Ashwagandha: is it safe? Part 3: A review of clinical safety.

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Abstract: Over the last decade, ashwagandha (*Withania somnifera* (L.) Dunal, AS) has been brought under increasing scrutiny regarding its safety for the use in food supplements, culminating in a recent recommendation for an Article 8 procedure according to Regulation (EC) No 1925/2006 in the European Union (EU). Once executed, this could lead to a ban of the use as an ingredient in food supplements. One of the regulators' concerns is the purported lack of clinical safety data combined with evidence for what may constitute a safe daily dose. In this review authors assess evidence stemming from 131 clinical trial reports and toxicological assessments conducted over a period of 45 years for recorded adverse events, and physiological effects of concern.

Keywords: adaptogen; *Withania*; ashwagandha; safety; clinical trials

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1. Introduction

Ashwagandha (AS) is a traditional herb used in Ayurvedic medicine. It is classified as an adaptogen. The use of adaptogenic ingredients in dietary supplements and herbal medicines has enjoyed continuously increasing popularity. While traditionally considered safe based on long-standing use, EU regulators have questioned the safety of AS as a food supplement ingredient culminating in a recent recommendation for an Article 8 procedure according to Regulation (EC) No 1925/2006 (Heads of Food Safety Agencies, 2024). Primary concerns include effects on (male) reproduction via effects on levels of sex hormones, effects on thyroid hormones, inhibition of acetylcholinesterase, effects on the immune system, liver toxicity (based on case studies), as well as more general questions pertaining to the causality of adverse events, the maximum safe dietary exposure, and potentially heightened sensitivity of vulnerable population subgroups. In the following we assess clinical trials conducted with AS mono preparations for physiological effects of concern in primary and secondary endpoints as well as adverse event reports.

2. Materials and methods

The search strategy has been previously described in the context of the quality assessment of clinical trials with ashwagandha by this group of authors (Rattray & Brendler, 2026). Here, we record both adverse events and safety-relevant study endpoints / outcomes, such as vital parameters, blood panels, immune and endocrinological markers where reported.

3. Results

Table 1 provides an overview of trials conducted in terms of study medication, study protocol, number of participants, dose and duration, safety-related endpoints, and adverse events (AEs) reported.

