

Herbal Extracts and Pure Products for the Pharmaceutical and Nutraceutical Industries

BOTANICAL EXTRACTS | PURE PRODUCTS

Select Botanical

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

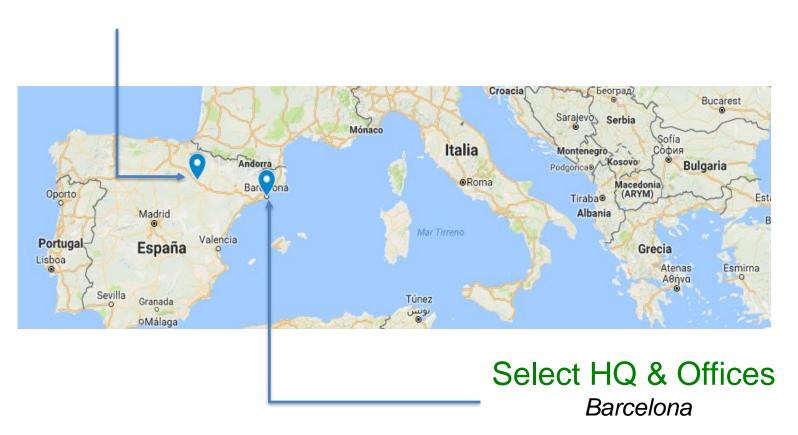


We manufacture conform to strictest EU GMP Part II standards, applying all regulatory aspects by health authorities to produce and market natural products

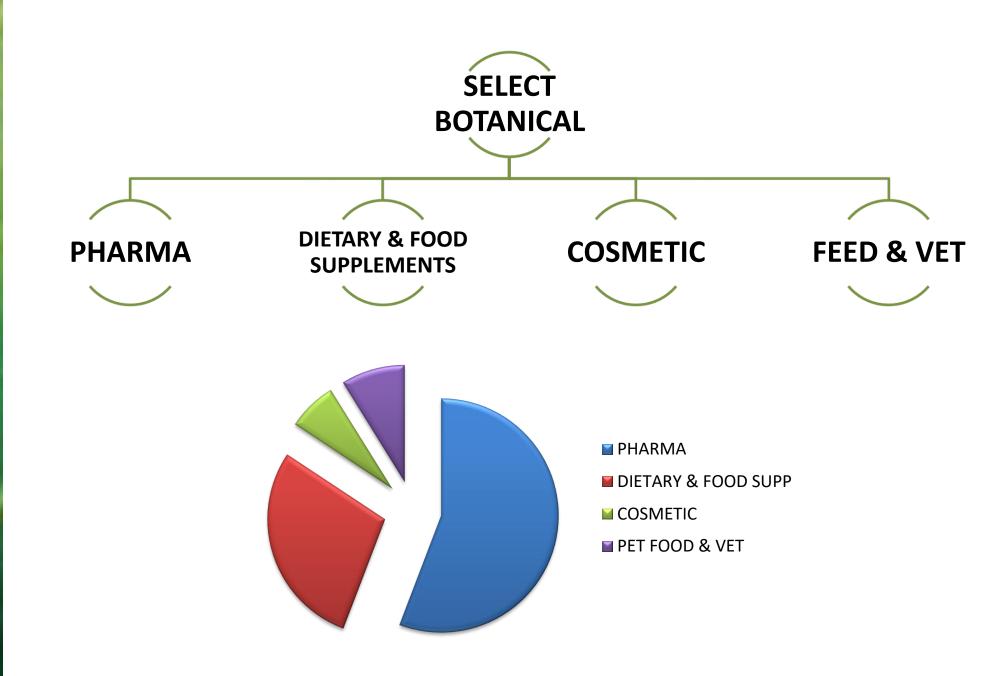
Location

Select Manufacturing Site

Buñuel - Navarra



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 m²
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



QUESTIONARY / AUDIT: SELECTION OF PARTNERSHIPS





CONTROL AT RECEPTION: ANALYSE, CONFORMITY AND VALIDATION



.

