Ashwagandha
Standards Alliance
अश्वगन्धा अत्युत्तम

Technical Rebuttal to Recent Claims Regarding Ashwagandha Leaf, "Adulteration," Method Validity, and the April 2026 Indian Regulatory Actions

April 2026

Executive Summary

Recent regulatory and media narratives have treated the use of *Withania somnifera* leaf as synonymous with adulteration. That framing is scientifically and technically inaccurate, false and misleading.

The **Ashwagandha Standards Alliance** supports truthful labeling, fit-for-purpose analytical testing, appropriate safety review, enforcement against undisclosed plant-part substitution, and scientifically valid potency claims.

The Alliance has discovered a second issue which now requires equal attention: potential adulteration of ashwagandha products related to falsification of product strength and potency related to method invalidity for withanolides.

A product's stated "withanolides" content is only meeting FDA requirements for Good Manufacturing Practices (cGMP) if the analytical method used is appropriate for the article tested, the compounds measured are clearly identified, the method is validated or scientifically justified for its intended purpose, and the result is reproducible within the product matrix.

A generic "X% withanolides" label claim is not scientifically valid if the method is undisclosed, not fit for purpose, not validated for the matrix, or measures only a limited subset of compounds while implying a broader total.

The ongoing misrepresentation of ashwagandha product potency illustrates a critical distinction between:

1. **Undisclosed substitution of leaf for root**, which may constitute adulteration or misbranding depending on the claim, specification, and jurisdiction;

2. **Disclosed, characterized use of leaf, aerial parts, or root-and-leaf material**, which must be evaluated as a question of identity, specification, composition, toxicology, exposure, labeling, and applicable regulatory category; and

3. **Potency or withanolides claims made without valid analytical support**, which independently raise GMP, labeling, specification, and substantiation concerns, regardless of whether the product is root-only or root-and-leaf.

The April 2026 actions by the Ministry of Ayush and FSSAI in India appear to establish or reiterate a root-only position for Ayush products and Indian food products which is not based on rigorous science.

These actions are likely to affect ashwagandha product supply and compliance in India and worldwide, and allow improperly labeled and potentially adulterated products to remain on the market.

Meanwhile, these actions may lead markets to the false conclusion that all leaf-containing ashwagandha products are inherently unsafe, inherently adulterated, or categorically unlawful in all jurisdictions.

On April 27, 2026, paid promotional content which presents potentially false claims regarding ashwagandha leaf was published by Nutraingredients.com. However, this content is written in the tone and voice of a neutral scientific consensus.

Where commercially sponsored coverage frames a disputed technical issue as settled fact, the industry deserves clear disclosure, independent review, and equal attention to method validity, label accuracy, and analytical substantiation of product claims made by those who sponsor that coverage.

Position of the Ashwagandha Standards Alliance

The Alliance supports the following principles:

- Ashwagandha products should be accurately identified by botanical species, plant part, extract type, solvent system where relevant, marker compounds, and manufacturing process.

- Products represented as “root” should be root-derived and should not contain undeclared leaf or aerial parts. Products containing leaf, aerial parts, or root-and-leaf material should be labeled and specified accordingly.

- Potency claims, including “withanolides” claims, must be supported by a scientifically valid analytical method.

- If a branded ashwagandha ingredient uses clinical studies to support marketing claims, the current commercial ingredient must be materially equivalent to the ingredient used in those studies. Product labeling used currently must be equivalent to those clinically studied products previously marketed.

- All analytical and clinical methods must be fit for purpose and capable of supporting the specific claim being made.

- For clinical and safety studies to apply to a given ashwagandha product, the actual article of commerce must match the identical specification, including the potency, stated in the safety assessment.

- Enforcement should focus on misrepresentation, undisclosed substitution and changes to specifications, unsupported potency claims, mismatched study articles, unsafe exposure, unsupported claims, and failure to meet specifications.

The Alliance does not support:

1. The use of leaf as an undisclosed substitute for root.
2. The claim that disclosed leaf or root-and-leaf use is considered adulteration on its own.
3. Potency or "withanolides" labeling that is not supported by a valid, fit-for-purpose method.

The term "adulteration" is misused, false and misleading

In food and dietary supplement commerce in the U.S., "adulteration" may refer to multiple problems, such as:

- Substitution of one plant species or plant part for those stated or labeled
- Undisclosed ingredients or allergens
- Dilution or economic substitution
- Overstated strength or potency
- Failure to meet identity, purity, strength, composition, or specification requirements.
- Use of analytical results that do not validly support the label claim or specification.

