Ashwagandha: What is the quality of the evidence?

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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 on its use as an ingredient in food supplements. In this review authors assess the quality and reporting quality of efficacy and safety evidence from 131 clinical trial reports conducted over a period of 45 years on the basis of Jadad, CONSORT, ConPhyMP and CONSORT-HARMS to contextualize clinical safety and efficacy assessments.

Keywords: *Withania*; ashwagandha; efficacy; safety; quality; clinical trials

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1. Introduction

AS is a traditional herb used in Ayurvedic medicine. It is classified as an adaptogen as it increases the ability of an organism to tolerate, adapt, and survive under stress. The use of adaptogenic ingredients in dietary supplements and herbal medicines has enjoyed continuously increasing popularity.

In light of recent regulatory scrutiny by EU competent authorities (Heads of Food Safety Agencies, 2024), in this review authors conduct an overall quality assessment of the clinical evidence, thereby providing context to reviews of clinical efficacy and safety that are being conducted by the same authors concurrently (Brendler & Rattray, 2026; Brendler & Williamson, 2026). Tools, such as Jadad score, as well as CONSORT, ConPhyMed and CONSORT-HARMS reporting guidelines are used to evaluate study and reporting quality.

2. Materials and methods

A search was conducted across PubMed, Scopus, Web of Science, and Google Scholar through February 2026 with the following keywords individually and in combination: *ashwagandha, Withania somnifera, clinical, trial, systematic, review, meta, analysis, effect, efficacy, safety, toxicology, toxicity, OECD,* and *withanolides(s)*. Manual searches were performed from reference lists of included studies and relevant review articles. Only clinical trials that investigated AS or its preparations on its own were included. Due to the heterogeneity of preparations used in studies, any attempt of meta-analysis would have not only severely restricted the scope of this assessment but also, as a result, not have yielded meaningful outcomes. Instead, we established raw material equivalents as a basis for efficacy and safety evaluations. Further, we evaluated the quality of studies by assessing them against select items from the Consolidated Standards of Reporting Trials (CONSORT)-OUTCOMES 2022 Extension (Butcher et al., 2022), CONSORT-HERBAL (Gagnier et al., 2006), CONSORT-HARMS 2022 (Junqueira et al., 2023) and ConPhyMP (Heinrich et al., 2022) guidelines as well as assigning an Jadad score (Jadad et al., 1996).

A database was generated with quality metrics from 130 clinical trial reports (see results). To assess methodological quality, the Jadad Scale was employed as the primary metric; a validated instrument for evaluating clinical trials across three domains: randomisation, blinding, and the description of withdrawals, yielding a score between 0 and 5. Studies were additionally evaluated against thirteen secondary criteria drawn from the CONSORT/CONSORT-HARMS and ConPhyMP guidelines, each scored on a binary scale (0 = absent, 1 = present). These criteria encompassed participant demographics, dosage accuracy, testing protocols, standardisation of interventions, use of placebos, power analysis, baseline comparability, outcome reporting, and the reporting of harms.

A composite quality score, termed the "Nett Score," was subsequently derived for each study by aggregating values across 13 criteria and normalising the result to a 0–100% scale, reflecting the degree of overall methodological adherence.

The heatmaps were generated using Python v3.12 (Python Software Foundation, 2026) with the Pandas (The Pandas Development Team, 2026), Seaborn (Waskom, 2021), and Matplotlib (Hunter, 2007) libraries.

3. Results

After elimination of duplicates and trials with combination products, 131 clinical trial reports were included in this assessment. Three data sets yielded two publications each, with the same study population, but different endpoints/outcomes (see results). One study could not be included in the evaluations due to the full texts not being obtainable and the abstract not containing enough detail (S. Mishra & Trikamji, 2013). Three studies were available as pre-publications only.