DELIVERY TO CUSTOMERS WORLDWIDE



BATCH NUMBER, END ANALYSIS & PRODUCT RELEASE





Documentation

FULL SPECIFICATION SHEET & COA

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



TECHNICAL DATA SHEET

Product name: IVY LEAF DRY EXTRACT 10 % Product Code: 0078-05-P Botanical name: Hedera helix I. 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 powde 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 2.6, 17 Eur Ph. current ed 2.4, 16 through 35 mesh through 50 mesh through 60 mesh	98,0 \$15,0 99-100 % 90-100 % 95-100 %	
Assay			
Hederacoside C (dry basis) (%)	HPLC-Internal method	≥10,0	
Residual solvents			
Ethanol (ppm)	GC (Acc.CPMPRCH/283/95 guidelines)	≤1000	
Microbiology			
Total aerobic microbial count (TAMC)	Eur.Ph.current ed 2.6.12	≤10000	
Total combined yeasts/moulds count (TYMC) (CPU/g)	Eur.Ph.current ed 2.6.12	≤100	
Bile-tolerant gram-negative bacteria (CFU/g)	Eur.Ph.ourrent ed 2.6.31	≤100	
Escherichia coli (g) Salmonella (g)	Eur.Ph.current ed 2.6.31 Eur.Ph.current ed 2.6.31	Absence 1 Absence 25	
Contaminants			
Pesticides Lead (ppm)	Eur.Ph.current ed 2.8.13	Raw material acc Eur Ph.current e	
Cadmium (ppm)	ICP	23 51	
Mercury (ppm)	IC.P	s0.10	



CERTIFICATE OF ANALYSIS

Product name: IVY LEAF DRY EXTRACT 10 % Product Code: 0078-05-P

Botanical name: Hedera helix I. 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