Table 1. Clinical trials with AS and safety-relevant outcomes

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
Shoden	RDBPC	71	+	120 mg (42 mg withanolides)	6 weeks	All biochemistry and hematology parameters within normal range.	Fever, headache, acid reflux, allergic dermatitis; all mild and of unlikely causality.	(Deshpande, Irani, Balkrishnan, & Benny, 2020)
	RDBCO	15	+	480 mg, 7,400 mg (both 185 mg withanolides)	SD	All biochemistry and hematology parameters within normal range.	No severe, serious, or life-threatening adverse events were reported.	(Kim, Venkatesan, Rathi, & Antony, 2023)
	RDBPCCO	50	+	600 mg (21 mg withanolides)	16 weeks (2x 8)	ST ↑, DHEA-S ↑, but not sustained after discontinuation.	None reported.	(Lopresti, Drummond, & Smith, 2019)
	RDBPC	30	+	240 mg (84 mg withanolides)	60 days	No clinically relevant difference in pre- and post-hematological measures.	None reported.	(Lopresti, Smith, Malvi, & Kodgule, 2019)
	RDBPCCO + OL	24	+	60 mg (21 mg withanolides)	30 + 30 days	No safety-relevant changes in immune parameters.	None reported.	(Tharakan et al., 2021)
	RDBPC	40	+	60 mg / 120 mg (21 / 42 mg withanolides)	60 days	SC ↓ 66%, ST ↑ 22 and 33%, respectively.	None reported.	(D. N. Mishra & Kumar, 2024)
****	SDRDBCO	15	+	480 mg (35% withanolides), 1,800 mg (10% withanolides), 3,700 mg (5% withanolides), 7,400 mg (2.5% withanolides)	Single dose with 7-day washout	n. a.	No severe, serious, or life-threatening adverse events were reported.	(Rathi & Kim, 2025)
KSM-66	RDBPC	37 (women)	+	300 mg	8 weeks	No significant changes in vital parameters.	Three women from each group reported mild nausea and drowsiness.	(Ajgaonkar, Jain, & Debnath, 2022)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
	OLRCO	14	+	300 mg Prolanza and 300 mg KSM-66 (30 mg withanolides each)	SD	No abnormalities in hemogram and serum glutamic-oxaloacetic transaminase, serum glutamate-pyruvate transaminase, bilirubin, creatinine and urea.	None reported.	(Alluri, Thanawala, & Upadhyay, 2021)
	RDBPC	21	-	675 mg	90 days	ST ↑ 17%.	Close to 95% reported good and better tolerability	(Ambiye et al., 2013)
	RDBPC	30	+	600 mg	60 days	No significant changes in laboratory parameters, SC ↓ 28%	Nasal congestion (rhinitis), constipation, cough and cold, drowsiness and decreased appetite.	(Chandrasekhar, Kapoor, & Anishetty, 2012)
	RDBPC	25	+	600 mg	8 weeks	ST ↑ 17%	Sleepiness, mild abdominal pain, and low-grade joint pain, all mild.	(Chauhan, Srivastava, & Pathak, 2022)
	RDBPC	25	+	600 mg	12 weeks	No changes in vital parameters.	Not reported.	(B. Choudhary, Shetty, & Langade, 2015)
	RDBPC	25	-	600 mg	8 weeks	No changes in vital parameters.	None reported.	(D. Choudhary, Bhattacharyya, & Bose, 2017)
	RDBPC	25	+	600 mg	8 weeks	SC ↓ 22%.	Two subjects reported giddiness, heaviness of head, blurring of vision, and/or hyperacidity.	(D. Choudhary, Bhattacharyya, & Joshi, 2017)
	RDBPC	25 (women)	+	600 mg	8 weeks	n. a.	None reported.	(Dongre, Langade, & Bhattacharyya, 2015)
	RDBPC	46 (women)	+	600 mg	8 weeks	Vital parameters unchanged, E ↑, FSH ↓.	Mild abdominal discomfort, abdominal pain, and	(Gopal et al., 2021)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
							nausea in 3 participants.	
	RDBPC	19 (elderly)	+	600 mg	12 weeks	Vitals unchanged.	None reported.	(Kelgane, Salve, Sampara, & Debnath, 2020)
	RDBPC	39	+	600 mg	10 weeks	n. a.	None reported.	(Langade, Kanchi, Salve, Debnath, & Ambegaokar, 2019)
	RDBPGPC	38	+	600 mg	8 weeks	Vitals and blood panels unchanged.	None reported.	(Langade, Thakare, Kanchi, & Kelgane, 2021)
	RDBPC	31 (women)	+	600 mg	8 weeks	No significant differences in serum hormone levels; hematological and biochemical parameters unchanged except for bilirubin ↓.	One adverse event of dizziness.	(Mutha, Mutha, Tejuja, & Langade, 2025)
