



# **QUALITY DOSSIER**

# **ORGANIC INDIA PRIVATE LIMITED**



## Company Profile

At the heart of ORGANIC INDIA is our commitment to promote holistic sustainable development for all beings through organic agriculture. We are committed to service, sanctity and integrity, and to operating an ethical and sustainable business that harms none and benefits all. ORGANIC INDIA is a global leader in promoting organic products and in supporting sustainable farming, wild crafting and village/tribal agricultural communities in India.

We cultivate, collect, process, manufacture and market Certified **Organic Tulsi Teas**, **Herbal Supplements**, **Psyllium**, Castor Oil, Ayurvedic and Medicinal Herbs, and many other **organic foods** and **organic spices**. Our products are of the highest quality and marketed all over the world. We are continually developing and expanding our range of organic foods and health products.

All ORGANIC INDIA facilities and processing centers have been awarded **SQF**, **HACCP**, **GMP**, **ISO-9001** and Kosher certifications, and are **EU**, **Skal**, **ECO-Cert** and **USDA** certified for organic production. We have designed and developed our unique processing methods and advanced dehydration technologies to ensure maximum retention of potency and nutritional values, so that we can remain true to our commitment to offer the highest quality organic products available today.



## **TULSI PROCESS DESCRIPTION**

## CULTIVATION OF TULSI:

Tulsi is cultivated organically by us through contract farming at different locations. Each cultivation site has The Organic India Company's office (OI) with a complete Agro team dedicated to ensure chemical free production (No use of any chemical during cultivation whether it is pesticides or fertilizers). The Agro team co-ordinates, trains and helps farmers in obtaining a good and sound Tulsi crop as per various Organic Production Standards eg. USDA, European Commission Standards (EEU), National Program for Organic Production (NPOP-India). The tulsi projects are certified by various International Certification agencies like ECO-Cert, CU (Control Union). etc



TULSI NURSERY Organic India<sup>®</sup> Azamgarh Project July 2007





TULSI NURSERY CLOSE UP Organic India<sup>®</sup> Azamgarh Project July 2007



TULSI PLANTATION IN PROGRESS Organic India<sup>©</sup> Rath Project July 2006





STANDING TULSI CROP Organic India<sup>®</sup> Azamgarh Project July 2005

## HARVESTING:

Harvesting is done as per the planning and scheduling given by Organic India to the farmers to exercise better control on its procurement, processing and storage. Harvesting of Tulsi is done after the crop has attained enough maturity (100-120 days) and has optimum levels of active ingredients responsible for its good quality.

Tulsi leaves are hand picked by the farmers; The Tulsi plants are cut using disinfected sickles from approximately six centimeters above the soil to avoid soil contact with the plants. The cut plant is collected in clean white cloths and is taken to a central place in the field for plucking leaves. The leaves are plucked by staff wearing hygienic face masks and proper head gear to prevent any contamination with the plucked leaves. The plucked leaves are transported to a drying place in cleaned and dried plastic crates. The Tulsi leaves are dried on a clean cloth laid above the tarpaulin which prevents any contamination from the ground surface. The drying of leaves takes place in such places which are well protected from contamination from the environment, birds or any other animals. Sun-dried leaves are brought to the Organic India procurement center in clean poly bags.





HAND WASHING AND DISINFECTION IN PLACE PRIOR TO HARVESTING Organic India<sup>®</sup> Azamgarh Project November 2006





HARVESTING OF TULSI CROP IN PROGRESS Organic India<sup>®</sup> Azamgarh Project November 2006



HARVESTING OF TULSI CROP IN PROGRESS Organic India<sup>®</sup> Azamgarh Project November 2006





PLUCKING OF TULSI LEAVES IN PROGRESS Organic India<sup>®</sup> Azamgarh Project November 2006



PLUCKING OF TULSI LEAVES IN PROGRESS (CLOSE UP) Organic India<sup>©</sup> Azamgarh Project November 2006





<u>COLLECTING PLUCKED TULSI LEAVES FOR SUN DRYING</u> Organic India<sup>©</sup> Azamgarh Project November 2006



SUN DRYING IN PLACE Organic India<sup>©</sup> Azamgarh Project November 2006



#### **RECEIVING OF TULSI:**

The farmers bring their sun dried Tulsi to the procurement center in neat and hygienic poly bags. **The incoming Tulsi is checked for any foreign and physical hazardous materials, moisture content, infestation or any other kind of damage**. The incoming tulsi is sampled here for each batch received and checked against established quality and safety parameters. The Quality representative at these centers ensures that Tulsi is accepted only when it meets the laid down requirements of quality and food safety. Tulsi of acceptable quality is properly identified, weighed and recorded into the company's books. The specification of the incoming quality of Tulsi is attached as Appendix A.