Table 1 shows the trends in AS clinical trial quality between 1996 and 2022 after the publication of the various guidelines. Table 2 elucidates the characteristics, composition and dosing recommendations for branded extracts and proprietary preparations used in human clinical trials, where available. Table 3 shows a heatmap of compliance with Jadad and selected CONSORT/ConPhyMP guidelines. It should be noted that some of the studies listed predate the publication of these guidelines, and adherence therefore cannot be expected. However, this assessment does serve as a good indicator for overall reporting quality across all the published studies.

Table 1. Impact of global reporting initiatives on the study corpus, before and after guideline publications.

Quality Metric	Guideline Era	Period	Mean Score	Improvement (%)
Jadad score	Pre-Jadad (1996)	< 1996	0.57	-
(Scale 0-1)	Post-Jadad	> 1996	0.74	+17.00%
CONSORT	Pre-CONSORT	< 2002	67.14	-
(Nett % Score)	Post-CONSORT	> 2002	82.58	+15.44%
Harms/ConPhy	Pre-ConPhyMP	< 2022	79.09	-
(Nett % Score)	Post-ConPhyMP	> 2022	85.94	+ 6.85%

A methodological choice was made regarding trials that produced multiple publications (Baker et al., 2022; Chengappa et al., 2013; Gannon, Forrest, & Chengappa, 2014; D. N. Mishra & Kumar, 2024; O'Connor et al., 2022; Verma, Gupta, Patil, Tiwari, & Mishra, 2023). We treated these not as redundant duplicates but as independent reporting events, since this review is an audit of reporting quality. Including all six sets ensures that our final 'Nett Score' reflects the total transparency of the trial's public record, rather than a snapshot from a single publication that might have omitted critical phytochemical or safety details.

Table 2. Preparations used in clinical trials with AS according to manufacturer's specifications

Product	Plant part	Solvent	DER	Withanolides*	Dosing recommendation	Raw material equivalence	Source
Shoden	Root + leaf extract	Ethanol, water 70:30	40:1	35%	60 – 120 mg	2.400 – 4.800 mg	Arjuna Natural
Somin-On	Root + leaf extract	Ethanol	?	Sominone >2% Withanoside IV >1% Withanolides >10%	250 mg	?	Arjuna Naturals
KSM-66	Root extract	Water	12:1	>5%	300 – 600 mg	3.600 – 7.200 mg	Ixoreal
Shagandha	Root extract	Ethanol, water 80:20	15-20:1	>2.5%	500 mg	7,500 – 10,000 mg	Sabinsa
Sensoril / Essentra	Root + leaf extract	Water	5:1	1%	125 – 500 mg	625 – 2,500 mg	Kerry (Natreon)
Prolanza / AshwaSR / ashwanova	Root extract	none	25:1	4-5%	300 mg	7,500 mg	Nutriventia/Laila Nutraceuticals
Strelaxin	?	?	?	?	800 – 1,200 mg	?	Crittherbs Pharma
API-1	Root			>0.15%	3 – 6 g	3,000 – 6,000 mg	(AYUSH, 2011a)
API-2	Root extract	Water	5:1	>0.3%	600 – 1,200 mg	3,000 – 6,000 mg	(AYUSH, 2011c)
API-3	Root extract	Ethanol, water 50:50	6-7:1	>1%	500 – 1,000 mg	3,000 – 6,000 mg	(AYUSH, 2011b)
NooGandha	Root + leaf extract	Ethanol, water	?	3.5-4%	225 – 400 mg	?	Specnova
Witholytin / AgeVel	Root extract	Ethanol, water 80:20	8:1	1.5%	200 – 400 mg	1.600 – 3.200 mg	Verdure Sciences
Stresscom	Root extract	?	?	?	300 mg	?	Dabur
Aswal	Root extract	Ethanol	?	?	500 mg	?	Gufic (Andrade, Aswath, Chaturvedi, Srinivasa, & Raguram, 2000)
AshwaMAX 400	Root extract	Water	?	4.5%	?	?	Pharmanza
LongeFera	Root extract	Ethanol, water 80:20	5:1	2.5%	400 mg	?	Phytoveda
Zenroot	Root extract	Ethanol, water	?	1.5%	125 mg	3,600 mg**	OmniActive Health Technologies
Ashwa 30	Root extract	Ethanol, water	?	>15%	30 mg		Natural Remedies
ASVAMAN	Root extract	?	?	2.5%	600 mg		Manipal Natural
Mother tincture	Root	Ethanol, water	?	?	?	1 – 3 ml	(Adi & Reddy, 2019)
PE-1	Root extract	Ethanol, water 70:30	16-17:1	?	120 mg	1,920 – 2,040 mg	(Jahanbakhsh et al., 2016)

