1.DOSAGE FORMS DESCRIPTION FOR MEDICINES

Application. A liquid or semi-liquid preparation containing one or more active ingredients intended for application to the skin.

Bar. A solid preparation containing one or more active ingredients in bar form.

Bar, Soap .A solid preparation derived from the action of a solution of alkali on fats or oils of animal or vegetable origin and containing one or more active ingredients in bar form..

Capsule. A solid preparation with hard or soft shell, of variable shape and capacity, usually containing a single dose of active ingredient(s) for oral administration.

Capsule, Enteric. A capsule prepared in such a manner that the shell, or the pelletized contents, resists the action of the gastric fluid but is attacked by the intestinal fluid to release the contents.

Capsule, Hard A capsule with a hard shell consisting of two prefabricated cylindrical sections one of which fits over the other. The active ingredients are usually in solid form.

Capsule, Modified Release

A capsule in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.

Capsule, Soft A capsule, the contents of which are liquid or semi-liquid.

The shells are usually thicker than those of hard capsules and consist of a single part.

Cement, Medicated A cement containing active ingredients applied to parts of the body to enable adherence.

Collodion. A liquid preparation usually containing pyroxylin and one or more active substances in a mixture of volatile solvents, usually ether and ethanol, intended for application to the skin. When allowed to dry, a flexible film is formed at the site of application.

Cream. A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base.

Diluent. A single substance or preparation usually in liquid form supplied individually or as part of a composite pack, intended to be mixed with one or more specified active ingredients before administration to produce required dosage form.

Ear Drops A suspension, emulsion or solution of one or more active ingredients in a vehicle suitable for instillation into the aural canal.

Ear Drops, Emulsion A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.

Ear Drops, Powder for One or more active ingredients in a dry form to be reconstituted for use as ear drops.

Ear Drops, Solution A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.

Ear Drops, Suspension A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Enema A liquid preparation composed of, or containing, one or more active ingredients for rectal administration.

Eye and Ear Drops A sterile solution, suspension or emulsion of one or more active ingredients intended for instillation into the conjunctival sac or aural canal.

Eye and Ear Ointment A sterile semi-solid preparation of homogeneous appearance intended for application to the conjunctiva or aural canal. It may contain one or more active ingredients dissolved or dispersed in a suitable base.

Eye Drops A sterile solution, suspension or emulsion of one or more active ingredients intended for instillation into the conjunctival sac.

Eye Drops; Emulsion A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.

Eye Drops, Powder for One or more active ingredients in a dry form to be reconstituted for use as eye drops.

Eye Drops, Solution A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.

Eye Drops, Suspension A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Eye Ointment A sterile semi-solid preparation of homogeneous appearance intended for application to the conjunctiva. It may contain one or more active ingredients dissolved or dispersed in a suitable base.

Gel A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent.

Granules, Effervescent Granules which evolve carbon dioxide when added to water. They are intended to be dissolved or dispersed in water before administration.

Granules, Enteric Coated Granules which resist the action of gastric fluid but are attacked by intestinal fluid to release the active ingredients.

Granules, Modified Release Granules in which the rate or place of release of active ingredients in the gastrointestinal tract has been modified.

Gum, Chewing A preparation containing one or more active ingredients in a gum base, to be chewed and subsequently discarded.

Herb, Dried Dried plant or parts of plants including mixtures of such, used for the extemporaneous preparation of infusions, decoctions or similar preparations for therapeutic use by oral administration.

Inhalation A preparation composed of, or containing, active ingredients which, when vaporized or dispersed in a suitable manner, is intended to be administered into the lungs or into the nasal, par nasal or ethmoid sinuses via the nasal or oral respiratory route. Inhalations may be intended for local or systemic effect.

Inhalation, Conventional A preparation composed of, or containing, active ingredient(s) which when vaporized or dispersed in a suitable manner (eg. hand actuated pump, nebuliser etc.) is intended to release the constituents for inhalation.

Inhalation, Powder for A powder preparation composed of, or containing, active ingredients which when dispersed in a suitable manner is intended to be self-administered by inhalation via the nasal or

the oral route for local or systemic effect. It is usually inhaled in controlled amounts.

Inhalation, Pressurized A metered dose preparation usually consisting of a solution, suspension or emulsion of one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended to be inhaled in controlled amounts and are delivered by the actuation of an appropriate metering valve.

