INDIAN PHARMACOPOEIA COMMISSION
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PPI MONOGRAPH SUBMISSION GUIDELINES

	Monograph	Example
Title of the Monograph	For monographs intended for inclusion in pharmacopoeias, the title of the monograph should be printed in bold letters in Times New Roman font size 14 pt. It should include the Latin binomial nomenclature or Synonym or Common Name whichever is appropriate and this is followed by the name of plant part(s) or plant material (e.g. resin, gum-resin) and where applicable, its state and type of herbal preparation (e.g. aqueous extract and Non aqueous extract and its dosage form (tablet, capsule, etc.). Subsidiary or abbreviated title or synonym (if any) may be shown two spaces below the main title (in ordinary letters). The main monograph headings viz. Identification and Tests etc. shall be in Times New Roman size 11 pt, and the headings of the individual tests in size 10 pt, and all in bold letters.	**Amaltas** Sonhali; *Cassia fistula* **Belladona Leaf** **Daruharidra Roots** Berberis, *Berberis arisata* **Daruharidra Stems** Berberis, *Berberis arisata* **Mandukaparni Dry Extract** Gotu Kola; *Centella asiatica*
Photograph	**Requirements for inclusion of photograph of an herb /part of the herb** a) A phytopharmaceutical ingredient monograph in IP provides photograph of the herb. Such a photograph shall provide a clear visual depiction of the herb, part of the herb. b) A photograph of the herb shall appear immediately after the title/synonym in the monograph. c) An authentic sample of herb/part of a herb, properly cleaned, kept within a grid printed on a paper which gives it the size denotation as illustrated in Table 1 shall be photographed using an appropriate camera with a minimum of 3 megapixels capacity. The pieces should be clearly visible. d) Alternatively, place such a sample on a glass plate which can be illuminated from	

below using a suitable lamp and photograph it from a suitable distance from the top with proper focus. While doing so depending on the colour of the backgrounds like butter paper, white paper, black paper etc. may be used suitably.

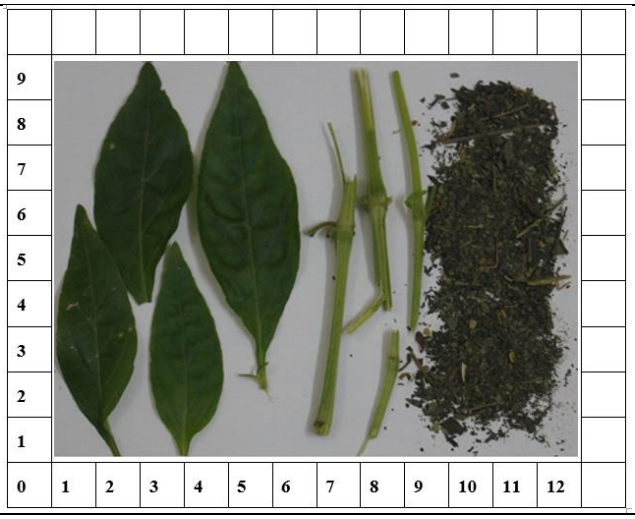
e) The photograph shall be saved and reproduced in the IP as a composite photograph occupying a size of 8 x 6 cm.

f) Alternatively, the same may also be reproduced in such a way to cover the requisite units occupying 5 x 6 cm and a photograph of 1 or maximum 2 single units in a "close up" mode occupying 3 x 6 cm size. In no case any photograph shall exceed 8 x 6 cm size. Table 1 describes the number of units of each material to be taken for the photograph.

Table 1: Description of number of units of each herbal material

Category	No. of Units	Category	No. of Units
Woody and available in large pieces–stem, wood, and heartwood, woody roots (eg. Deodar, Erandmool)	4-6	Stems and roots with smaller diameters (eg. Ephedra, Manjistha, Kutaki)	8-14
Leafy and creepers cut into parts (eg. Bhringraj, Neem)	10-12	Stigma, Style, Anthers, Small Petals, Buds (eg. Keshar, Lavang)	20-40
Fleshy Dried Rhizomes (eg. Vidarikand, Varahi)	4-8	Minute seeds and parts of seeds (eg. Vakuchi, Isabgol)	More than 40
Flowers, Larger Petals, Small Fruits (eg. Japakusum, Kusumphool)	10-20	Resins, Gums in dried form (eg. Heeng, Babool)	4-8
Bark cut into pieces (eg. Arjuna, Kutaz)	3-8	Minute parts like epidermal hair (eg. Kamela)	5-10