	RDBPC	27	+	2 ml lotion (8% KSM-66) topically	60 days	n. a.	Local irritation, erythema, and swelling reported by 4 patients.	(Narra, Naik, Ghatge, & Ghatge, 2023)
	RDBPGPC	39	+	250 mg / 600 mg	8 weeks	SC ↓.	None reported.	(Salve, Pate, Debnath, & Langade, 2019)
	RDBPC	25	+	600 mg	8 weeks	No changes in physical, hematologic, and vital parameters.	Four subjects reported fever, asthenia, cough, and headache, all mild and transient.	(A. K. Sharma, Basu, & Singh, 2018)
	RDBPC	25	+	600 mg	8 weeks	Vital signs remained within the normal limits.	One subject of reported mild ear pain.	(Tiwari, Gupta, & Pathak, 2021)
	RDBPC	37	+	600 mg	8 weeks	Hematology, renal function, liver function and thyroid function	None reported.	(Verma, Gupta, Patil, Tiwari, & Mishra, 2023; Verma, Gupta, Tiwari, et al., 2023)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
						remained in normal range.		
	RDBPC	40	+	600 mg	8 weeks	Vital signs remained within the normal limits.	None reported.	(Verma, Gupta, Tiwari, & Mishra, 2021)
	RDBPC	25	+	600 mg	8 weeks	ST ↑.	No serious side effects were reported.	(Wankhede, Langade, Joshi, Sinha, & Bhattacharyya, 2015)
	RDBPC	61	+	600 mg	8 weeks	Vital signs remained within the normal limits.	Dizziness, bloating, frequent urination in 2, 1, 1 participants, respectively.	(Kale, Lopresti, Suri, Garg, & Langade, 2024)
	RDBPC	42 (children)	+	300 mg	8 weeks	n. a.	None reported.	(Suri et al., 2024)
	RDBPC	25 (elderly)	+	600 mg	8 weeks	CRP, SC, and creatinine kinase ↓, hematology and hepatic parameters unchanged.	Mild headache (n=2), nausea (n=1), vomiting (n=1) and body pain (n=1).	(Naik, Gudla, Bade, & Wankhade, 2024)**
	RDBPC	17	+	600 mg	8 weeks	Mean values of all hematological parameters within the reference range for the study population.	None reported.	(Jówko et al., 2025)
	RDBPC	15	+	600 mg	28 days	n. a.	None reported.	(Coope et al., 2025)
	RDBPC	30	+	600 mg	8 weeks	Serum hormones (estradiol, progesterone, FSH, LH ↑).	Cough and cold (n=1), unrelated to the study treatment.	(Vani, Muralidhar, & Rao, 2025)**
	RDBPC	30	+	600 mg	75 days	n. a.	None reported.	(Yerram, Jillella, & Reddy, 2023)
	OLPCR	35 (pregnant)	+	600 mg	12 weeks	AST levels were significantly reduced in the verum group at week 12. Other liver markers showed no significant	None reported.	(Ajgaonkar, Tayade, & Nayak, 2026)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
						differences across time points. Renal function and cardiac marker CK-MB remained stable and comparable between groups. Thyroid function also showed no significant differences, with changes.		
	RDBPC	18	+	600 mg	8 weeks	Lipids studied did not exceed accepted reference ranges. Adiponectin and irisin concentrations changed significantly.	None reported.	(Charmas et al., 2025)
	RDBPC	25 (elderly)	+	600 mg	8 weeks	Tolerability was reported excellent (48%) and good (48%), remainder undisclosed.	None reported.	(Honnutagi, Ingale, & Naikawdi, 2026)
***	PGOL	32 (women)	-	600 mg (in addition to conventional treatment)	10 weeks	TSH ↓, T3 ↑, T4 ↑	Not reported.	(Javed et al., 2025)
	RDBPC	41	+	600 mg	75 days	number and frequency of treatment-emergent adverse events was used to assess safety	Few adverse reactions like pruritus, macular erythema, transient minute red spots on the skin, tiredness	(Jillella, Keerthi, & Venkateswar Reddy, 2026)
	RDBPC	38	+	600 mg	8 weeks	ST ~, hemoglobin ↑, serum creatinine, blood urea nitrogen ↓; liver parameters remained within normal limits.	None reported.	(Khanna, Khanna, & Panchal, 2026)
***	RDBPC	16	+	1,000 mg	12 weeks	SC ~	Not reported.	(Köstler, Thull, Nolte, de Marées, & Platen, 2025)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
	DRBPC	47	+	600 mg	8 weeks	ST ↑, no changes in hepatic and renal parameters.	None reported.	(Mutha, Mutha, Tejuja, Beldar, et al., 2025)