Insufflation A powder containing one or more active ingredients usually diluted with a suitable inert powder. It is intended for introduction into the ear, nose, throat, body cavities or wounds.

Liniment A liquid or semi-liquid preparation composed of or containing one or more active ingredients intended to be applied to the unbroken skin with friction.

Liquid, Multipurpose A liquid (or oily) preparation composed of, or containing one or more active ingredients intended for multipurpose use. eg. Aroma therapy oils can be used for inhalation, topically or orally.

Lotion A liquid or semi-liquid preparation composed of or containing one or more active ingredients usually intended to be applied to the unbroken skin without friction.

Lotion, Powder for Solid substance to be reconstituted in an appropriate liquid before application to the unbroken skin.

Lozenge A solid preparation, containing one or more active ingredients, usually in a flavored base, which is intended to dissolve or disintegrate slowly in the mouth to effect a local action.

Mouth Wash An aqueous solution of one or more active ingredients intended, usually after dilution with warm water, for use in contact with the mucous membranes of the oral cavity, including gargling.

Nasal Drops A liquid preparation for instillation into the nostrils by means of a dropper.

Nasal Drops, Emulsion A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended.

Nasal Drops, **Powder** for One or more active ingredients in a dry form to be reconstituted for use as nasal drops

Nasal Drops, Solution A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.

Nasal Drops, Suspension A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Ointment A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually non aqueous.

Oral Liquid A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.

Oral Liquid, Emulsion A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.

Oral Liquid, Powder for One or more active ingredients in a dry form to be reconstituted for use as an oral liquid.

Oral Liquid, Solution A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.

Oral Liquid, Suspension A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Paint A liquid preparation containing one or more active ingredients for application to broken skin or mucous surfaces.

Paint, Concentrated A liquid which must be diluted with another liquid in order to prepare a paint.

Paint, Powder for One or more active ingredients in a dry form to be reconstituted for use as a paint.

Paste A semi-solid preparation for external application usually containing a high proportion of finely powdered active ingredients mixed with soft or liquid paraffin or with a nongreasy base made with glycerol, mucilage or soap.

Pastille A solid preparation containing one or more active ingredients incorporated in a mass of sweetened gum, glycerol, and gelatin base which is intended to be sucked.

Patch, Dermal A system containing active ingredients which is affixed to the skin and is intended to produce a local effect by diffusion of the active ingredients to the skin.

Pessary A solid preparation containing one or more active ingredients intended for vaginal administration.

Pessary, Compressed A solid preparation, generally similar to an uncoated tablet, but intended for vaginal administration. Also known as vaginal tablet.

Pessary, Modified Release A pessary in which the rate of release of active ingredients in the vagina has been modified.

Pessary, Moulded A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for vaginal administration.

Pessary, Shell A solid preparation, similar to a soft capsule, but intended for vaginal administration. Also known as vaginal capsule.

Pill A spherical or ovoid solid preparation containing a unit dose of one or more active ingredients for oral administration.

Powder A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.

Powder, Dusting A finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.

Powder, Dusting, Sterile A sterile finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.

Powder, Oral A finely divided powder composed of, or containing one or more active ingredients for oral or nasogastric administration, generally with water. The dose is obtained either by measuring a volume of the powder or from an individual container e.g. sachet, paper tube or vial.

Solution A liquid preparation composed of, or containing, one or more active substances dissolved in a suitable vehicle.

Spray A liquid preparation for application after dispersion with a spraying device.

Spray, Pressurized A liquid preparation usually consisting of a solution, suspension or emulsion containing one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended for local application and are delivered by the actuation of an appropriate valve.

Spray, Solution A liquid preparation for application after dispersion with a suitable device other than aerosol.

Spray, Suspension A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Stick A solid preparation containing one or more active ingredients in stick form.

Stick, Lip A solid preparation containing one or more active ingredients in stick form for application to the lips.

Suppository A solid preparation containing one or more active ingredients intended for rectal administration, usually as a single dose.

Suppository, Compressed A solid preparation generally similar to an uncoated tablet, but intended for rectal administration.

Suppository, Moulded A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for rectal administration, usually as a single dose.