Ratio plant / extract Extraction solvent Composition Maltodextrin (%) Silicon dioxide (%) Physico-Chemical Total ash (% w/w) Loss on drying (% w/w) Particle size (%) Part	h brown to	
Ratio plant / extract Extraction solvent Composition Maltodextrin (%) Silicon dioxide (%) Physico-Chemical Total ash (% w/w) Loss on drying (% w/w) Particle size (%) Part	powder	
Ratio plant / extract Ethenol 24 Composition Maltodextrin (%) Billicon dioxide (%) Physico-Chemical Total ash (% w/w) Loss on drying (% w/w) Particle size (%) Residual solvents Ethanol (ppm) GC (Acc.CPMPACH/28398 guidelines) Microbiology Total aerobic microbial count (TAMC) (CFU/g) Total combined yeasts/moulds count (TYMC) (CFU/g) Bille-tolerant gram-negative bacteria (CFU/g) Bille-tolerant gram-negative bacteria (CFU/g) Ex.Ph.cumert ed.2.6.31 Abs		Complie
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Physico-Chemical Fotal ash (% w/w) Loss on drying (% w/w) Particle size (%) Particl		
Physico-Chemical Total ash (% w/w) Loss on drying (% w/w) Particle size (%) Particl	10.0	Complie
Fotal ash (% w/w) Loss on drying (% w/w) Loss on drying (% w/w) Particle size (%) Par	2,0	Complie
Loss on drying (% w/w) Particle size (%) Particle		
Particle size (%) Particle siz	\$15,0	10.1
Particle size (%) through 35 mash prough 35 mash particle size (%) through 35 mash prough 50 mas	98,0	3.8
Particle size (%) Prough 80 mesh 90- Assay Particle size (%) Prough 80 mesh 90- Assay Prough 80 mesh 90- Assay Prough 80 mesh 90- Assay Prough 80 mesh 90- Bresidual solvents Ethanol (ppm) 90 (Acc.CPMP/ICH28398 guidelines) 90 (CFU/Q) 80 (Acc.CPMP/ICH28398 guidelines) 90 (Acc.CPMP/ICH28398 guidelines) 90 (CFU/Q) 80 (Acc.CPMP/ICH28398 guidelines) 90 (Acc.CPMP/ICH28398 guidelines) 90 (CFU/Q) 80 (Acc.CPMP/ICH28398 guidelines) 90 (Acc.CPMP/ICH28398	100 %	100
Assay Hederacoside C (dry basis) (%) HPLC-internal method Residual solvents Ethanol (ppm) GC (Acc.CPMPACH/28395 guidelines) Microbiology Total aerobic microbial count (TAMC) (CPU/g) Total combined yeasts/moulds count (TYMC) (CPU/g) Bille-tolerant gram-negative bacteria (CPU/g) Eur.Ph.cument ed 2.6.31 (CPU/g) Bille-tolerant gram-negative bacteria (CPU/g) Eur.Ph.cument ed 2.6.31 Abo	100 %	99
Residual solvents Ethanol (ppm) GC (Acc.CPMP/ICH28308 guidelines) Microbiology Total aerobic microbial count (TAMC) (CPU/g) Total combined yeasts/moulds count (TYMC) (CPU/g) Bille-tolerant gram-negative bacteria (CPU/g) Eur.Ph.cument ed 2.6.12 (CPU/g) Eur.Ph.cument ed 2.6.13 Eur.Ph.cument ed 2.6.31 Eur.Ph.cument ed 2.6.31 Eur.Ph.cument ed 2.6.31 About the count of	100 %	96
Residual solvents Ethanol (ppm) OC (Acc.CPMP/ICH/28398 guidelines) Microbiology Total aerobic microbial count (TAMC) (CPU/g) Total combined yeasts/moulds count (TYMC) (CPU/g) Bile-tolerant gram-negative bacteria (CPU/g) Ex.Ph.curret ed 2.6.31 (CPU/g) Bile-tolerant gram-negative bacteria (CPU/g) Ex.Ph.curret ed 2.6.31 About the count of the coun		
Ethanol (ppm) GC (Acc.CPMP/ICH/28396 guidelines) S Microbiology Total eerobic microbial count (TAMC) (CFU/g) Dille-tolerant gram-negative bacteria (CFU/g) Etx.Ph.curert ed 2.6.12 Etx.Ph.curert ed 2.6.12 Etx.Ph.curert ed 2.6.12 Etx.Ph.curert ed 2.6.31 Etx.Ph.curert ed 2.6.31 Etx.Ph.curert ed 2.6.31 About the county of the cou	≥10,0	10.1
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(CFU/g) Total combined yeasts/moulds count (TYMC) (CFU/g) Bile-tolerant gram-negative bacteria Eur.Ph.current ed.2.6.31 Abs		
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Bile-tolerant gram-negative bacteria Exr.Ph.coment ed 2.631 (CPU/g) Excherichia coli (g) Exr.Ph.coment ed 2.631 Abo	£100	<10
Escherichia coll (g) Eur.Ph.current ed 2.6.31 Abs	≤100	<10
	ence 1	Absenc
	ence 25	Absence
Contaminants		
	material	Complie
Lead (ppm) ICP	1.017ent eo. ≤3	Complie
Cadmium (ppm)	51	Complie
	SD.10	Compile



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)



Documentation

DRUG MASTER FILE (ASMF / DMF) CTD FORMAT



Strategic products with DMF available:

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





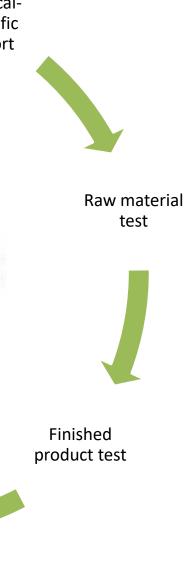






Full DMF / Technical-**ASMF in CTD** Scientific Format Support Tailor made herbal solutions 5b select botanical Analytical validations Manufacturing process validations