Grid to be used to place the herbs for photograph (Each block is of 1 cm^2)



Definition	Some or all of the following are usually included in the definition: • the state of the drug: whole, fragmented, peeled, cut, fresh or dried; • the complete scientific name of the plant (genus, species, subspecies, variety, author); commonly used synonyms may be mentioned; • the part or parts of the plant used; • where appropriate, the stage in the growth cycle when harvesting takes place, or other necessary information; • wherever possible, the minimum content of at least four quantifiable constituents (of them at least one constituent is responsible for the biological activity of the herb (bio-marker) and the remaining chemical compound may known to be present in the herb even if not responsible for biological activity (chemical/ analytical marker).	Bael consists of dried pulp of ripe or half ripe fruit of *Aegle marmelos* (Linn.) Correa (Fam. Rutaceae). Milk thistle dry extract is obtained by extracting *Silybum marianum* (Linn.) Gaertn. (Fam. Asteraceae) fruit or seed with *methanol* or any other suitable solvent.
Statement of Purity	A definitive statement of the purity of the article, two spaces below Chemical name, and expressed in the following manner: AB contains not less than X per cent of a class of the phytochemical constituents, calculated on the dried basis as the sum of individual components. Where, AB is the pharmacopoeial name of the article and X is the lower percentage figures respectively, expressed to one decimal place only.	Bael contains not less than 0.3 per cent w/w of coumarins calculated on the dried basis as the sum of the *marmelosin*, *scopoletin*, *psoralen*, *umbelliferone* and *marmesin*.
Category	Category is to be given as informative part of the drug. Only the category needs to be mentioned.	**Amaltas** **Category**. Purgative, diuretic, antipruritic, febrifuge, vibandha. **Belladona Leaf** **Category**. Anticholinergic. **Daruharidra Roots** **Category**. Hepatoprotective, antiinflammatory, anticancer, amatisara. **Coleus Dry Extract** **Category**. Cardiac stimulant, hypotensive, spasmolytic.
Usual Strength	Usual strength needs to be mentioned in case of processed herbs.	**Garcinia Aqueous Extract** **Usual strengths**. 50 per cent;

		60 per cent w/w. **Haritaki Extract** **Usual strength**. 15 per cent w/w.
Description	A brief description of the organoleptic characters of the drug such as colour, odour, taste etc.	**Amaltas** **Description**. Pulp is dark brown, sticky, sweet and mucilaginous; odour characteristic, somewhat disagreeable. **Haritaki Extract** **Description**. Light yellowish to yellowish brown powder with odour, characteristic; taste, bitter.
Identification	The purpose of this section is to ensure that article under examination is in agreement with what is stated in the Definition of the article. All the identifications mentioned below are not necessarily included: some may be absent when they are not feasible or are not significant for the purpose of identification. 1) Macroscopic: The important macroscopic botanical characteristics of the herbal materials are specified to permit a clear identification. Where two or more species of a genus or subspecies are included in the definition, the differences, if any, between them should be indicated. 2) Microscopic: It involves gross microscopic examination of the drug and it can be used to identify the organized/ unorganized drugs by their known histological characters. It is mostly used for qualitative evaluation of organized crude drugs in entire and powder forms with help of microscope. It involves using microscope for detecting various cellular tissues and their arrangements such as trichomes, stomata, starch granules and calcium oxalate crystals etc. Crude drug can also be identified microscopically by cutting the thin TS (transverse section)/ LS (Longitudinal section) especially in case of wood. Quantitative aspects of microscopy include study of stomatal number and index, palisade ratio, vein-islet number, size of starch grains and length of fibers etc.	**Bael** *A. Macroscopic* – Fruit, sub-globose, 5-18 cm in diameter, externally greenish when young, yellowish-brown when ripe, rind about 1.5–3 mm thick, hard and woody, surface smooth or slightly granular bearing a circular scar at the point of attachment with peduncle, carpels, 10-15, central, each containing several hairy seeds embedded in yellowish brown, extremely sticky mucilage. Seeds oblong, flat, woody and having white hair, fresh pulp of ripe fruit, brown, of sticky shreads, dried pulp hard and pale to dark red in colour, frequently breaks away from the rind during drying, leaving a thin layer attached to it. Odour is faintly aromatic, taste, mucilaginous and slightly astringent. *B. Microscopic* – Pulp constitutes mainly the mesocarp portion of the fruit