Suppository, Shell A solid preparation, similar to a soft capsule, but intended for rectal administration, also known as a rectal capsule.

Suspension A liquid preparation composed of, or containing one or more active substances suspended in a suitable vehicle. It may also contain dissolved active substances.

Suspension, Powder for A finely divided powder composed of, or containing, one or more active ingredients to be reconstituted in a suitable liquid for use as a suspension.

Tablet A solid preparation containing one or more active ingredients, usually a measured quantity, with or without suitable diluents in a wide variety of sizes, shapes and surface markings prepared by moulding or compression for oral, sublingual or other use.

Tablet, Chewable A tablet with a palatable formulation designed to be chewed rather than swallowed whole.

Tablet, Dispersible A tablet which rapidly produces a uniform dispersion in water and is intended to be dispersed prior to administration.

Tablet, Effervescent A tablet generally containing acid substances and carbonates or bicarbonates which react rapidly in the presence of water to release carbon dioxide. It is intended to be dissolved or dispersed in water before administration.

Tablet, Enteric-Coated A tablet covered with one or more layers of coatings intended to resist the gastric fluid but permit disintegration in the intestinal fluid.

Tablet, Film-Coated A tablet surrounded by a thin layer of various substances usually polymeric in nature.

Tablet, Gelatin-Coated A tablet surrounded by a layer of gelatin with or without other substances.

Tablet, Modified Release A coated or uncoated tablet in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.

Tablet, Multilayer A compressed tablet comprising two or more layers of different composition. The layers may be concentric (compressed coated) or parallel.

Tablet, Soluble An uncoated tablet that is intended to be dissolved in water prior to administration. The solution produced may be slightly opalescent due to excipients used in the manufacture of the tablet.

Tablet, Sugar Coated A tablet surrounded by a layer of sugar with or without other substances.

Tablet, Uncoated A compressed solid preparation containing a unit dose of one or more active ingredients for oral administration. The tablet is not coated and not multilayer.

Wafer A thin flat solid preparation containing one or more active ingredients. If is usually intended to disintegrate or dissolve rapidly in contact with body fluids.

2. EXPIRY DATE.

(1) The date of expiry for all finished products shall be conspicuously displayed on the label of the container or package of alternative medicines and health products.

(2) The shelf life of imported medicines and health products shall base on the accelerated and long-term stability data submitted with the enlistment application.

(3) Shelf life of imported medicinal products and health products will base on the stability data generated through stability studies in accordance with WHO or ICH Stability guidelines.

(4) The Shelf-life for alternative medicine and health products shall be two years provided liquid preparations containing vitamins shall have shelf life of eighteen months..

(5) After the said date of expiry, alternative medicines or health products shall not be in circulation for use.

(6) The shelf life of locally manufactured medicines, herbal medicinal products or phytopharmaceuticals and health products including food supplements will be given on the bases of letter of commitment submitted by the manufacturer for conducting stability study to generate supportive data.

(7) Maximum shelf life of any finished product shall not exceed 5 years in any case.

Stability Data

S.No.	Stability Study	Shelf Life
1.	i) 2 batches of complete real-time stability study at 30 ± 2 ºC / RH 75± 5% for the claimed shelf-life. OR ii) 2 batches of on-going real time stability study (at least 6 months) at 30 ± 2 ºC / RH 75 ± 5% + Letter of commitment (LOC) to submit complete real time stability data when study is for pilot scale batches/ when requested. AND 2 batches of 6 months accelerated stability study at 40ºC.	- Shelf life will be based on data stability at 30ºC of not more than 5 years. - 2 years
2.	i) 2 batches of complete real time stability study at a temperature and relative humidity (RH) different from the Zone IVB for at least 2 years + LOC to conduct real time stability study at Zone IVB and submit when the study is complete/ when requested OR ii) 2 batches of on-going real time and accelerated stability study (at least 6 months) at a temperature/ relative humidity (RH) different from Zone IVB + LOC to conduct real time stability study at Zone IVB and submit when the study is complete/ when requested.	- Shelf life will be based on data stability at specified temperature. - 2 years at specified temperature in the stability study.
3.	2 batches of complete real-time stability study at temperature and RH other	- Shelf life will be based on data stability at specified

	than zone IVB for very unstable active ingredient(s)/ product (must be substantiated).	temperature.