***	RC	60	+	600 mg	8 weeks	n. a.	No serious adverse events occurred, minor gastric discomfort (n=4).	(Reddy & Sharma, 2025)
	OBS	191	+	600 mg	12 months	SC ↓,ST ↑, hepatic, renal, and thyroid function otherwise normal.	18 mild adverse events (nausea, abdominal pain, diarrhea, dizziness, headache, vomiting).	(Salve et al., 2025)
Shagandha	RDBPC	25	+	500 mg	60 days	Biochemical parameters unchanged except for decreased LDL-cholesterol levels.	Mild discomforts observed in 8 participants, all transient.	(Majeed, Nagabhushanam, & Mundkur, 2023)
	RDBPC	36	+	500 mg	90 days	Biochemical and hematological parameters remained in normal ranges.	Mild discomforts observed in 18 participants, all transient.	(Majeed et al., 2024)
	RDBPC	21	-	500 mg	40 days	No biochemical markers indicated safety concerns.	None reported.	(Ballesteros-Torres, Vázquez-Aguilar, Luzardo-Ocampo, Escalante-Aburto, & Caballero-Prado, 2025)
Sensoril / Essentra	RDBPGPC	83	+	125 mg, 250 mg, 500 mg	60 days	Cardiovascular risk factors (blood panel) significantly reduced.	None reported.	(Abedon, Auddy, Hazra, Mitra, & Ghosal, 2008)
	RDBPC	30	-	250 mg, 500 mg	8 weeks	Vitals did not raise clinical concerns; increase in thyroxine levels was observed.	Vivid dreams, sleepiness and gastrointestinal symptoms in the study group, overall mild and transient.	(Chengappa et al., 2013; Gannon, Forrest, & Chengappa, 2014)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
	RDBPC	28	-	500 mg, 1,000 mg	12 weeks	Systolic and diastolic blood pressure readings, pulse, and temperature unchanged.	Occurrence <5%, mild and transient, mostly gastrointestinal and sleepiness	(Chengappa, Brar, Gannon, & Schlicht, 2018)
	RDBPC	28	-	500 mg, 1,000 mg	12 weeks	n. a.	Mostly gastrointestinal and sleepiness, no difference between groups.	(Gannon, Brar, Rai, & Chengappa, 2019)
	RDBCO	12	+	1,000 mg	SD	Hemogram, complete urine examination, renal function, hepatic function, electrocardiogram and random blood sugar unchanged.	None reported.	(Krishnamurthy, Gundagani, Nutalapati, & Pingali, 2019)
	RDBPGPC	74	+	125 mg, 250 mg, 500 mg	8 weeks	SC, salivary amylase, ACHT and cytokine ↓, no changes in vitals, blood panels, liver and renal function	Heartburn, abdominal discomfort, and trouble sleeping among 48% of participants, not group-specific	(Pandit et al., 2024)
	RDBCO	20	+	500 mg	2 weeks	Safety parameters remained within normal values.	None reported.	(Pilli, Koilagundla, GSH, & Pingali, 2016)
	RDBCO	20	+	1,000 mg	2 weeks	SC and MDA ↓; safety parameters remained normal.	None reported.	(Pingali, Pilli, & Fatima, 2013)
	RDBCO	20	+	1,000 mg	2 weeks	Hemoglobin, complete blood picture, renal function tests, liver function tests, lipid profile, and complete urine examination	None reported.	(Pingali, Pilli, & Fatima, 2014)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
						including ECG all remained normal.		
	RDBPGPC	40	-	500 mg, 1,000 mg + metformin	12 weeks	Hemoglobin, blood urea and serum creatinine, liver function test, lipid profile; TC, LDL and TGs ↓.	None reported.	(Pingali, Fatima, Kumar, & Kishan, 2014)
	RDBPGPC	10	-	1,000 mg	12 weeks	No significant changes in laboratory safety parameters (hematological, renal and hepatic parameters).	None reported.	(Pingali, Kishan, Fatima, & Kumar, 2014)
	RDBPGPC	40	-	500 mg, 250 mg + 650 mg paracetamol for rescue	4 weeks	Hematological and biochemical variables remained within normal limits.	6 patients complained of nausea and 1 patient developed mild gastritis.	(Ramakanth, Kumar, Kishan, & Usharani, 2016)
	RDBPC	5	+	1,000 mg	SD	Hematological, hepatic and renal parameters remained within normal limits.	None reported.	(Nalini, Manjunath, Reddy, & Usharani, 2013)
	RDBPC	19	+	500 mg	12 weeks	Slight polycythemia effect.	1 = arthralgia, 1 = myalgia, 1 = abdominal pain	(Ziegenfuss et al., 2018)