	3) TLC/ HPTLC: The method used must be able to distinguish the material of interest from other materials with potential for species substitution and suspected adulteration. For methods of TLC/HPTLC, description must include color and position of the characteristic bands.	devoid of seeds, scattered with vascular bundles occasionally getting anastomosing throughout the parenchymatous tissue of the ground mass, the cells of which are varying in the size and shape. The cells lying adjacent to the vascular strands and the central axis being smaller in size, vascular bundles are composed of vessels, tracheids, fibers and scalerids.
	Vessels are bordered pitted thickened while tracheids shows spiral thickening. Fibers are long and thick walled. Sclereids are mostly rectangular in shape with broad lumen and beaded thickened walls. C. Determine by thin layer chromatography (2.4.17), coating the plate with silica gel GF254. *Mobile phase.* A mixture of 7 volumes of *toluene*, 3 volumes of *ethyl acetate* and 1volume of *glacial acetic acid.* *Test solution.* Reflux about 2.0 g of the coarsely powdered substance under examination with 50 ml *methanol* on a water bath for 15 minutes, cool and filter. Reflux the residue further 2 x 50 ml of *methanol*, cool and filter. Combine all the filtrates and concentrate under vacuum to 50.0 ml. *Reference solution.* A 0.01 per cent w/v mix solution of *marmelosin* RS, *scopoletin* RS, *psoralen* RS, *umbelliferone* RS and *marmesin* RS in *methanol.* Apply to the plate 10 µl of each solution as bands of 10 mm by 2 mm. Allow the mobile phase to rise 8 cm. Dry the plate in air and examine under ultraviolet light at 254 nm and 366 nm, spray with anisaldehyde sulphuric acid reagent. Heat the plate at 105° for 5 minutes and examine in day light. The chromatographic profile of the test solution is similar to that of the reference solution.	
Tests	Depending on the article few tests may be omitted or specific tests other than this may be performed.	
	Raw Herb	**Processed Herb**
	Foreign organic matter	Total ash
	Ethanol-soluble extractive	Acid-insoluble ash
	Water-soluble extractive	Heavy metals
	Total ash	Pesticide residues
	Acid-insoluble ash	Aflatoxins
	Heavy metals	Loss on Drying
	Pesticide residues	Microbial contamination
	Aflatoxins	
	Loss on Drying	
	Microbial contamination	

Foreign organic matter	Generally a limit of 2% of foreign matter is imposed, unless otherwise prescribed in a specific monograph. Where a limit for foreign matter greater than 2% is to be prescribed, it is stated in the specific monograph with an indication of the type of foreign matter. Where necessary, the monograph should indicate how the foreign matter is identified.	**Bael** **Foreign organic matter** (2.6.1). Not more than 2.0 per cent.
Ethanol/water soluble extractive	This method determines the amount of active constituents extracted with solvents from a given amount of herbal material.	**Bael** **Ethanol-soluble extractive** (2.6.2). Not less than 7.0 per cent. **Water-soluble extractive** (2.6.3). Not less than 45.0 per cent.
Total ash/Acid-insoluble ash	The *total ash* method is designed to measure the total amount of material remaining after ignition. *Acid-insoluble ash* measures the amount of silica present, especially as sand and siliceous earth	**Bael** **Total ash** (2.3.19). Not more than 3.0 per cent. **Acid-insoluble ash** (2.3.19). Not more than 1.0 per cent.
Heavy metals	Usually 1g of material is taken unless otherwise justified.	**Bael** **Heavy metals** (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).
Pesticide residues	The monographs should refer to the General chapter 2.6.9 with a statement that it complies with the pesticide residue tests.	**Bael** **Pesticide residues** (2.6.9). Complies with the pesticide residues tests.
Aflatoxins	The monographs should refer to the General chapter 2.6.8 with a statement that it complies with the aflatoxin tests.	**Bael** **Aflatoxins** (2.6.8). Complies with the aflatoxins tests.
Loss on Drying	It is the loss of weight expressed as percentage w/w resulting from water and volatile matter of any kind that can be driven off under specified conditions.	**Bael** **Loss on drying** (2.4.19). Not more than 7.0 per cent, determined on 5.0 g by drying in an oven at 105°.
Microbial contamination	The monographs should refer to the General chapter 2.2.9 with a statement that it complies with the microbial contamination tests.	**Bael** **Microbial contamination** (2.2.9). Complies with the microbial contamination tests.
Assay	**By TLC/HPTLC** **Assay**. Determine by thin-layer chromatography (2.4.17), coating the plate with silica gel GF254. **By HPLC method** **Assay**. Determine by liquid	**Bhuiamla** **Assay**. Determine by liquid chromatography (2.4.14). *Test solution.* Reflux about 0.5 g of powdered substance under examination with 10 ml *methanol* for 30-45 minutes, cool and filter. Reflux the residue further 2 x 50 ml of