(i) Storage Conditions with Type of Container Closure System/ Stability Study

Table 10: No.	**Type of Container Closure System/ Study**	**Storage Condition**
1.	Products in primary containers permeable to water vapour	30°C + 2°C/75% RH + 5%RH
2.	Products in primary containers impermeable to water vapour	30°C + 2°C
3.	Accelerated studies	40°C + 2°C/75% RH + 5%RH

(ii).Reports of stability studies shall provide details of:

a) the batches placed under study (a minimum of 2 batches are required).
b) containers/ packaging type.
c) conditions of storage during study (temperature, humidity, etc).
d) duration of study and frequency (interval) of the tests/ observations.
e) the tests performed and acceptance limits.

(iii).Stability study data checklists are as under.

Data Required	**Remarks**
Company name	- From product holder/ manufacturer/ third party lab
Product name	- To be same with other documentation
Dosage form	- To be same with A3
Packaging particulars	- Material and pack size must be stated - To be same with C1
Storage condition	- Temperature and humidity must be stated - Shall comply with Zone IV requirement (30±2°C/75±5%RH) - If different storage condition (e.g. 25°C, 2-8°C), must provide justification/ supporting data.
Frequency of testing	For example: - 0, 3, 6, 9, 12, 18, 24 months and annually for the proposed shelf life

List of relevant tests	- All tests required for each dosage form shall be conducted, for example: o Physical appearance changes o Disintegration test (if applicable) o Chemical Assays for active ingredients (if applicable) o Microbial tests
Specifications	- Acceptance limit for each test must be stated - To be supported by established references (e.g. USP, BP) if available
Results for each test	- Must meet the specifications
Approval by authorized person	- Must have the name, post and signature of authorized person

3. PRODUCT NAME VALIDATION

1) Applicant may include product name, dosage form and strength (e.g. XYZ Capsule 500mg)
2) Dosage form and strength of product would need to be entered as part of product name to allow for multiple dosage forms (e.g. tablet, capsule) and strengths (e.g. 200mg and 400mg) for any particular named (proprietary or generic) product.
3) In any event if found that registered product name is similar to another registered product, Authority reserve the rights to request for the change in the product name.
4) Product with more than 1 active ingredient could not include strength of active ingredients in the product name.
5) Product name may be included together with the brand name or trademark name, if applicable.
6) Any product name which is the same or similar either in writing/ pronunciation, with the product name of an adulterated product is prohibited.
7) Product name of already registered product will be maintainable whereas new one has to change the name in case of resemblance.
8) In case of resemblances between product names of two enlisted products, the one having trademarked will retain the name. If both are non trademark, the one having less market life will has to change the name.

List of Non-Permissible Product Name

List of Non-Permissible Product Name for medicine and food Supplement Products S. No.	Issue	Example
1.	**Prohibited use of disease names**	Diabetes, Asthma, Cancer
2.	**Prohibited use of a single active ingredient as a product name in products containing more than one active ingredient unless product name contains words such as „Plus, Compound, Complex, Herbanika**	If the product contain Vitamin C, Vitamin E and Fish Oil Product name: “Vitamin C” is not allowed but product name: “Vitamin C Plus” is allowed.
3.	**Prohibited use of superlative Names which indicates superiority inefficacy**	Power, Superior, Pure, Mustajab, Safe, Healthy, Penawar, VIP, Good, World Number 1
4.	**Prohibited use of spelling of words which may cause confusion i)Words which involve names of/part thereof: 20 disease names prohibited under these rules ii) Other diseases without scientific proof iii) Prohibited indication**	Go Out = GOUT (label) Utix
5.	**Prohibited use of names which may cause ambiguity Ambiguous product name**	B For Energy?
6.	**Prohibited use of names which may be offensive or indecent**	SENXBIG=SEnXBIG(label) Sexy, Enjoy, Paradise, Heavenly, Blue boy, Casanova, Desire
7.	**Product name which is not congruent with the active ingredient.**	The active ingredient is Evening Primrose oil (EPO) and the product name: “Marine tablet” is not allowed.
8.	**Prohibited use of product names which has elements of ludicrous belief Statements referring to ancient believe/negative**	Words such as miracle, magic, magical, miraculous, saintly, heavenly