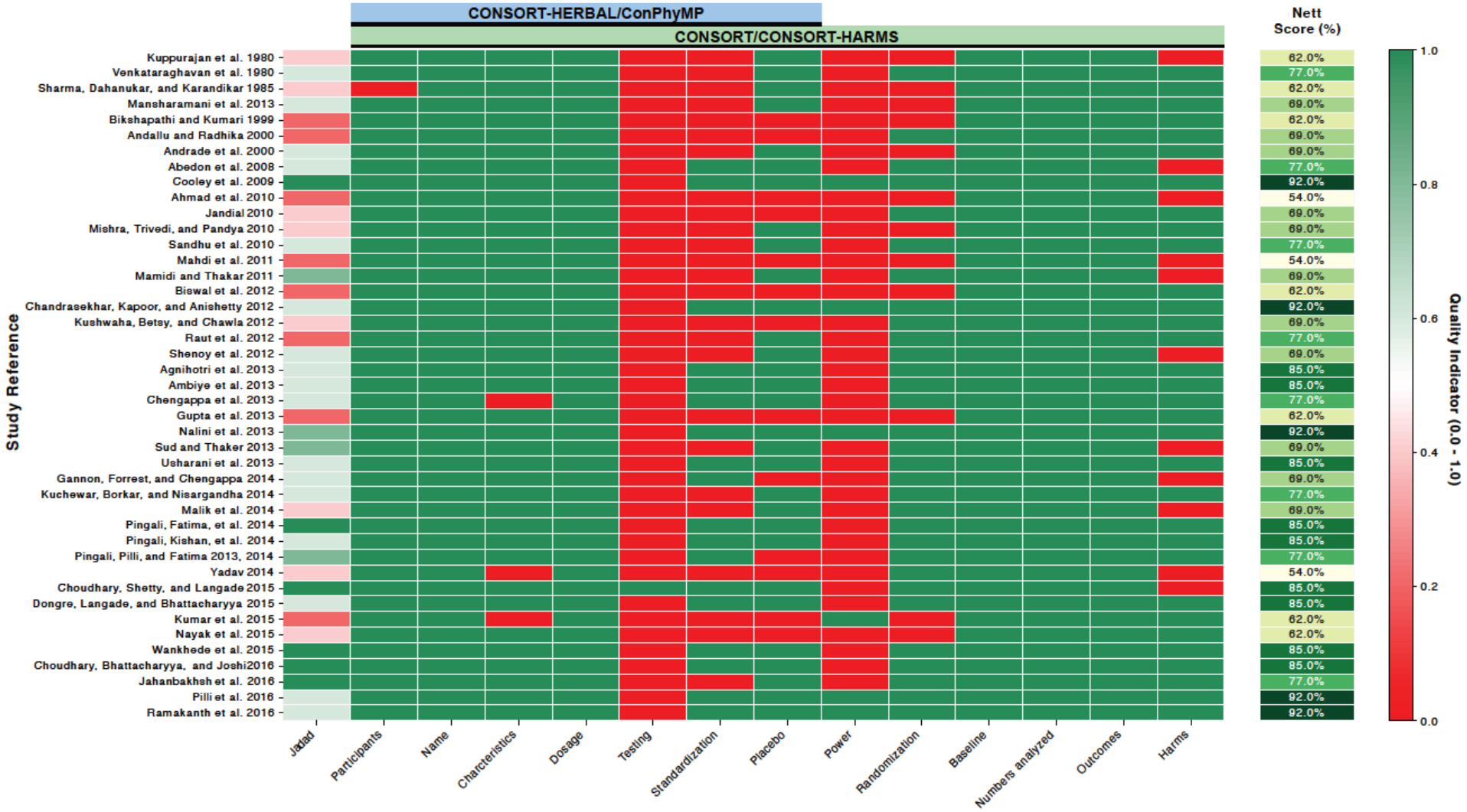
PE-2	Root extract	Water	8:1	?	750 – 1,250 mg	6,000 – 10,000 mg	(Raut et al., 2012)
PE-3	Root extract	Water	?	?	500 mg	?	(Sandhu et al., 2010)
PE-4	Root + root extract	Ethanol, water 55:45	7-8:1	>0.7%	700 mg	2.700 mg	Gaia Herbs
PE-5	Root extract	?	?	?	1,000 mg	?	(R. Kumar, Rai, Kajal, & Devi, 2018)
PE-6	Root extract	?	?	1.5%	600 mg	?	Swisse (Cooley et al., 2009)
PE-7	Root extract	?	?	?	300 mg	?	(Meto et al., 2024)
PE-8	?	?	?	?	?	?	(Pérez-Piñero et al., 2024)