<u>RECEIVING OF SUN-DRIED TULSI AT PROCESSING CENTERS</u> Organic India<sup>©</sup> Azamgarh Project December 2006





DRIED TULSI LEAVES BEING PUT INTO TROUGH FOR INSPECTION Organic India<sup>©</sup> Azamgarh Project December 2006





QUALITY SAMPLING IN PLACE Organic India<sup>®</sup> Azamgarh Project December 2006





PREPARING FOR WEIGHING AFTER INSPECTION Organic India<sup>©</sup> Azamgarh Project December 2006



## DRYING:

The primary purpose of this step is to bring Tulsi leaves to a uniform moisture content, which ensures that the growth of **microorganisms** and infestation by **insects** is **inhibited and controlled**. The moisture content at this stage is maintained at **less than 10%**. This is achieved by drying tulsi leaves at a temperature of **56<sup>o</sup>C for about 2 hours**. This process of drying is verified and validated by determining the moisture content of each lot. Only when a moisture content of less than 10 percent is achieved, are the leaves allowed to be cooled to room temperature before they are filled into the clean poly bags. This low temperature of drying ensures that tulsi does not lose any essential oil in the process.

#### **INTERMEDIATE STORAGE:**

Procured Tulsi packed in barrier poly bags, identified with detailed batch tracking labels, is stored in intermediate storage on pallets to prevent any cross contamination. Tulsi is stored at ambient temperature. Good Storage Practices ensure that the growth of microorganisms, like fungi, yeasts and bacteria are inhibited. It is a well known fact that at a moisture content of less than 10 percent, microbial growth does not take place. We are not doing any micro-testing at this stage because we are further treating our product in a Steam sterilizer, which takes care of any microbial growth.

A Composite sample of procured Tulsi drawn from the crop is analyzed by a qualified independent laboratory for heavy metals (lead, cadmium, mercury and arsenic), pesticide residues and Afla toxins and other essential ingredients present. The specifications of heavy metals and pesticides are attached in the Appendix B.

The stocks at different locations are checked for physical quality parameters: for example infestation, pack seal integrity or any change in the appearance of Tulsi leaves from time to time





TULSI STORAGE Organic India<sup>®</sup> Azamgarh Project August 2007





TULSI STORAGE Organic India<sup>®</sup> Azamgarh Project August 2007





TULSI STORAGE Organic India<sup>®</sup> Azamgarh Project August 2007

## **GRADING & STALK REMOVAL:**

Tulsi leaves are rubbed gently on a screen to reduce the size of the leaves, which renders them suitable for further processing. The breaking of leaves also allows for the separation of the stalks from leaves, which further improves the quality of Tulsi. This is done mechanically using different sizes of sieves. This process is done in a closed environment (room) with persons wearing hygienic equipments like hair nets; face masks overshoes and gloves to prevent any contamination taking place at this step. The machine is cleaned after each shift operation with pressurized air and clean and dry cloths. The graded and cleaned Tulsi leaves are collected in clean poly bags to prevent any contamination-taking place at this stage. The



stalks are collected separately for disposal. This step also removes dust, dirt, small stones or dust balls that may come along because of Tulsi being an agricultural product.



<u>GRADING & STALK REMOVAL IN PROGRESS</u> Organic India<sup>©</sup> Azamgarh Project August 2007

#### **SORTING**:

The physical impurities present in the form of other plant parts, stems, twigs, mud balls etc. still present in Tulsi leaves are picked out manually to ensure that the product is free from these impurities. The sorting is done manually on a sorting conveyer. This step is also a Critical Control Point for Physical contamination. The Tulsi leaves coming out after sorting are inspected for the presence of any foreign material at a defined interval. Any product found to be containing any foreign material exceeding quality standards is reprocessed.