If a product is sold as ashwagandha root extract but contains substantial undeclared leaf material, that may be an adulteration or misbranding issue.

If a product is sold as ashwagandha root-and-leaf extract, with appropriate specifications and safety support, the term "adulteration" is not technically appropriate merely because the article contains leaf.

Likewise, if a product is sold as 5% withanolides, the label claim is not automatically valid simply if the Certificate of Analysis reports "5%." The question is whether the analytical method actually measures what the label states, whether it is valid for the product matrix, and whether the result is reproducible.

A disclosed botanical composition is not automatically adulteration, and a reported potency value is not automatically valid. Both require substantive evidence.

Indian regulatory actions appear to be misled by unknown factors, and should not be globalized beyond their scope

The April 2026 Indian regulatory actions establish or reiterate a root-only position for certain Indian regulatory categories, including Ayush products and Indian food products.

These actions have not sufficiently answered the following questions which regulators and industry should expect :

- Whether a disclosed root-and-leaf extract has adequate safety data.
- Whether a leaf-containing product has been lawfully marketed in another jurisdiction.
- Whether root-and-leaf preparations are currently widely and safely consumed in international supplement and food markets.
- Whether a U.S. dietary supplement ingredient is lawful under DSHEA.
- Whether a given extract has acceptable toxicology at its intended exposure.
- Whether withaferin A or other constituents are present at levels of toxicological concern.
- Whether the product is labeled truthfully and not misleadingly.
- Whether the product's stated withanolide potency is supported by a valid analytical method.
- Whether a "total withanolides" result is truly total, partial, estimated, hydrolyzed, calculated, or method-specific.

It is important to note that the United States and other regulated countries do not fall under the jurisdiction of AYUSH or FSSAI, and no ruling in India should be considered a restriction for U.S. commerce of ashwagandha products.

The regulatory actions in India not considered a scientific or science-guided finding, and this jurisdiction-specific ruling falls far short of any conclusion of adulteration. Likewise, this regulatory decision does not excuse weak, vague, or unsupported potency labeling by any market participant.

Science, not tradition, determines safety and regulatory status

Ashwagandha root has a long and prominent history of use in Ayurveda. But that fact alone does not support the claim that leaf-containing articles are categorically adulterated or unsafe.

Traditional-use evidence is relevant to identity, historical use, and safety context. But modern commercial extracts must also be evaluated by composition, dose, exposure, manufacturing method, marker profile, contaminant profile, method validity, and clinical or toxicological data.

A botanical material is not safe merely because it is traditional, and is not unsafe merely because it is less traditional. Further, a potency or strength claim is not valid merely because it is found on product labels.

Science guides market regulation and use: What is the composition of the specific article of commerce, what is the intended exposure, what valid method supports the stated potency, what safety data support that exposure, and how is the product represented to the market?

The Alliance stands by science to determine market freedom and regulation, and not the wishes of those who act in an unfair and anti-competitive fashion.

Disclosure of plant part is basic GMP, while use of invalid methods is adulteration

The concern around ashwagandha leaf relating to withaferin A is unfounded in the science. The toxicological relevance of withaferin A as part of ashwagandha products has been clearly defined as part of composition, exposure, dosage, safety margin, product specifications, batch consistency, analytical methods, and clinical and toxicological evidence

Ashwagandha products containing leaf which use scientifically valid methods for potency and standardization are considered safe and meeting GMP's.

Meanwhile, products with undisclosed or unreliably measured compositions contain an undefined composition, including an undefined amount of withanolides. These products may be considered adulterated.

The Alliance acknowledges that disclosure of product identity, potency, strength and purity, in addition to plant part, are required to meet FDA requirements. This includes the identity of measured compounds, the method used, the validation status of methods used, the limits for relevant constituents where appropriate, and a scientifically justified specification.

Lack of analytical method disclosures are central to the ashwagandha dispute

Different methods may measure different sets of compounds. Some methods may be more appropriate for total withanolides, some for selected marker compounds, some for withanolide glycosides, some for aglycones, and some for fingerprint comparison.