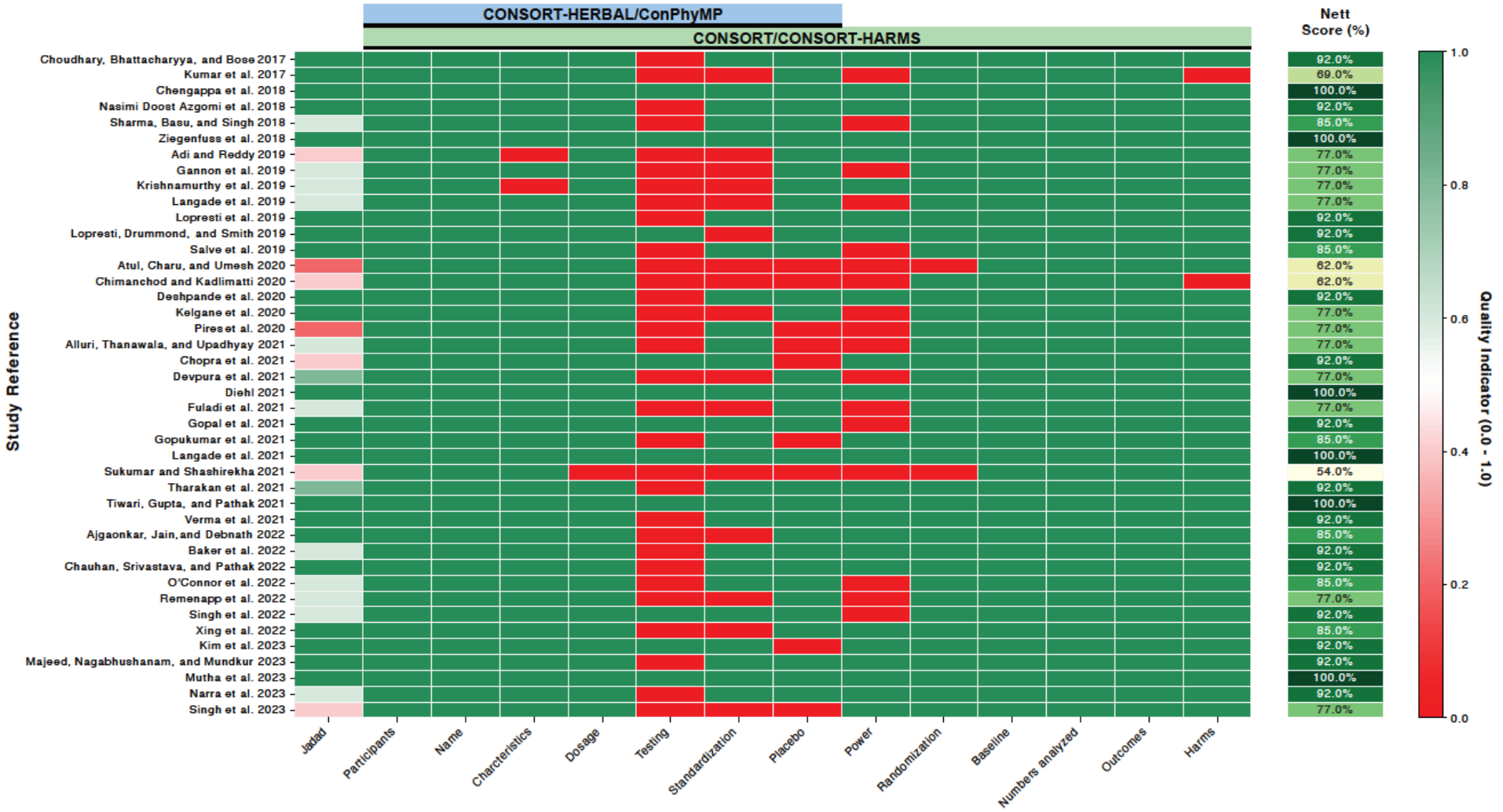
PE = Proprietary extract

* some values may be derived from proprietary assay methods that do not conform with pharmacopoeial standards

** 2.1x bioavailability compared to KSM-66

Table 3. Trial quality evaluation.