	chromatography (2.4.14). *Test solution.* Directions for preparing to be given *Reference solution.* Directions for preparing to be given Chromatographic system: • details of the column, • mobile phase composition and flow rate, • detector and wavelength setting, • injection device (if any), and • any other detail. *Note* - Commas are to be put after each item except the last where a full stop is to be given. Instructions for carrying out the determination, including the volumes to be injected, sequence of injections etc. Calculate the percentage content of class of the phytochemical constituents, calculated on the dried basis as the sum of individual components mentioned in the opening purity statement.	*methanol*, cool and filter. Combine all the filtrates and concentrate under vacuum to 5.0 ml. *Reference solution.* A 0.01 per cent mix w/v mix solution of *phyllanthin* RS, *hypophyllanthin* RS, *nirtetralin* RS and *niranthin* RS in *methanol.* Chromatographic system - a stainless steel Chromolith® performance RP-18 column 10 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (2 µm), - mobile phase: 0.5 per cent v/v of 1,4 *dioxan* in a mixture of 40 volumes of *water* and 60 volumes of *methanol*, - flow rate: 1 ml per minute, - spectrophotometer set at 230 nm, - injection volume: 10 µl. Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent. Inject the reference solution and the test solution. Calculate the content of lignans, calculated on the dried basis as the sum of the *phyllanthin*, *hypophyllanthin*, *nirtetralin* and *niranthin.*
Storage	Directions for storing the product with particular reference to the nature of the pack and storage temperatures (as appropriate) shall be stated.	**Storage**. Store protected from heat, moisture and against attack by insects and rodents.
Labelling	Any specific requirement relating to the standard of the product or the storage directions shall be given.	Labelling. The label states the strength in terms of the equivalent amount of gugulsterones (Z and E).
HPLC Chromatogram	a) A HPLC Chromatograms if present shall be incorporated in Volume I of IP. b) Separate chromatogram for the Phytochemical Reference Substances (PRS) and sample under examination should be provided. c) The peak of the PRS/ compound under examination shall be labelled accordingly in the respective chromatograms. Other peaks that may appear in the chromatogram, whose chemical identity is not known, need not be labeled. d) While supplying such HPLC chromatograms please ensure that the chromatogram should; complies with;	

	• Contain appropriate scale in X and Y axis with respective units. • Not contain any notations given by the equipments like date, sample details, annotation and all such other matter. • Not contain names of analyst, firms that may appear as a routine part due to settings
TLC Chromatogram	a) A "Typical TLC/HPTLC profile" depicts the results of the test for identification/assay used. b) Identification tests by TLC/HPTLC shall be performed as per specification given in the respective monograph. c) As a common practice, the plate shall be of at least 5 cm width and 10 cm height. In this dimension 2 bands each of 10 mm width would be spotted. d) As a rule the extreme left track (track 1) shall always be a Botanical Reference Substance (BRS)/ Phytochemical Reference Substance (PRS). The track 2 of 10 mm width band shall be of a solution of material under examination. e) All the bands shall be applied at a height of 20 mm from the base of the plate. f) During development, the solvent front shall be allowed to move to at 80% of the plate height. g) A photo-documentation of the plate developed as above, after visualization under UV 254 nm and 365 nm, and/or by any derivitizing or by spraying reagents shall be photographed.