

INSOLENT [LABS]

TECHNICAL DATA SHEET

Version : 1

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Content : Organic Acacia Seyal gum purified and instantised (soluble dietary fibre)

Legal position : Regulations 231/2012/EC, USP/NF, FCC, Eur.Ph / Regulation (EC) 834/2007/EC and USDA-NOP (Certified by ECOCERT FR-BIO-01)

Standard Packaging : Net 25 kg multilayer paper bag with inner polyethylene liner

Maximum Storage : 3 years

Storage Condition : Keep closed in a cool and dry place in original intact packaging

MATERIAL CHARACTERISTICS

Physical and chemical data

Analysis	Description	MINI	MAXI	UNIT	Test Method
Molsture	5h @ 105°C		10	%	USP <921> Method III
Colour @ 25%	Aqueous solution 25% - Lovibond AF900	Brown		-	-
pH	25% aqueous solution, @ 20°C	4,1	4,8	-	Eur. Ph. 2.2.3
Viscosity 25%	25%, Brookfield LVF 60 rpm @ 20°C	60	130	mPa.s	-
Total Ashes @ 600°C	8h @ 600°C		4	%	Eur. Ph.
Acid insoluble ashes	Ashes + acid hydrolysis		0,5	%	USP<561>
Acid insoluble matters	Gravimetric determination after acid hydrolysis		0,5	%	-
Total dietary fibre (on dry weight)	Enzymatic & gravimétric	90		%	AOAC 985.29
Mesh size powder through 63 µm	Vibro - sieving		15	%	-
Glucose and Fructose*	Chromatography	Pass test		-	Eur. Ph.
Starch, Dextrin and Agar*	Iodine solution test	Pass test		-	Eur. Ph.
Sterculia gum*	Eur. Ph (A-B)	Pass test		-	Eur.Ph
Tragacantha*	Chromatography	Pass test		-	HPLC
Identification test*	Eur. Ph (A-B-C-D)	Pass test		-	Eur. Ph
Tannin test*	reaction with ferric chloride solution	Pass test		-	Eur, Ph
Solubility and reaction*	solution in water	Pass test		-	USP

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*tested 1/year (product of the same grade)

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Total heavy metal*			5	ppm	FCC (Method 2)
Arsenic*	ICP-Mass spectrometry		0,5	ppm	ICP -OES/ICP-MS
Lead*	ICP-Mass spectrometry		0,1	ppm	ICP -OES/ICP-MS
Mercury*	Atomic Absorption spectrometry		0,1	ppm	SAA / ICP-MS
Cadmium*	ICP-Mass spectrometry		0,1	ppm	ICP -OES/ICP-MS
Bacteriology					
Analysis	Description	MINI	MAXI	UNIT	Test Method
Total Plate Count	72 h @ 30°C - PCA		1000	cfu/g	ISO 4833-1
Yeast	5 days @ 25°C - YGC		100	cfu/g	ISO 6611
Molds	5 days @ 25°C - YGC		100	cfu/g	ISO 6611
E. coli (test for the presence of)	48 h @ 44°C - EP without indole + Kovacs reagent	abs	/5g	-	ISO 7251
Salmonella (presence)	Pre-enrichment, 24 h @ 41°C	abs	/25g	-	ISO 6579-1

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Technical Specification

Item : Empty Hard Hypromellose Capsules Size #1

Color (Cap / Body) : CLEAR (A51) / CLEAR (A51)

No.	Test Items		Specifications
1	Purity a) Solubility b) pH c) Odor		It is soluble within 10 minutes (at $37\pm 2^{\circ}\text{C}$). The solution is neutral or slightly acid. The solution is odorless.
2	Arsenic (ppm)		Less than 3
3	Lead (ppm)		Less than 3
4	Cadmium (ppm)		Less than 0.5
5	Mercury (ppm)		Less than 0.1
6	Residue on ignition (%)		Less than 3.0
7	Approx. Weight (mg)		$75\pm 11\%$
8	Length (mm)	Cap	9.8 ± 0.4
		Body	16.6 ± 0.4
		Open L.(Empty)	21.3 ± 0.5
		Closed L.(Filled)	19.4 ± 0.4
9	Outside diameter (mm)	Cap	6.91 ± 0.06
		Body	6.63 ± 0.06
10	Volume (ml)		0.50
11	Loss on Drying (%)		3.0 ~ 7.0
12	Disintegration (minutes)		Less than 20
13	TAMC		Less than 500 cfu/g
	TYMC		Less than 100 cfu/g
	Escherichia coli		Negative / 10g
	Salmonella Species		Negative / 10g
	Pseudomonas aeruginosa		Negative / 10g
	Staphylococcus aureus		Negative / 10g

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No.	Test Items		Specifications					
14	Visual Inspection	Capsule Appearance	Lot Size	Quantity of Sampling	Classification	Ac	Re	AQL(%)
			Over 500,001 capsules	1,250	Critical	0	1	0.010
				1,250	Major A	1	2	0.040
				1,250	Major B	2	3	0.065
		1,250	Minor	10	11	0.400		
		Imprinting Appearance	Lot Size	Quantity of Sampling	Classification	Ac	Re	AQL(%)
			Over 500,001 capsules	1,250	Critical	0	1	0.010
				1,250	Major A	1	2	0.040
1,250	Major B			2	3	0.065		
1,250	Minor	10	11	0.400				
15	Capsule Composition	Ingredient	Cap		Body		Capsule	
			%	mg	%	mg	%	mg
		HPMC	qsp 100	28.5000	qsp 100	42.7500	qsp 100	71.2500
Purified Water	5.0000	1.5000	5.0000	2.2500	5.0000	3.7500		

Expiration date : 5 years from the manufacturing date

Storage conditions : The ideal storage condition for capsules are 22°C and 50% RH. When kept in the well-sealed original package, however, capsules can be stored without deterioration at temperature between 15°C to 25°C and a relative humidity of 35% to 65%.

Packaging unit : 90,000 pcs