Regardless of method used, a technically sound framework meeting GMP must distinguish:

- Botanical identity testing
- Plant-part confirmation
- Marker-compound quantification
- Full chromatographic fingerprinting
- Detection of undeclared substitution
- Fit-for-purpose potency testing
- Safety-relevant constituent limits
- Batch-to-batch consistency
- Finished-product verification
- Label-claim substantiation

The Alliance recommends the development and disclosure of scientifically valid, reliable and repeatable methods.

Like FDA, the Alliance also prohibits and abhors the use of ‘black box’ methods, especially for the purpose of creating false and misleading label claims

If a company claims “root extract standardized to 5% withanolides,” on a product label, that company must disclose methods to the extent that the result can be replicated by a competent independent party. If a company claims “root only,” it should be able to show that its identity and plant-part methods support that representation.

If a company claims lower withaferin A, it should be able to show that withaferin A is measured using a valid method in the relevant matrix. If a company challenges leaf-containing products, it should apply the same analytical rigor to its own potency and composition claims.

Standards, especially those related to Good Manufacturing Practices, must not be selectively applied in one manner and selectively ignored in another.

The media narrative has confused commercial positioning with technical consensus

Recent promotional coverage in Nutraingredients on April 27, 2026 has framed the Indian regulatory action as placing “leaf adulteration” under scrutiny. This coverage

Commercially sponsored educational content is not inherently improper. But when sponsored, paid content describes one side of a contested technical matter, readers should be able to distinguish between independent journalism, sponsored promotional content, regulatory analysis, scientific consensus, and competitor claims.

The unauthored article in Nutraingredients mixes many of the same elements together, and the Alliance is concerned that this public framing has blurred the line between sponsored promotion and factual reporting.

It is not lost on readers that a root-only branded ingredient supplier has an obvious commercial interest in promoting a root-only interpretation of ashwagandha quality. That does not automatically make the supplier wrong, but it does mean the framing should be evaluated with transparent disclosure and independent review.

The same applies to analytical claims. A supplier's statements must not be accepted as scientific consensus unless its identity, composition, safety, and potency claims are supported by transparent, valid, fit-for-purpose methods.

The Alliance calls on trade media, trade associations, and industry organizations to ensure that coverage of this issue includes independent experts, competing scientific interpretations, method-validity questions, and a full and clear disclosure of commercial interests.

The correct standard is truthful identity, valid potency, and safety by composition and scientific standards

A scientifically serious ashwagandha standard should answer practical questions:

- What plant part is present?
- Is the plant part accurately labeled?
- Is the species identity confirmed?
- Is the extract composition fully characterized?
- What compounds are included in the withanolide claim?
- What method was used?
- Is the method valid for the matrix and intended purpose?
- Is the result reproducible by independent laboratories?
- What is the withanolide profile?
- What is the withaferin A content and exposure?
- What safety data match and support the article of commerce?
- What clinical data match the article?

- What jurisdictional requirements apply?
- Is the label truthful and not misleading?
- Are claims substantiated?
- Does the product meet GMP requirements?

These questions don't just comprise a standards-based framework, they also comprise the letter of FDA law.

We propose minimum standards for ashwagandha products

The Alliance recommends that ashwagandha suppliers and finished-product brands adopt the following minimum documentation standards.

A. Botanical identity

Each article should identify:

- Genus and species: *Withania somnifera*.
- Plant part: root, leaf, aerial part, root-and-leaf, or other specified material.
- Country or region of cultivation or wild harvest.
- Harvest and post-harvest controls where relevant.

B. Extract identity

Each extract should identify:

- Starting plant material
- Plant-part ratio where mixed parts are used
- Extraction solvent system
- Native extract ratio where applicable
- Carriers or excipients
- Standardized marker compounds
- Full analytical method used for potency
- Whether the stated potency is based on native compounds, selected markers, calculated equivalents, conversion-based measurement, or another method.

C. Withanolide characterization

Each product should not rely solely on a generic "total withanolides" claim where safety or quality questions depend on specific compounds.

Specifications should consider, where relevant:

- Withanolide A
- Withanolide B
- Withanoside IV
- Withanoside V
- Withaferin A
- 12-deoxywithastramonolide
- Other relevant withanolides based on extract type
- Chromatographic fingerprint
- Limits or reporting thresholds, where toxicologically relevant.
- Clear identification of which compounds are included in any “total” value.

