





 <b>JAIRAMDASS</b> <b>KHUSHIRAM</b> SINCE 1875	<b>S.A. HERBAL BIOACTIVES LLP</b>		 OVER <b>140</b> Years of Quality Trust
	<b>Finished Product Specification</b> <b>Product Name: Gymnema Dry Extract</b> <b>Botanical Name: <i>Gymnema sylvestre</i></b>		
<b>Document No.</b>	SAH/QCD/F/FGS/GRM/30	<b>Date of issue</b>	03/02/2023
<b>Effective date</b>	04/02/2023	<b>Next revision due date</b>	02/02/2026
<b>Supersedes</b>	SAH/QCD/F/FGS/002	<b>Version No.</b>	02
<b>Part Used</b>	Leaves	<b>Herb Ratio</b>	20:1




Sr. No	Test Parameter	Reference	Specification
<b>1.0</b>	<b>Description</b>		
1.1	Appearance	Organoleptic (SAH/SOP/QCD/OL/FG/00)	Greenish brown colour powder
1.2	Odor		Characteristic
1.3	Taste		Characteristic
<b>2.0</b>	<b>Analytical Data</b>		
2.1	Identification (By Gravimetry)	SAH/MOA/QCD/GV/GA/16	Presence of Gymnemic acid- Positive
2.2	Loss on drying (at 105 °C)	IP 2014 (SAH/STP/QCD/LOD/01)	NMT 5.0%
2.3	Total ash	IP 2014 (SAH/STP/QCD/ASH/05)	NMT 10.0%
2.4	Bulk density (gm/ml)	IP 2014 (SAH/STP/QCD/BDTD/06)	NLT 0.25gm/ml
2.5	Tapped density (gm/ml)	IP 2014 (SAH/STP/QCD/BDTD/06)	NLT 0.30gm/ml
2.6	Particle size	Dry Sieve analysis (SAH/STP/QCD/PS/07)	NLT 95.0% Passing through 40mesh
2.7	pH (1% w/v solution)	IH (SAH/STP/QCD/PH/02)	4.0 to 7.0
<b>3.0</b>	<b>% Assay (On a dried basis)</b>		
3.1	Gymnemic acid (By Gravimetry)	SAH/MOA/QCD/GV/GA/16	NLT 75.0%
<b>4.0</b>	<b>Heavy Metals</b>		
4.1	Lead	ICP-MS (By NABL-approved external laboratory)	NMT 2.0 ppm
4.2	Arsenic		NMT 1.1 ppm
4.3	Cadmium		NMT 0.3 ppm
4.4	Mercury		NMT 0.1 ppm
<b>5.0</b>	<b>Residual Solvents</b>		
5.1	Residual Solvents	SAHB/GC-HS/RS/00	Complies as per EU regulations
<b>6.0</b>	<b>Pesticides</b>		
6.1	Total Pesticides	GC-MS (By NABL-approved external laboratory)	Complies as per EU regulations


	Prepared by	Checked by	Approved by
<b>Name</b>	Mr. Ram Prajapati	Mrs. Ranjana Kobal	Mr. Vijay Baghel
<b>Designation</b>	QC Executive	QC Head	QA Head
<b>Signature</b>			

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<b>7.0</b>	<b>Ethylene Oxide (ETO)</b>		
7.1	Ethyleneoxide	GC-MS/MS (By NABL-approved external laboratory)	NMT 0.1ppm
<b>8.0</b>	<b>Pyrrolizidine Alkaloids (PA)</b>		
8.1	Pyrrolizidine alkaloids	LC-MS/MS (By NABL-approved external laboratory)	Complies as per EU regulations
<b>9.0</b>	<b>Poly aromatic hydrocarbons ( Sum of 4 PAH)</b>		
9.1	Benzo(a)pyrene	GC -MS/MS (By NABL Approved External Lab)	NMT 10ppb
9.2	Sum of 4 PAH		NMT 50ppb
<b>10.0</b>	<b>Microbiological Enumeration</b>		
10.1	Total aerobic microbial Count	SAH/SOP/QCD/MIC/MLTTPC/11 (USP)	NMT 1000 cfu/gm
10.2	Total yeasts & molds count	SAH/SOP/QCD/MIC/MLTYMC/17 (USP)	NMT 100 cfu/gm
<b>10.3</b>	<b>Pathogens</b>		
10.3.1	Escherichia coli	SAH/SOP/QCD/MIC/MLTE/13 (USP)	Absent/gm
10.3.2	Salmonella	SAH/SOP/QCD/MIC/MLTS/16 (USP)	Absent/10gm

<b>Storage Condition</b>	Store in a cool and dry place away from direct sunlight, heat & moisture.
<b>Shelf life</b>	Three years in original packed conditions from the date of manufacturing.
<b>Packaging</b>	25 Kg Suitable for foodstuff packed in double poly bags unless otherwise required by the customer.
<b>Declaration</b>	The product is neither derived from GMO nor any kind of GMO ingredients used in the manufacturing process.
	The product is not subjected to radiation and doesn't consist of, or contain allergen products.
	The product is fit for human consumption.

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**Revision History:**

Version No.	Effective Date	Reason for Revision
02	04/02/2023	New format adopted.

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<b>Name</b>	Mr. Ram Prajapati	Mrs. Ranjana Kobal	Mr. Vijay Baghel
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