SORTING OF TULSI BEING CARRIED OUT Organic India<sup>©</sup> Azamgarh Project December 2006

## **CUTTING OF LEAVES:**

Sorted Tulsi leaves are cut into tea bag cut size with the use of a Cutting machine. The Cutting machine cuts the leaves with the help of four sets of cutters. This type of cutting ensures that Tulsi is cut to the required sizes depending on the subsequent use. This technology also ensures that the temperature of the product does not rise much to cause any quality loss.

## <u>SIFTING</u>:

Cut Tulsi leaves are then passed through various sieve sizes to separate different kind of cuts to be used in manufacture of different products. The sifting machine also uses magnets to ensure that the tulsi coming out of this machine is free from any iron impurities.





TULSI CUTTING AND SIFTING IN PROGRESS Organic India<sup>®</sup> Azamgarh Project December 2006



Tulsi and other ingredients are blended in a mechanized Paddle blender for a maximum of 10 minutes to ensure uniform blending depending on the type of mix. The organoleptic properties of the blends are checked to ensure uniformity in the quality of the finished products. The blending process is validated to achieve uniformity of the blends with respect to the sensory properties and moisture content of the blended product.



FEEDING THE TULSI INTO THE CONE BLENDER Organic India<sup>©</sup> Lucknow Production Unit January 2007





<u>OFF-LOADING OF TULSI LEAVES FROM THE CONE BLENDER</u> Organic India<sup>©</sup> Lucknow Production Unit January 2007

## **STEAM DISINFECTION:** (OPTIONAL & AS PER BUYER'S REQUIREMENT)

The blends are disinfected in the Steam disinfection at **95<sup>o</sup>C for 1-5 minutes** under vacuum to reduce the microbial count up to WHO standards for infusion. Dry super heated steam at 130<sup>o</sup>C is injected in an air tight chamber under minus 9 bar vacuum. Vacuum ensures that that all the air pockets are removed from the product and once the steam is injected into the vacuumised chamber, it spreads uniformly throughout the product and raises the product temperature quickly to the preset temperature.

This method ensures very efficient, effective and uniform penetration of heat throughout the product, which reduces the microorganism in very short time without causing any perceptible loss to the product quality.

The time and temperature combination of steam disinfection can be manipulated to ensure very low levels of microorganisms in Tulsi. Apart from reducing microbes, it also kills any insect eggs that might be present and might hatch afterwards under favorable growth conditions. We are attaching a sheet (Appendix C) showing how different time and temperature combinations affect microbial growth during steam sterilization.

This is a **Critical Control Point** for **Microbial Contamination**.





LOADING OF TULSI LEAVES INTO THE STEAM DISINFECTION MACHINE Organic India<sup>©</sup> Lucknow Production Unit January 2007





SETTING OF STEAM DISINFECTION PARAMETERS Organic India<sup>©</sup> Lucknow Production Unit January 2007





UNLOADING OF TULSI INTO THE BARRELS Organic India<sup>©</sup> Lucknow Production Unit January 2007



The steam-sterilized material is subjected to final metal detection to ensure that the finished product is metal free. This step is a **Critical Control Point** for **Physical Contamination**.

## PACKAGING:

## A) TEA BAGS-

The blends are packed in an automatic tea bagging machines into tea bags under GMP and hygienic factory conditions. These tea bags are stacked in a box depending on customer requirement and standard packaging size. All boxes are batch coded on line to ensure proper identification throughout the supply chain. The tea bagging is done in an enclosed room well protected from the outside environment so as to avoid any cross contamination with the product. The persons working in production are equipped with all protective equipment like face- masks, hairnets for protecting hair, hand gloves, overshoes etc. to ensure that the product is uncontaminated in Production.



TEA BAGGING IN PROGRESS Organic India<sup>©</sup> Lucknow Production Unit January 2007



Product is packed in a Master/shipper carton manually as per the requirements of the customers. The Master and Shipper cartons are also coded to identify the product throughout supply chain.