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

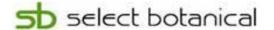


LICORICE



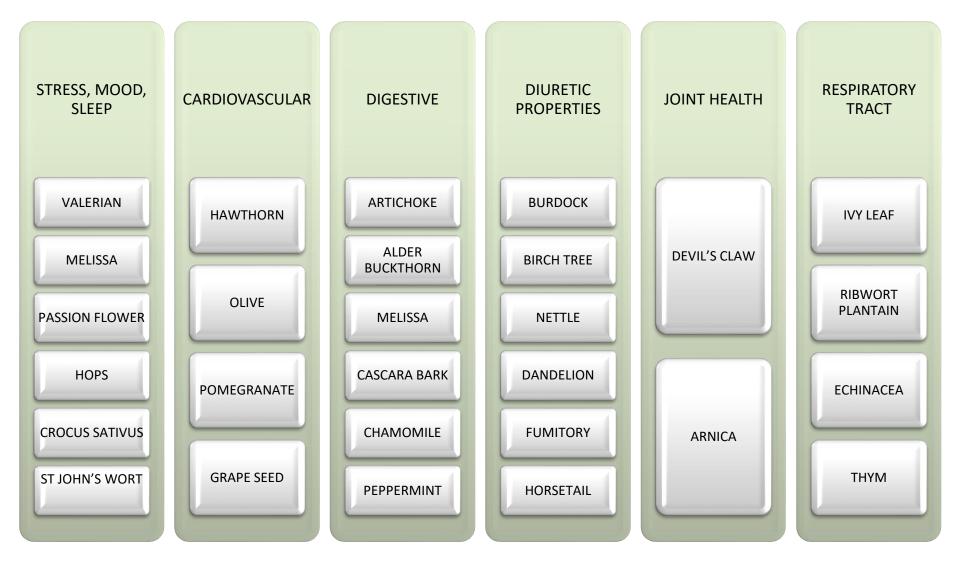
ECHINACEA





Botanical Extracts

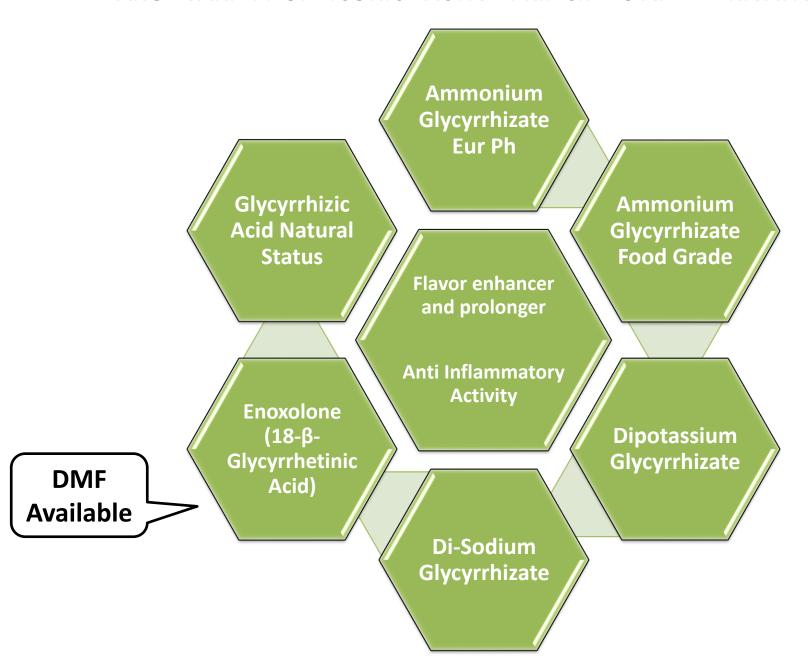
Therapeutic indications of our herbal extracts...



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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