	RDBPC	42 (women)	+	250 mg, 500 mg	24 weeks	n. a.	Mild gastrointestinal disturbances.	(Pingali, Nutalapati, & Wang, 2025)
	DRBPC	24	-	500 mg, 1,000 mg (as of week 2); adjunct to medication	12 weeks	MPRC Side Effect Checklist, vital signs and stress ratings.	None reported.	(Marder, Kelly, DeVera, Zaranski, & Buchanan, 2025)**
Prolanza / AshwaSR / ashwanova	RDBPC	62	+	300 mg	90 days	Complete blood count, aspartate aminotransferase, alanine aminotransferase, serum creatinine, serum brain-derived neurotrophic	None reported.	(Gopukumar et al., 2021)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
						factor remained in normal limits, serum cortisol significantly reduced.		
	RDBPC	85	+	150 mg, 300 mg	60 days	SC ↓ at 300 mg	Five reports of mild, and transient AEs such as pyrexia, myalgia, emesis, pruritus, and gastroesophageal reflux	(Thanawala et al., 2025)
Strelaxin	RDBPC	12	-	1,200 mg	30 days	Significant hypoglycemic and hypolipidemic effects.	None reported.	(Agnihotri, Sontakke, Thawani, Saoji, & Goswami, 2013)
Ashwa 30	RDBPC	44	+	30 mg	8 weeks	Vital signs and lab parameters (hematology and clinical biochemistry) remained within normal ranges.	One AE (headache).	(Prajapati, Satia, Shah, Basera, & Shah, 2026)
ASVAMAN	RDBPC	18	+	600 mg	42 days	SC ↓, ST ↑	Not reported.	(Puttaswamy, Singh, Mayachari, Parameswaran, & Kudiganti, 2025)
AshwaMAX 400	Escalation study	13	+	72, 108, 144, 216 mg withanolides	3 + 3 dose escalation	Five subjects (38.46%) had elevations in AST and ALT. All liver enzyme level elevations were grade 1 in severity.	Elevation of liver enzymes (n=5) and skin rash (n=2), fatigue, fever, edema, and diarrhea (n=1 each)	(Pires et al., 2020)
***	RPGOL	186	+/-	500 mg	12 weeks	TNF-α, IL-2 ↑, MCP 1 ↓.	No serious adverse events; 53 AEs reported (abdominal discomfort, nausea, vomiting, hyperchlorhydria,	(Kulkarni-Munshi et al., 2025)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
							constipation, diarrhea)	
Somin-On	RDBPC	20	-	250 mg	60 days	Biochemical tests (complete blood count, renal function test, vitamin B12 and liver function test) remained in normal ranges.	None reported.	(Rai & Mishra, 2025)
LongeFera	OLSD	12	+	400 mg	Single dose	Vital signs assessment, clinical examination, clinical laboratory test, urine analysis, ECG were found to be within the normal range	None reported.	(E. Sharma et al., 2025)
	RDBPC	20	+	200 mg	180 days	ST ↑, hematological, liver and renal parameters remained within reference ranges.	None reported.	(N. Vaidya et al., 2026)
Zenroot	RDBPC	45	+	125 mg	84 days	SC ↓; hematology, biochemistry, and urinalysis parameters remained within normal ranges	Pyrexia (n=6), gastritis (n=3), 33% reports overall	(Mahadevan et al., 2025)
	SD	20	+	125 mg, 600 mg (KSM-66), 500 mg (Sensoril)	Single dose with 8-day washout	Vital signs and lab parameters remained within normal ranges	None reported.	(Ramapalaniappan et al., 2025)
API-2	ROL	200	+	500 mg	16 weeks	n. a.	26 mild AEs	(Chopra, Srikanth, Patwardhan, & AYUSH CCRAS Research Group, 2021)
	RDBPC	10	+	1,000 mg	6 months	n. a.	None reported.	(Kuchewar, Borkar, & Nisargandha, 2014)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
NooGandha	RDBPGPC	38	+	225 mg, 400 mg	30 days	SC ↓.	None reported.	(Remenapp et al., 2022)
	RDBPCCO	14	+	400 mg	SD	n. a.	None reported.	(Xing et al., 2022)
	RDBPC	30	+	225 mg	30 days	Lymphocytes lower; red blood cells, neutrophils platelets higher, HDL higher; bilirubin lower, protein and calcium higher (overall profile improved).	Dizziness, headache, tachycardia, dyspnea, palpitations and nervousness, not group-specific, mostly minimal.	(Leonard et al., 2024)
Witholytin / AgeVel	RDBPGPC	55	+	400 mg	12 weeks	ST ↑, E ↑, LH, DHEA-S, MDA ↑.	Digestive and mood disturbances.	(Smith, Lopresti, & Fairchild, 2023)