TEA BOXES BEING PUT INTO THE MASTER CARTONS Organic India<sup>©</sup> Lucknow Production Unit August 2007



### FINISHED PRODUCT QUALITY INSPECTION:

The finished product is inspected for laid down specifications mainly covering Physical, Chemical and Microbiological quality of the product. The samples of the finished product are collected as per MIL-STD-105D plan and procedure. Only the product meeting all the requirements for quality is shipped to the customers. The quality standards of Tulsi tea are attached with this document as an Appendix D



DETERMINATION OF MOISTURE CONTENT Organic India<sup>©</sup> Lucknow Production Unit January 2007





PHYSICAL INSPECTION OF TULSI IN PLACE Organic India<sup>©</sup> Lucknow Production Unit January 2007



INNOCULATION (MICRO-BOILOGICAL) IN PROGRESS Organic India<sup>©</sup> Lucknow Production Unit January 2007





COLONY COUNTING (MICRO-BIOLOGICAL) IN PLACE Organic India<sup>©</sup> Lucknow Production Unit January 2007





IDENTIFICATION OF BACTERIA IN PLACE Organic India<sup>©</sup> Lucknow Production Unit January 2007





DETERMINATION OF ALCOHOL EXTRACTIVES IN TULSI IN PLACE Organic India<sup>©</sup> Lucknow Production Unit January 2007



The quality passed material is shipped to the customers as per agreed terms and conditions of quality, quantity and price.

Organic India is a certified ISO 9001:2000 (Quality Management Systems), HACCP (Food Safety Management System), GMP (Good Manufacturing Practices) and SQF (Safe Quality Food) company. These systems have been established to ensure that foods produced by Organic India Pvt Ltd are as per globally accepted quality norms and safe for consumption.











## APPENDIX A

## RAW MATERIAL SPECIFICATION- TULSI Farm Grade Tulsi Specification:

Sl.No.	Description	Specifications
1	Physical Appearance	Dark Green to light green with some brownish leaf for Rama and Vana (Dark to light purple for Krishna Tulsi), dry brittle leaves containing few twigs and other vegetative parts of Tulsi plant. Free from rotten, infected and infested leaves
2	Tulsi seeds	Up to 0.1%
3	Tulsi flowers	1% to 2 %
4	Vegetative parts of plants other than Tulsi	<1%
5	Dust, soil and clay	0.5%
6	Visible glass, metals, stones and plastic pieces	Nil
7	Live insects	Nil
8	Dead insects and insects fragments	Max. 50 Nos./100g
9	Moisture	< 12%



## **APPENDIX B**

## Specifications for pesticide & Heavy metals

Pesticide	OIPL's Specifications.
	Not to be detected at
	following Detection
	limit (ppm)
a. Organochlorine pesticide	
Alfa BHC	0.01
Beta BHC	0.01
Delta BHC	0.01
Lindane	0.01
O,p' – DDD	0.01
O,p' – DDE	0.01
O,p' – DDT	0.01
P,p' – DDD	0.01
P,p' – DDE	0.01
p,p' – DDT	0.01
Endosulfan 1	0.01
Endosulfan 2	0.01
Endosulfan sulfate	0.01
Aldrin	0.01
Dieldrin	0.01
Heptachlor	0.01
Heptachlor epoxide	0.01
Endrin	0.01
Methoxychlor	0.01
alachlor	0.01
Butachlor	0.01
Chlordane	0.01
Decofol	0.01
Hexachlorobenzine (HCB)	0.01
b. Organophosphorous	
pesticide residues group	
Chlorpyrifos methyl	0.01
Phosphamidon	0.01
Fenitrothion	0.01
Parathion	0.01
Methyl paraoxon	0.01
Malathion	0.01
Methyl parathion	0.01
Malaoxon	0.01
Dimethoate	0.01
Phosalone	0.01



0 1 1 1	0.01
Quinalphos	0.01
Primiphos methyl	0.01
Monochrotophos	0.01
Fenthion	0.01
Phorate	0.01
Phorate sulphone	0.01
Phorate sulphoxide	0.01
isoproturon	0.01
Methidathion	0.01
Dichlrvos	0.01
Carbofenotion	0.01
Clorfenvinfos	0.01
Diazinon	0.01
Azinphos methyl	0.01
Triazophos	0.01
Ethion	0.01
c. Organosulphur pesticide	
Alfa – endosulphan	0.001
Beta – endosulphan	0.001
Endosulphan - sulphate	0.001
Deltamethrin	0.001
Propargite	0.001