CONSORT-HERBAL/ConPhyMP
CONSORT/CONSORT-HARMS
Nett Score (%)
Study Reference
Choudhary, Bhattacharyya, and Bose 2017
Kumar et al. 2017
Chengappa et al. 2018
Nasimi Doost Azgomi et al. 2018
Sharma, Basu, and Singh 2018
Ziegenfuss et al. 2018
Adi and Reddy 2019
Gannon et al. 2019
Krishnamurthy et al. 2019
Langade et al. 2019
Lopresti et al. 2019
Lopresti, Drummond, and Smith 2019
Salve et al. 2019
Atul, Charu, and Umesh 2020
Chimanchod and Kadlimatti 2020
Deshpande et al. 2020
Kelgane et al. 2020
Pires et al. 2020
Alluri, Thanawala, and Upadhyay 2021
Chopra et al. 2021
Devpura et al. 2021
Diehl 2021
Fuladi et al. 2021
Gopal et al. 2021
Gopukumar et al. 2021
Langade et al. 2021
Sukumar and Shashirekha 2021
Tharakan et al. 2021
Tiwari, Gupta, and Pathak 2021
Verma et al. 2021
Ajgaonkar, Jain, and Debnath 2022
Baker et al. 2022
Chauhan, Srivastava, and Pathak 2022
O'Connor et al. 2022
Remenapp et al. 2022
Singh et al. 2022
Xing et al. 2022
Kim et al. 2023
Majeed, Nagabhushanam, and Mundkur 2023
Mutha et al. 2023
Narra et al. 2023
Singh et al. 2023
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100.0%