	OL	18	+	1,000 mg	4 weeks	No clinically significant changes in vital signs, anthropometric evaluation, hematological and biochemical testing, urine analysis, ECG, chest X-ray, and cardiorespiratory endurance.	None reported.	(V. G. Vaidya et al., 2023)
	OL	18	+	500 mg	SD	Hematological and biochemical parameters including urine remained within normal limits.	None reported.	(V. G. Vaidya et al., 2024)
	RDBPC	28	+	500 mg	60 days	Inflammatory biomarkers high-sensitivity C-reactive protein and interleukin-6 ↓, serum creatine phosphokinase ↑.	None reported.	(Raut et al., 2024)
Stresscom	RDBPC	30	-	300 mg + Metformin 500 mg + Glimepride 1 mg	6 (12) weeks	FBS ↓, PPBS ↓, TC ↓, BG ↓	None reported.	(Nayak, Nayak, Panda, & Das, 2015)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
	RPC	18	+	1,000 mg	8 weeks	n. a.	Not reported.	(Shenoy, Bhaskaran, Sandhu, & Paadhi, 2012)
	RDBPC	47	-	600 mg	12 weeks	Clinical parameters remained in normal range.	Minor self-limiting nausea in 3, heart burn in 1, belching with epigastric fullness in 1 and menorrhagia in 1 patient	(Mansharamani, Makkar, Koreth, Dutta, & Mukherjee, 2013)
Aswal	RDBPC	11	-	1,000 – 2,500 mg (individual titration)	6 weeks	n. a.	Drowsiness (6), dyspepsia (5) at the beginning.	(Andrade, Aswath, Chaturvedi, Srinivasa, & Raguram, 2000)
PE-1	RDBPC	15	-	120 mg + SSRIs	6 weeks	n. a.	None reported.	(Jahanbakhsh et al., 2016)
	RDBPC	22	-	1,000 mg + SSRI	6 weeks	n. a.	Dyspepsia, headache, fatigue and drowsiness, no difference between groups.	(Fuladi et al., 2021)
PE-2	OL	18	+	750 – 1,250 mg	30 days	Clinical parameters remained within normal range, TC ↓	One increase in appetite, libido, and hallucinogenic effects with vertigo.	(Raut et al., 2012)
PE-3	RSBPC	10	+	500 mg	8 weeks	n. a.	None reported.	(Sandhu et al., 2010)
PE-4	RDBPC	29	+	700 mg	30 days	n. a.	Not reported.	(Baker et al., 2022; O'Connor et al., 2022)
PE-5	RDBPC	30	-	1,000 mg + first line antitubercular drugs	12 weeks	Favorable effects on liver transaminase levels and serum uric acid levels.	Attenuated drug side effects of gastritis, joint pain and numbness.	(R. Kumar, Rai, Kajal, & Devi, 2018)
PE-6	RDBPC	36	-	600 mg (1.5% withanolides)	12 weeks	n. a.	Two cases of gastrointestinal	(Cooley et al., 2009)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
							upset and overstimulation.	
PE-7	RSBPC	8	+	300 mg	7 days	n. a.	Not reported.	(Meto et al., 2024)
PE-8	RDBPC	26	+	250 mg, 600 mg	12 weeks	BP and blood panels remained in normal ranges.	Three cases of poor digestion and abdominal bloating.	(Pérez-Piñero et al., 2024)
Mother tincture	RDBPC	15	+	200 µl/kg body weight	12 weeks	Lipid profile, liver enzymes; TC ↓, TG ↓, LDL ↓, HDL ↑, BP ↓	None reported.	(Adi & Reddy, 2019)
Root powder	RDBPG	20	+	3,000 mg	30 days	n. a.	None reported.	(Chimanchod & Kadlimatti, 2020)
	RPC	54	+	12,000 mg	90 days	n. a.	Not reported.	(Sukumar & Shashirekha, 2021)
	RDBPC	50	-	500 mg	12 weeks	n. a.	None reported.	(Singh, Salman, Shameem, & Warsi, 2022)
	OL	75	-	5,000 mg	3 months	ST ↑, LH ↑, FSH ↓, prolactin ↓.	Not reported.	(Ahmad et al., 2010)
	RDBPC	28 (elderly)	+	6,000 mg	30 days	n. a.	None reported.	(Atul, Charu, & Umesh, 2020)
	RSB	77	-	9,000 mg	6 weeks	n. a.	Not reported.	(Bikshapathi & Kumari, 1999)
	OL	180	-	5,000 mg	3 months	ST ↑, LH ↑, FSH ↓, and prolactin ↓.	Not reported.	(Ashish Gupta et al., 2013)
	OL	78	-	10,000 mg	3 weeks	No significant change in serum levels of ALT, AST, ALP, bilirubin, urea, creatinine, β2MG and NGAL.	Not reported.	(G. Kumar, Srivastava, Sharma, Rao, & Gupta, 2015)
	RDBPG	46	-	5,000 mg	90 days	n. a.	Nausea and epigastric pain in 1 patient.	(Nasimi Doost Azgomi et al., 2018)
	RPG	51	-	2,000 mg	91 days	n. a.	Not reported.	(Kushwaha, Betsy, & Chawla, 2012)