## SPECIFICATIONS FOR HEAVY METALS

Heavy Metals	Limits
Lead	Not more than 5 ppm
Arsenic	Not more than 0.05 ppm
Cadmium	Not more than 0.3 ppm
Mercury	Not more than 0.01 ppm



## APPENDIX C

# Effect of heat treatment on the microbial load reduction and reduction in volatile oil content

	Treatr	nent								%	
Replication No.	Time	Temp.	TPC/g before treatment	TPC/g after treatment	Y&M/g before treatment	Y&M/g after treatment	Coliform before treatment	Coliform after treatment	% Volatile oil before treatment	Volatile oil After treatment	% reduction
1	1800 seconds	95 <sup>0</sup> C	750000	28400	92700	<10	430000	<10	1.2	0.95	20.83
2	1800 seconds	95 <sup>0</sup> C	6500000	82000	116300	<10	2040000	<10	1.2	0.9	25.00
1	30 seconds	95 <sup>0</sup> C	814000	91800	410000	<10	132000	<10	1.025	0.95	7.32
2	30 seconds	95 <sup>0</sup> C	3900000	81000	94000	<10	1150000	<10	1.05	0.95	9.52
1	1800 seconds	70 <sup>0</sup> C	5450000	95400	87700	20	1360000	<100	1.15	1	13.04
2	1800 seconds	70 <sup>0</sup> C	6040000	102000	100400	<10	1490000	<100	1.05	0.9	14.29
1	30 seconds	70 <sup>0</sup> C	3460000	4100000	168000	28000	1360000	1040000	1.1	1.05	4.55
2	30 seconds	70 <sup>0</sup> C	4460000	1390000	88900	93000	4230000	1460000	1.05	0.95	9.52

We have been recommending a treatment of 95 degree centigrade temperature and a time of 30 seconds that is sufficient enough to bring down the microbial load to an acceptable level as can be seen in the table (highlighted in blue)



## PROCESS CONTROL CHART

Date:

## 1. Grinding/Siffing.

Time of observation	Product	Bar code	Sieve size	Intactness of sieve	Particle size	Remark

## 2. Blending

product:

Blend No.	Name of	Bar code	Category	Quantity	Uniformity	Time of	Remark
	Herb					mixing.	

3. Heat treatment



Time of observation	Product	Temperature °C	Treatment Time	Bar code/Blend No.	Remark

#### 4. Filling/Tea bagging

Time of observa tion	Product	Blend No.	Batch No.	Packin g size	Weights (6 nos for Psyllium,2 from each head)	Aver age wt.	range	Sealing/ capping /Inducti on	Material in Tea bag	Remark

#### 5. Metal Detection

	Time of Proc	duct Bat	tch number T	lest Run	Remark
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ORGANIO	C		
observation			

## 6. Labeling & Batch coding

Time of	Product	Batch	Batch coding				Labeling		Remark
observation		number	Pasting quality	/ cor	ntent /	Positioning Alignment/	Smudging /Fading/ Misregistration	Bubbling/ Creazing	



Time	Product	Batch No.	Packing operation	Remark

## 8. Storage:

Time	Hygiene & cleanliness	Humidity	Temperature	Palletization	Stacking and identification	Remark

Q.C. Supervisor

Production shifts In-charge



## **Microbiological Specifications of deferent regulation**

<u>S. no.</u>	Parameters	WHO* Specification	USP specification	EHIA specification
1.	Total plate count	<100000 per gram	<1000 per gram	Max 1 x 10 <sup>8</sup> per gram
2.	Yeast and moulds	<1000 per gram	<1000 per gram	Max 2 x 10 <sup>6</sup> per gram
3.	Escherichia coli	<10 per gram	Absence	Max 1 x 10 <sup>4</sup> per gram
4.	Other enterobacterria	<1000 per gram		
5.	Salmonellae	None	Absence	Absent in 25 gram

\* Internationally accepted limits for direct consumption.



