

SECTION III: ANNEXURE 3C - PADD AYUSH MARK PR 01 PERMISSIBLE LEVELS OF
CONTAMINANTS FOR AYUSH STANDARD MARK

Annex C

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS
SECTION III
Certification Criteria

Permissible Levels of Contaminants for AYUSH Standard Mark

1. Heavy Metals*

S.No.	Parameters	Permissible limit
1.	Lead (Pb)	10 ppm
2	Cadmium (Cd)	0.3 ppm
3.	Arsenic (As)	3 ppm
4.	Mercury (Hg)	1 ppm

*Heavy metal testing is only applicable for herbal products

2. Aflatoxins

S. No.	Parameters	Permissible Limit
1	B 1	5.0 ppb
2	B1+ G1 + B2 + G2 sum	10 ppb

Note- These shall be as per Ministry of AYUSH /Importing country current regulations.

Ref: API Part II Volume IV (Formulations)

NMT- Not more than

3. Pesticide Residues

S.no	Substance	Limit (mg/kg)
1.	Alachlor	0.02
2.	Aldrin and Dieldrin (sum of)	0.05
3.	Azinphos-methyl	1.0
4.	Bromopropylate	3.0
5.	Chlordane (sum of cis-, trans - and Oxythlordane)	0.05
6.	Chlorfenvinphos	0.5
7.	Chlorpyrifos	0.2
8.	Chlorpyrifos-methyl	0.1
9.	Cypermethrin (and isomers)	1.0
10.	DDT (sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and	1.0
11.	Deltamethrin	0.5

Version Number: 1
Revision no: 2

Version Date 29 April 2024
Issued by : Project Manager

Approved by: TC
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12.	Diazinon	0.5
13.	Dichlorvos	1.0
14.	Dithiocarbamates (as CS ₂)	2.0
15.	Endosulfan (sum of isomers and Endosulfan	3.0
16.	Endrin	0.05
17.	Ethion	2.0
18.	Fenitrothion	0.5
19.	Fenvalerate	1.5
20.	Fonofos	0.05
21.	Heptachlor (sum of Heptachlor and	0.05
22.	Hexachlorobenzene	0.1
23.	Hexachlorocyclohexane isomers (other than	0.3
24.	Lindane (γ-Hexachlorocyclohexane)	0.6
25.	Malathion	1.0
26.	Methidathion	0.2
27.	Parathion	0.5
28.	Parathion-methyl	0.2
29.	Permethrin	1.0
30.	Phosalone	0.1
31.	Piperonyl butoxide	3.0
32.	Pirimiphos-methyl	4.0
33.	Pyrethrins (sum of)	3.0
34.	Quintozone (sum of quintozone,	1.0
35.	Methyl pentachlorophenyl sulphide)	

4. Microbial Contamination

S.no	Parameters	Permissible limits
1.	<i>Staphylococcus aureus</i> /g.	Absent
2.	<i>Salmonella</i> sp./g .	Absent
3.	<i>Pseudomonas aeruginosa</i> /g	Absent
4.	<i>Escherichia coli</i>	Absent
5.	Total microbial plate count (TPC)	10 ⁵ /g*
6.	Total Yeast & Mould	10 ³ /g*

*For topical use, the limit shall be 10⁷/g.

- **Note** – These shall be as per Ministry of AYUSH current regulations.

Only for homeopathy products: the total microbial count not more than 100 per gm of lactose/biochemical tablet and 1 gm sample free from *Escherichia coli* and *Salmonellae*. (Reference: HPI, Volume IIV, Page no 115)