Product	Protocol	Power*	Health	Dose	Duration	Safety-Related Endpoints*	AEs*	Reference
	RSBPC	16	+	500 mg	8 weeks	n. a.	Not reported.	(Malik, Mehta, Malik, & Sharma, 2014)
	OL(?)	60	+	5,000 mg	3 months	ST ↑, LH ↑, FSH ↓, and prolactin ↓, SC ↓.	Not reported.	(Mahdi et al., 2011)
	OL(?)	75	-	5,000 mg	3 months	Metal ions ↑	Not reported.	(Shukla et al., 2011)
	RSBPC	41	-	5.400 mg	60 days	n. a.	Not reported.	(Mamidi & Thakar, 2011)
	OL	12	+/-	3,000 mg	30 days	BG ↓	None reported.	(Andallu & Radhika, 2000)
	OL	10	+	1.250 – 1.500 mg	12 weeks	n. a.	Not reported.	(Yadav, 2014)
	RDBPGPC	13 (children)	+	2,000 mg	60 days	n. a.	Not reported.	(Venkataraghavan et al., 1980)
	RDBPC	50	+	3,000 mg	1 year	n. a.	Not reported.	(Kuppurajan et al., 1980)
	RDBPC	77	+	2.500 – 8,000 mg	6 weeks	n. a.	Not reported.	(R. K. Mishra, Trivedi, & Pandya, 2010)
	RDBPC	44	-	12,000 mg	60 days	n. a.	Not reported.	(Sud & Thaker, 2013)
	OLPC	47	-	6,000 mg	Chemo cycle	n. a.	Three cases of oral intolerance, gastritis, and flatulence.	(Biswal, Sulaiman, Ismail, Zakaria, & Musa, 2013)
	ROL	15	-	5,000 mg	60 days	n. a.	Not reported.	(Anil Gupta, 2024)
	ROL	15	-	10,000 mg	60 days	Blood and urine panels, no changes reported.	Not reported.	(Jandial, 2010)
	ROL	15	+	6,000 mg	2 days	Vitals stable, BP ↓.	Not reported.	(G. Sharma & Singh, 2024)
	RDBPC	8	+	750 mg	6 days	n. a.	Not reported.	(Diehl, 2021)
	OL	19	-	n. a.	8 weeks (?)	n. a.	Not reported.	(Kumari, Kumar, Laxmi, & Tiwari, 2025)
	OBS	30 (children)	-	750-1,000 mg	45 days	n. a.	None reported.	(R. Sharma & Upadhyay, 2025)
	OBS	30 (children)	+	n. a.	30 days	n. a.	Not reported.	(Sarada & Punitha, 2016)