D. Method validity

For any quantitative potency or marker claim, suppliers and brands should maintain and provide upon reasonable request documentation showing:

- Method identity and version
- Intended purpose of the method
- Validation or qualification summary
- Matrix applicability
- Specific analytes measured
- Reference standards or calibration approach
- Accuracy/recovery
- Precision
- Linearity
- Range
- Specificity
- Limits of detection and quantitation where relevant
- Robustness where relevant
- Laboratory qualification
- Batch-to-batch reproducibility
- Suitability for label-claim verification

E. Safety documentation

Each article must have safety support matching the article in commerce relating to identity, purity, strength, potency and consistency.

F. Labeling and claims

Finished products must accurately disclose:

- Plant part where material to consumer understanding or regulatory compliance
- Extract type
- Amount per serving
- Marker standardization
- Compounds included in the marker value where “withanolides” are claimed
- Directions for use
- Warnings where appropriate
- Claims supported by evidence from the same or sufficiently similar extract
- Method-valid potency support available in supplier or brand documentation

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We request corrections to the public narrative

The Alliance strongly recommends that trade organizations and media outlets adopt the following clarifications.

Incorrect framing

> Ashwagandha leaf is adulteration.

Correct framing

> Undeclared substitution of leaf for root may be adulteration or misbranding. Disclosed use of leaf or root-and-leaf material must be evaluated based on identity, composition, safety, labeling, applicable jurisdiction, and valid analytical support.

Incorrect framing

> The Indian action demonstrates or suggests that leaf-containing ashwagandha products are unsafe.

Correct framing

> The Indian action establishes or reiterates a root-only position for certain Indian regulatory categories. It does not, by itself, establish that leaf-containing or root-and-leaf extracts are unsafe.

Incorrect framing

Root-only products are inherently high quality, while leaf-containing products are inherently low quality.

Correct framing

Quality depends on truthful identity, specifications, analytical verification, contaminant controls, method validity, safety support, GMP compliance, and claim substantiation. Plant part is important, but it is not the only determinant of quality.

Incorrect framing

Percent withanolides is sufficient to compare ashwagandha products.

Correct framing

Percent withanolides is method-dependent and incomplete without knowing which compounds were measured, by what method, in what matrix, with what validation, and for what intended analytical purpose.

Incorrect framing

A COA showing “5% withanolides” is sufficient proof of potency.

Correct framing

A COA result is only as meaningful as the method behind it. The method must be valid for the article tested, the compounds measured must be identified, and the result must support the specific label or specification claim.

Alliance request for transparency

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Given the commercial significance of the April 2026 Indian actions and the immediate use of those actions in promotional market narratives, the Alliance calls for transparency regarding:

- Scientific evidence relied upon by regulators
- Expert committee composition and evaluations
- Conflict-of-interest declarations
- Stakeholder submissions
- Communications with commercial entities
- Basis for extrapolating from Ayush drug standards to food, supplement, or export contexts
- Rationale for treating leaf use as a categorical prohibition rather than a composition- and exposure-specific safety question
- Analytical methods relied upon in public claims about ashwagandha root, leaf, withanolides, withaferin A, potency, and adulteration
- Whether methods cited in regulatory or promotional arguments were validated for the relevant matrices and intended purposes

This request is not an opposition to regulation - it is a request to support and verify the aims and substantiation for the regulation. This is a request for transparent, evidence-based regulation and scientifically valid quality standards.

Conclusion

The **Ashwagandha Standards Alliance** supports enforcement against misbranded, substituted, adulterated, unsafe, poorly specified, or analytically unsupported ashwagandha products.

But the Alliance rejects the scientifically overbroad claim that all disclosed use of ashwagandha leaf, aerial parts, or root-and-leaf extracts is inherently adulteration.

The Alliance also rejects vague potency labeling that relies on undefined, undisclosed, or non-fit-for-purpose “withanolides” methods.

The industry needs to uphold the standards we claim to follow and endorse. These standards require more from us than nodding our head to misguided regulatory actions, consumer health freedom, and “root good, leaf bad.”

These standards also require more than saying “5% withanolides” without proving what was measured, how it was measured, and whether the method is valid.

These standards require evidence.

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The Ashwagandha Standards Alliance invites regulators, trade associations, analytical laboratories, suppliers, brands, toxicologists, pharmacognosists, and independent researchers to participate in the development of a transparent technical framework for ashwagandha identity, plant-part labeling, withanolide method validity, potency verification, safety, and claims substantiation.

The goal is to prevent a commercially convenient narrative from misleading industry and consumers, and replacing scientific standards.

Signed,

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