





	S.A. HERBAL BIOACTIVES LLP		
	Finished Product Specification Product Name: Gymnema Dry Extract Botanical Name: <i>Gymnema sylvestre</i>		
Document No.	SAH/QCD/F/FGS/GRN/30	Date of issue	03/02/2023
Effective date	04/02/2023	Next revision due date	02/02/2026
Supersedes	SAH/QCD/F/FGS/002	Version No.	02
Part Used	Leaves	Herb Ratio	8:1




Sr. No	Test Parameter	Reference	Specification
1.0	Description		
1.1	Appearance	Organoleptic (SAH/SOP/QCD/OL/FG/00)	Greenish brown colour powder
1.2	Odor		Characteristic
1.3	Taste		Characteristic
2.0	Analytical Data		
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
3.0	% Assay (On a dried basis)		
3.1	Gymnemic acid (By Gravimetry)	SAH/MOA/QCD/GV/GA/16	NLT 25.0%
4.0	Heavy Metals		
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
5.0	Residual Solvents		
5.1	Residual Solvents	SAHB/GC-HS/RS/00	Complies as per EU regulations
6.0	Pesticides		
6.1	Total Pesticides	GC-MS (By NABL-approved external laboratory)	Complies as per EU regulations



	<b>Prepared by</b>	<b>Checked by</b>	<b>Approved by</b>
<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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7.0	Ethylene Oxide (ETO)		
7.1	Ethylene oxide	GC-MS/MS (By NABL-approved external laboratory)	NMT 0.1ppm
8.0	Pyrrolizidine Alkaloids (PA)		
8.1	Pyrrolizidine alkaloids	LC-MS/MS (By NABL-approved external laboratory)	Complies as per EU regulations
9.0	Poly aromatic hydrocarbons ( Sum of 4 PAH)		
9.1	Benzo(a)pyrene	GC –MS/MS (By NABL Approved External Lab)	NMT 10ppb
9.2	Sum of 4 PAH		NMT 50ppb
10.0	Microbiological Enumeration		
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
10.3	Pathogens		
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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