





 JAIRAMDASS KHUSHIRAM <small>SINCE 1875</small>	S.A. HERBAL BIOACTIVES LLP		
	Finished Product Specification Product Name: SIVI Passion Flower Dry Extract Botanical Name: <i>Passiflora incarnata</i>		
Document No.	SAH/QCD/F/FGS/SVE/01	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	Aerial Part	Herb Ratio	8:1

Sr. No	Test Parameter	Reference	Specification
1.0	Description		
1.1	Appearance	Organoleptic (SAH/SOP/QCD/OL/FG/00)	Brown colour powder
1.2	Odor		Characteristic
1.3	Taste		Characteristic
2.0	Analytical Data		
2.1	Identification (By HPLC)	SAH/MOA/QCD/HPLC/PV/52	Presence of Total Flavonoids as Vitexin - Positive
2.2	Loss on drying (at 105 °C)	IP 2014 (SAH/STP/QCD/LOD/01)	NMT 5.0%
2.3	Bulk density (gm/ml)	IP 2014 (SAH/STP/QCD/BDTD/06)	NLT 0.30gm/ml
2.4	Tapped density (gm/ml)	IP 2014 (SAH/STP/QCD/BDTD/06)	NLT 0.35gm/ml
2.5	Particle size	Dry Sieve analysis (SAH/STP/QCD/PS/07)	NLT 95.0% Passing through 40mesh
2.6	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	Total Flavonoids as Vitexin (By HPLC)	SAH/MOA/QCD/HPLC/PV/52	NLT 5.0%
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

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

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7.0	Ethylene Oxide (ETO)		
7.1	Ethyleneoxide	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	Microbiological Enumeration		
9.1	Total aerobic microbial Count	SAH/SOP/QCD/MIC/MLTTPC/11 (USP)	NMT 1000 cfu/gm
9.2	Total yeasts & molds count	SAH/SOP/QCD/MIC/MLTYMC/17 (USP)	NMT 100 cfu/gm
9.3	Pathogens		
9.3.1	Escherichia coli	SAH/SOP/QCD/MIC/MLTE/13 (USP)	Absent/gm
9.3.2	Salmonella	SAH/SOP/QCD/MIC/MLTS/16 (USP)	Absent/10gm

Storage Condition	Store in a cool and dry place away from direct sunlight, heat & moisture.
Shelf life	Three years in original packed conditions from the date of manufacturing.
Packaging	25 Kg Suitable for foodstuff packed in double poly bags unless otherwise required by the customer.
Declaration	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.

Revision History:

Version No.	Effective Date	Reason for Revision
02	04/02/2023	First issue.

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	Prepared by	Checked by	Approved by
Name	Mr. Ram Prajapati	Mrs. Ranjana Kobal	Mr. Vijay Baghel
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