PE = Proprietary extract; R = Randomized; DB = Double-blind; SB = Single-blind; PG = Parallel group; PC = Placebo controlled; CO = Cross-over; OL = Open label; OBS = Observational trial; SD = Single dose; n. a. = not available; ST = Serum testosterone; SC = Serum cortisol; LH = Luteinizing hormone; FSH = Follicle-stimulating hormone; E = Estradiol; DHEA-S = Dehydroepiandrosterone sulfate; TC = Total cholesterol; MDA = Malondialdehyde; BP = Blood pressure; BG = Blood glucose; CRP = C-reactive protein; T3 = Triiodothyronine; T4 = Thyroxine; TSH = Thyroid stimulating hormone

* Treatment group (who completed the study) included in analysis only; ** Preprint; *** Study product assumed from description and dosing; **** multiple commercial products

Mishra & Trikamji (2013) could not be included due to unavailability of the full text and the abstract not containing enough data for analysis (S. Mishra & Trikamji, 2013). Unfortunately, the authors did not respond to requests to connect.

4. Discussion

Table 2 summarizes the results of available toxicological investigations of branded products. Applying common principles of dose conversion (Nair & Jacob, 2016; Reagan-Shaw, Nihal, & Ahmad, 2008), pre-clinical safety studies would suggest a safe human daily dose of 325 - 650 mg/kg body weight or 19,500 – 39,000 mg of the aforementioned preparations for a human weighing 60 kg (FDA, 2007). However, since the raw material equivalents vary between extracts, this translates into a range which compares well to the stipulations of the Ayurvedic Pharmacopoeia (AYUSH, 2011), even after applying a commonly utilized safety factor of 100 (FDA, 2007).

Table 2. NOAELs and raw material equivalents.

Product	DER	NOAEL	Human dose	Human dose (total)	Raw material equivalent	Safety factor x100	API
		mg/kg body weight		mg			
Shoden	40:1	2,000	325	19,500	780,000	7,800	
KSM-66	12:1	2,000	325	19,500	234,000	2,340	
Witholytin	8:1	2,000	325	19,500	156,000	1,560	3,000 – 6,000
Shagandha	15-20:1	2,000	325	19,500	341.250	3,412	
Sensoril	5:1	4,000	650	39,000	195,000	1,950	

Animal toxicity studies have shown safety of AS up to ~8,000 mg of raw material equivalent (Williamson & Brendler, 2025). In human clinical trials safety and good tolerance have been demonstrated with up to 24,000 mg of raw material equivalent over up to 52 weeks (duration of most trials ranged between 4 and 16 weeks) (Rattray & Brendler, 2026).

Looking more closely at the clinical evidence shown in Table 1, it is striking that three proprietary extracts/products have been more extensively trialed in more patients, by authors in different countries, using randomized, controlled double blind (RDB) protocols, either placebo-controlled (PC), or crossover (CO). In total these have involved >2,000 participants. Both branded proprietary products and trial-specific preparations (mostly of root powder) have been included in this overview; reporting on the specification of these preparations varies (Rattray & Brendler, 2026). KSM-66 extract is the subject of 38 studies, almost all of which were RDB PC in healthy populations. Two were observational studies, and one was in pregnant women). In 21 of the RDB PC studies, no AEs of any kind were reported, and in 12 studies, mild AEs were recorded in a minority of patients. Sensoril was studied in 16 RBD PC/CO studies, involving 495 patients. In 9 of these, no AEs were reported, and in 7 only mild AEs were cited. Shoden was used in 7 RDB PC/CO studies, in 245 patients, and in 5 studies no serious AEs were observed, 4 with no AEs at all, and 1 with mild AEs.

5. Conclusion

In summary, of 127 clinical trials, 53 trials reported no AEs of any kind, 47 reported only mild and transient AEs in a minority of patients. Most reported AEs included digestive discomforts, headaches and drowsiness, all were nonserious, transient and occurred mostly at the beginning of the treatment. Based on high quality evidence of products of known composition and made according to good manufacturing practice (GMP), this is a remarkable safety profile. Only 28 trials did not report AEs.

This does not mean that all AS products and extracts are devoid of toxicity or deny the occurrence of idiosyncratic and rare serious reactions. Clinical studies generally exclude vulnerable patients as part of their inclusion criteria for ethical approval and are therefore expected to show a lower incidence of serious AEs than the general population who purchase these products for self-medication.

Of the safety-relevant endpoints, only effects on hormone, blood glucose, lipid and immune biomarkers levels, as well as blood pressure are noteworthy and respective warning may be considered for consumers with pre-existing conditions or who take prescription medications that could be affected by concurrent AS consumption.

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