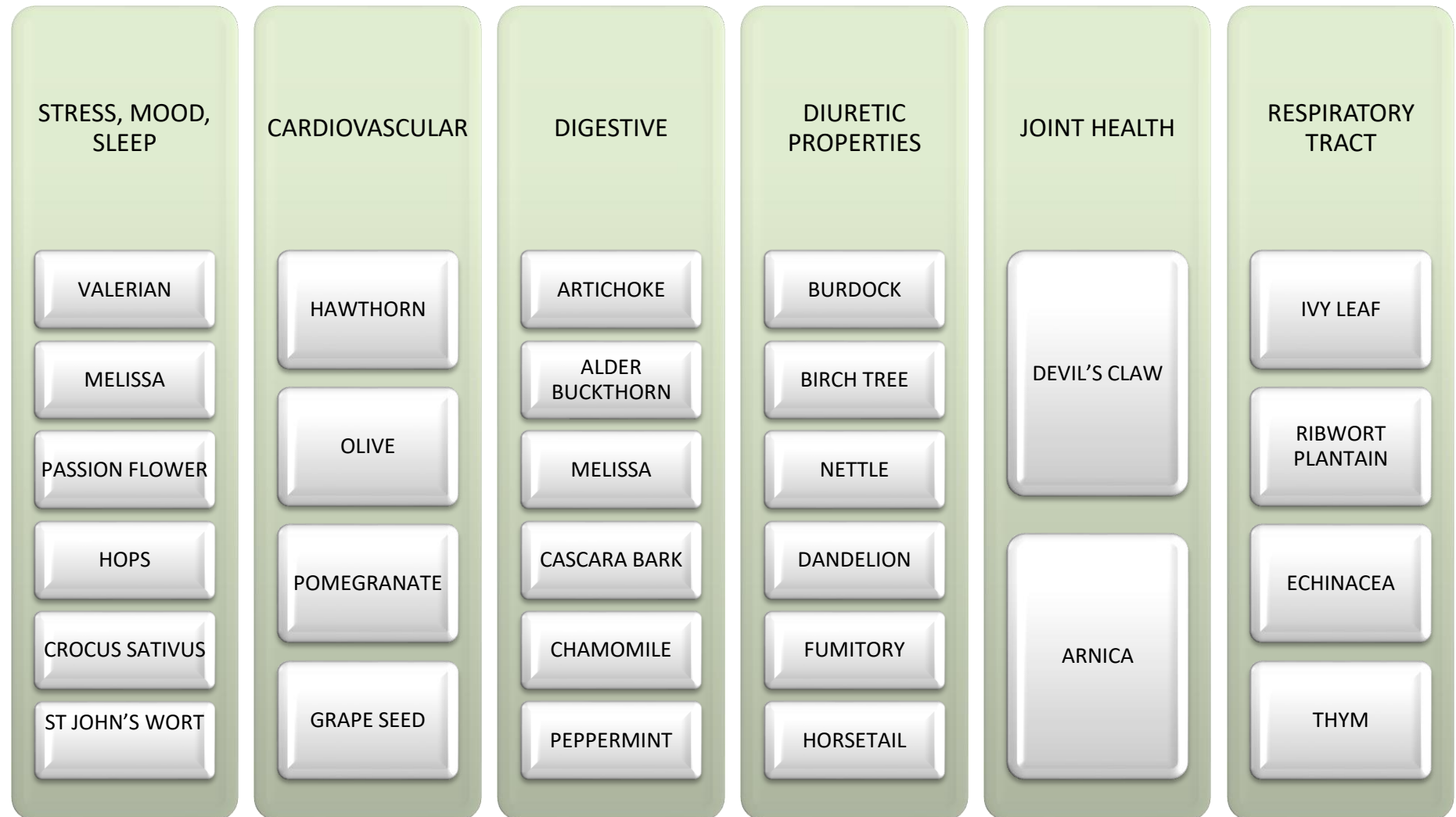


ECHINACEA



Botanical Extracts

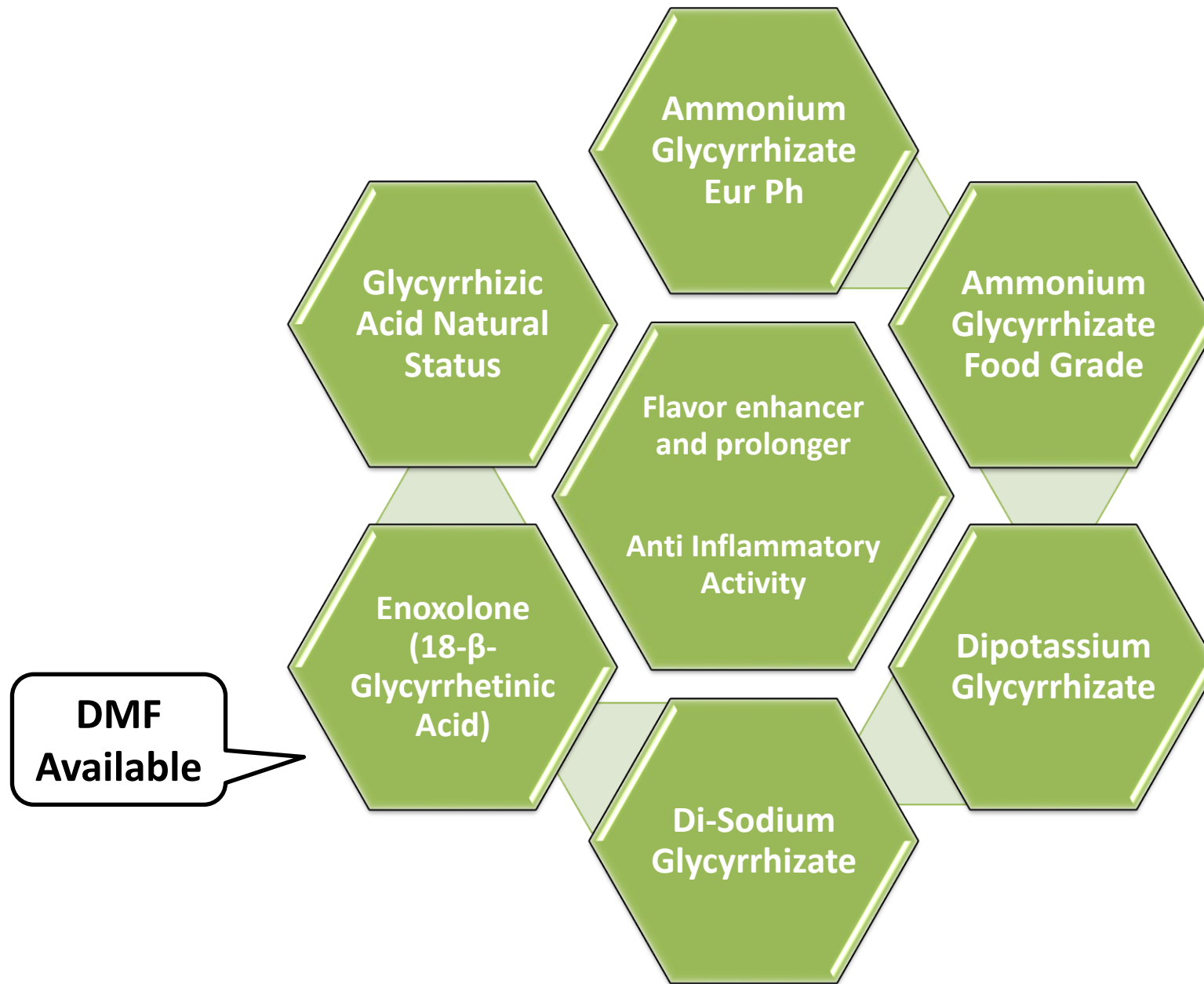
Therapeutic indications of our herbal extracts...



THEY CAN BE COMBINED AND FORMULATED TOGETHER IN CONTRIBUTING TO IMPROVE THE EFFECTS ON EACH THERAPEUTIC INDICATION

Licorice Derivatives

LARGE VARIETY OF LICORICE ACTIVE PRINCIPLES AND DERIVATIVES



Why Select Botanical ??



Your reliable partner for any new project to be developed together



Tailor made solutions → what type of extract do you need?



Full range of botanical extracts, organic and conventional



Manufacturing conforms to strict GMP standards and DMF support is provided for our key products.



Own Control and R&D laboratories.



Flexibility due to a slim company structure.

Contact

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