92.0%
85.0%
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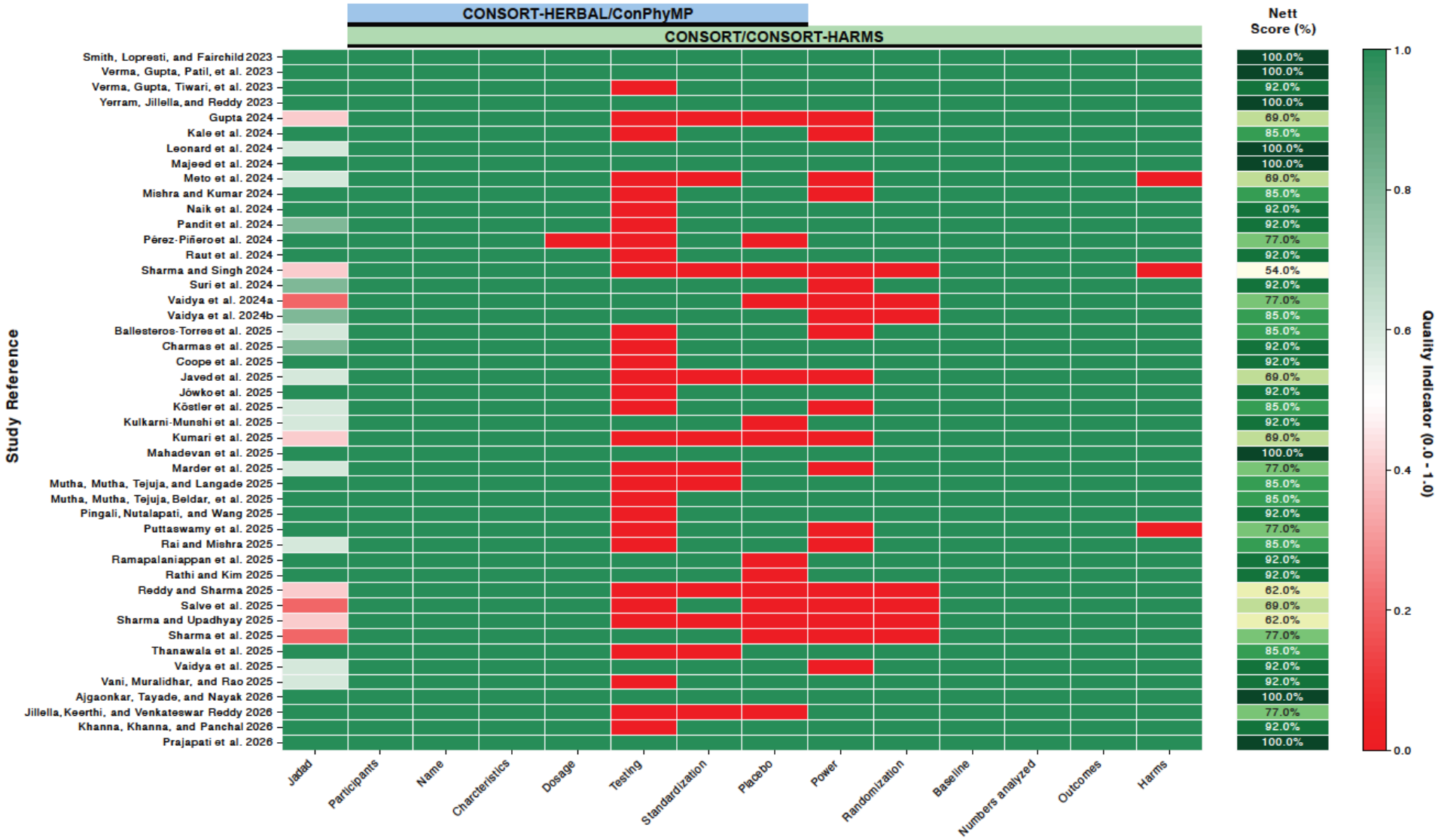
Jadad
Participants
Name
Charcteristics
Dosage
Testing
Standardization
Placebo
Power
Randomization
Baseline
Numbers analyzed
Outcomes
Harms
Quality Indicator (0.0 - 1.0)
1.0
0.8
0.6
0.4
0.2
0.0



The heatmaps provide a visual synthesis of trial quality across 130 study reports, categorized into four functional domains: Methodological Quality (Jadad, Randomization, Placebo), Botanical Integrity (Name, Characteristics, Dosage, Testing, Standardization), Statistical Transparency (Power, Baseline, Numbers Analyzed, Outcomes), and Safety Accountability (Harms, Nett Score). Color-coding indicates the degree of adherence to established JADAD, CONSORT, and ConPhyMP/ConPhyMed criteria: Green indicates full compliance; Light green to white represents partial compliance or ambiguous reporting; and Red signifies the complete omission of the parameter. The "Nett Score" column represents the sum total percentage of reporting, providing an overall score to the study's compliance across the reporting standards.