## <u>APPENDIX D</u> <u>SPECIFICATION SHEET FOR FINISHED PRODUCT</u>

## <u>Tulsi Mix</u>

Name of Product	Tulsi Mix (Tea cut)				
Category	100%Organic				
Ingredients	Rama Tulsi ( <i>Ocimum sanctum</i> ) Vana Tulsi ( <i>Ocimum gratissimum</i> ) Krishna Tulsi ( <i>Ocimum sanctum</i> )				
Parameter	LIMIT	PROTOCOL			
Appearance	Tea cut	Visual inspection			
Colour	Greenish brown	Visual inspection			
Mesh Size a) On # 8 % b) Thru # 30 %	≤ 5.0 ≤ 5.0	Sieve analysis			
CHEMICAL SPECIFICATIONS	5				
Moisture (Loss on drying)	NMT 10 %				
Total Ash	NMT 16.0 %				
Acid Insoluble Ash	NMT 3.0 %	The Ayurvedic			
Water soluble Extractive value	NLT 16.0 %	Pharmacopoeia of India			
Alcohol soluble Extractive value	NLT 5.0 %				
Volatile Oil	NLT 0.4 %				
MICROBIOLOGICAL SPECIFI	CATIONS FOR HERBAL INF	USION IN HOT WATER			
Total Viable Count	<10 <sup>8</sup> cfu/g	USFDA (BAM)			
Mould	<10 <sup>6</sup> cfu/g	USFDA (BAM)			
Yeast	<10 <sup>6</sup> cfu/g	USFDA (BAM)			
E.coli	<10 <sup>4</sup> cfu/g	USFDA (BAM)			
Salmonella	Absent in 25 g	USFDA (BAM)			
Pesticides	< 0.05 ppm each for Organo phosphorous, Organo sulfur and Organo chloro compounds	AOAC Methods			
HEAVY METALS	Lead: NMT 0.5 ppm Arsenic:NMT 0.5 ppm Cadmium:NMT 0.3 ppm Mercury: NMT 0.01 ppm	AOAC Methods			



CERTIFICATION	Certified Organic as per the NOP standards of USDA and/or EEC No. 2092/91	AOAC Methods
PRODUCT PACKAGING	As per Buyer's requirement	
STORAGE INSTRUCTION (Ambient condition)	A Cool and dry place, away from	n direct sun light
SHELF LIFE	3 years from the date of packing	



## **RATIONALE AND JUSTIFICATEION FOR USING EHIA STANDARDS**

We are following EHIA norms for microbiology and it is well accepted in Europe for teas and we have already done certain experiments on different kind of Tulsi infusing it in hot water which is normally use the brew which is consume.

We have taken Tulsi from different region for experiment in triplicate.

**OBJECTIVE:** To analyze Microorganism load after infusion and prove that brew are okay for direct consumption and meet WHO internal norms.

**PROCEDURE:** Tea bags Prepared from Untreated Tulsi were infused by pouring 130 ml boiling water over the tea bags at aseptic condition. Tulsi Powder, Infusion and residue inside tea bag was analyzed in triplicate for TPC and Coliform as per the BAM method.

Results of the analysis are presented in the Table as mentioned below.

Sr No.	Date	Tulsi Source	Initial counts		Infusion counts		Wet Tea Bag counts	
			TPC	Coliform	TPC	Coliform	TPC	Coliform
		Boiling Water*			Absent	Absent		
		Bundelkhand	891000	477500	7100	ND	29000	ND
1 27.04	27.04.07				2800	ND		
					2900	ND		
2 17.04.07		7.04.07 Azamgarh	1200000	500000	282	ND	Not Done	Not Done
	17.04.07				112	ND		
					55	ND		
3 1	10.04.07	)7 Azamgarh	710000	180000	2	ND	Not Done	Not Done
					3	ND		
					ND	ND		

TABLE

\*Boiling Water: Counts were same (Absent) for all three trials.

#### **FINDINGS**

- **1** After Infusion, significant reduction observed in TPC and Coliform which is much below than WHO standards.
- 2 E.coli is the part of Coliform and in brew it is not detected.



## **CONCLUSION**:

Based on above finding we can safely conclude that these Tulsi tea when infuse in hot water reduces not only microbes but pathogen also to the safe level. The fact is very much stabilized in international market.

**R.C.PARASHER** 

(General Manager-Quality Management Systems)

#### ORGANIC INDIA PRIVATE LIMITED

LUCKNOW

INDIA

DT. 08.04.2009