Table 4 provides a summary of products, number of trials conducted with number of participants (overall vs healthy), maximum and average daily doses, raw material equivalents (where discernible) and duration of trials (maximum and average). Duplicate reports are not included here. Noteworthy is that in the 127 trials summarized here, approximately 70% of the >4,600 study population was healthy. As for vulnerable populations, four studies were conducted in children (n = 115) (Sarada & Punitha, 2016; R. Sharma & Upadhyay, 2025; Suri et al., 2024; Venkataraghavan et al., 1980), five in the elderly (n = 97) (Atul et al., 2020; Honnutagi et al., 2026; Kelgane et al., 2020; Kuppurajan et al., 1980; Naik et al., 2024), and six in women only (n = 248) (Ajgaonkar et al., 2022; Dongre et al., 2015; Gopal et al., 2021; Javed et al., 2025; Mutha, Mutha, Tejuja, & Langade, 2025; Pingali et al., 2025), and one in pregnant women (n = 35) (Ajgaonkar et al., 2026).

Table 4. Summary of clinical trials with AS

Product	# of studies	# of participants (treatment only)	# of healthy participants (treatment only)	Daily dose max	Daily dose average	Raw material equivalent max	Raw material equivalent average	Duration max	Duration average
						mg		weeks	
Shoden	7	245	245	600	260	24,000	10,400	16	10
KSM-66	38	1,349	1,263	600	400	7,200	4,800	52	8
Shagandha	3	82	61	500	500	~9,000	~9,000	12	8
Sensoril / Essentra	16	495	295	1,000	700	5,000	3,500	12	8
Prolanza / Ashwanova	2	147	147	300	300	7,500	7,500	12	12
Strelaxin	1	12	0	1,200	1,200			4	4
Ashwa 30	1	44	44	30	30			8	8
ASVAMAN	1	18	18	600	600			6	6
AshwaMAX 400	2	199	106	500	208			12	12
Somin-On	1	20	0	250	250			8	8
LongeFera	2	32	32	400	300			26	26
Zenroot	2	65	65	125	125	3,600	3,600	12	12
API-2	2	210	210	1,000	750	5,000	3,750	26	21
NooGandha	3	82	82	400	310			4	4
Witholytin / AgeVel	4	119	119	1,000	630	8,000	5,000	12	8
Stresscom	3	95	18	1,000	600			12	8
Aswal	1	11	0	2,500	1,750			6	6
Mother tincture	1	15	15	12,000	12,000			12	12
PE-1	2	37	0	1,000	560	16,000	9,000	6	6
PE-2	1	18	18	1,250	1,000	10,000	8,000	4	4
PE-3	1	10	10	500	500			8	8
PE-4	1	29	29	700	700	2,700	2,700	4	4
PE-5	1	30	0	1,000	1,000			12	12
PE-6	1	36	0	600	600			12	12
PE-7	1	8	8	300	300			1	1
PE-8	1	26	26	250	600			12	12
Root powder	28	1,236	381	12,000	4,800	12,000	4,800	52	12
Total	**127**	**4,670**	**3,192**			**9,000**	**6,000**	**13**	**9**

4. Discussion

Our analysis of 130 clinical trial publications shows that of the 127 trials published after 1996 and evaluated using the Jadad scale, 52 (40.9%) achieved a perfect 5/5 score (a value of 1.0 when normalized to a 0–1 scale). However, this success is contrasted by the 22.8% (29) of studies scoring 0.6 or below, suggesting that almost a quarter of the literature remains sub-optimal in their reporting. Similar trends were observed in the CONSORT compliance across 124 post-2006 studies; while 33 trials (26.6%) scored above 80, a perfect "Nett Score" was achieved by only 4% (5) of those studies. Interestingly, the post-2022 period shows the most significant progress. Using the CONSORT-HARMS/ConPhyMed framework, 70.6% (36) of the 51 most recent studies scored above 80, with 14 (27.45%) achieving a perfect 100. While this likely reflects the successful adoption of modern reporting standards, the total omission of harms data in 16 separate studies represents a persistent and concerning gap in the clinical literature for AS.

The systematic assessment of this dataset of clinical trials offers a comprehensive overview of the landscape of reporting quality for AS. When the metrics are considered as a whole, the data indicate that the state of clinical reporting is generally adequate, as identified by a clear upward trajectory in transparency and methodological structure over the past three decades. The notable increase in CONSORT scores (from 67.14 to 82.58) and the post-1996 rise in Jadad scores (+17%) suggest that the literature and studies have adopted a level of reporting that offers reasonable reliability for clinicians and researchers. This analysis reflects that clinical trial reporting for AS is increasingly aligning with global standards, moving away from the less accurate reporting practices of the pre-guideline period. However, a closer look of the data reveals that significant gaps remain. While authors have largely embraced the structural "checklist" of the CONSORT statement, fundamental methodological quality, as measured by the Jadad scale, has stabilized at a post-1996 mean of only 0.74. This discrepancy suggests a "superficial modernization": researchers are improving the formal presentation of their work, yet the underlying execution of trials, particularly regarding randomization and blinding protocols, has not advanced at the same pace.

The most obvious deficiency identified in this analysis lies at the intersection of botanical authenticity and safety reporting (ConPhyMP). Although the post-2022 mean score for CONSORT-HARMS and ConPhyMP is high (85.94), the corresponding growth rate of 6.85% is the lowest across all categories. This indicates that researchers more readily satisfy general clinical formatting than the specialized, rigorous phytochemical standards required for herbal preparations. The 12.6% of studies which omitted harms data entirely, underscores a critical flaw; in phytotherapy, safety cannot be evaluated in a vacuum. It must be tethered to a verifiable chemical profile to ensure that any adverse events (or the absence thereof) are reproducible and attributable to specific, known metabolites.

A key limitation of this assessment is that it evaluates reporting quality rather than risk of bias or the underlying clinical evidence or the internal validity of the clinical trials. A high CONSORT or ConPhyMP score confirms a transparently written manuscript, but it does not preclude operational bias or errors in data entry. While it provides a reliable benchmark of the current state of the field, certain parameters fall outside the scope of guideline compliance, including the actual accuracy of the collected data and the potential influence of unpublished null results. Additionally, trials published before the respective guidelines cannot reasonably be expected to conform to standards that had not yet been established. Indeed, older studies may have utilized rigorous protocols but received lower scores simply because they predated modern reporting frameworks.

Finally, our use of a "Nett Score" as a composite metric assumes an equal weighting of all the parameters. In practice, certain omissions, such as a failure to provide a botanical voucher or chemical fingerprint, may represent a more significant scientific oversight than minor deviations from the CONSORT formatting guidelines.

5. Conclusion

Incomplete or absent reporting of the composition of the active substances used in clinical trials limits the applicability of our assessment to those disclosed. It is as surprising as it is disconcerting that publishers of clinical trial reports to this day have not adopted appropriate and harmonized reporting standards, such as CONSORT (see above), that would obligate authors and investigators to disclose the exact composition of trial medications, especially when these are branded products. Instead, the authors of this review were forced to conduct their own detective work. Indeed, multiple trials did not disclose composition or preparation of the trial medication. Authors did not respond to requests for clarification.

To strengthen the evidence base for AS, future research must bridge the divide between general transparency and botanical accuracy. The current standard of "adequate" reporting must be elevated to "comprehensive" by accelerating the slow growth rate (6.85%) in specialized reporting. Specifically, we argue that chemical fingerprinting, GMP compliance, and standardized harms reporting must become non-negotiable foundations of trial design that investigate herbal therapies. Only by addressing these remaining gaps can the clinical community ensure that the therapeutic potential of AS is grounded in evidence that is both methodologically sound and chemically reproducible.

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