	spirits/supernatural power	
9.	**Prohibited use of product names similar to the existing approved product names** **Product name similar to the spelling and pronunciation of words of an existing product names**	Elegen vs L-gen vs L-jen Forte vs Fort
10.	**Prohibited use of product names which may cause ambiguity in the nature of product (drug/ food/ beverage)** **Product name similar to a food/ beverage name**	Juice, Health drink, Beverage, Kooky
11.	**Prohibited use of product names which represents professional advice or opinion**	Dr Sunny, Professor
12.	**Product name that symbolize a claim**	Vigour, Youthful, High, Hi
13.	**Product name that uses strength but formulation contains more than one active ingredient.**	If the product contains multivitamins and minerals. Product name: "XXX multivitamins and minerals 500mg" is not allowed.
14.	**Other prohibited product names**	Minda, IQ, Smart, Unique, Ultra Mega, Detox
15.	**Names of organs and brain**	Heart, kidney, skin, liver

16.Prohibited use of product names which may cause ambiguity in the nature of product (drug/ food/ beverage)
Product names similar to a food/ beverage product

Example:
Juice, Health drink, Beverage, Kooky

17.	**Prohibited use of product names which represents professional advice or opinion or referring to the profession**	**Example:** Dr Sunny, Dr Noortier Rooibose Tea, Professor, Herbalist, Doctor

18.	**Prohibited use of product names which represent weight loss/ slimming properties**	**Example:** Slim, Langsing, Trim, Trimnfit, *Sleen, Kurus, Susut perut*
19.	**Prohibited use of product names which are incoherent with the approved indication Name containing a product claim whereas product is indicated for more than the approved indication**	**Example: Cough Syrup X= Approved indication for cough, dizziness, flu and itch**

4. SPECIFICATION MONOGRAPH.

Alternative medicine and Health Product specifications herein *of* finished products are applicable for the release of manufactured products for marketing and supply. Specifications for product quantity and purity (where relevant) should be applicable for the duration of the product's shelf life. Manufacturers are required to release their enlisted finished products using specifications templates as a certificate of analysis to conform test parameters as per tolerances using referred methodology therein for the respective products.

1. Physical specifications required for different dosage forms in addition to other tests are stated below.

Serial no.	**Dosage Form**	**Physical Specifications Required**
1	Capsule/Tablet	Filling variation/weight variation, Water content Disintegration or dissolution
2	**Granules**	Filling/filling variation(for single dose packing) Water content, Granules size variation and Dispersibility
3	**Liquid (Mixture)**	Filling/filling variation (for single dose packing), pH ,Relative density, Sucrose content (where applicable), Preservatives (where applicable) Determination of methanol(where applicable)
4	**Liquid (Syrup)**	Filling/filling variation(for single dose packing) pH Fill volume for multidose liquid or syrup Relative density Sucrose content (where applicable) Preservatives (where

		applicable) Determination of methanol(where applicable)
5	**Liquid(Tincture)**	Filling/filling variation(for single dose packing) Relative density Determination of methanol(where applicable)
6	**Pills**	Filling/filling variation (for single dose packing) , Weight variation, Water content ,Disintegration
7	**Powder**	Filling/filling variation (for single dose packing) Water content and Particle size variation
8	**Suppository**	Weight variation, Disintegration, Water content
9	**Tea**	Weight variation (for tea lumps only), Dispersibility (for sugar containing tea lumps only)

2. Product Description:

Product description shall be defined, briefly, based on visual **and physical characteristics** of the product, including as described in the following **Table (**where applicable):

Dosage Form		**Description**
(1).	Tablet	Shape, size, colour, odour, taste, marking, emboss, type of tablet (e.g. coated, uncoated, film, sugar etc.)
(2).	Capsule	Shape, size, colour, odour, taste, marking, emboss, coating, content of capsule, type of capsule (e.g.: soft, hard, chewable etc.)
(3).	Liquid	Clarity, type (e.g. solution/ suspension/ émulsion etc.), taste, odour, colour.
(4).	Powder	Colour, odour, taste etc.
(5).	Pill	Colour, odour, taste, size

		etc.
(6).	Granules	Colour, odour, taste, size etc.

3. Limit Test for Heavy Metals shall be within the following prescribed limits which is *required for products with ingredients from natural sources. The test shall be conducted either on the raw material or finished product.***.**

a) Lead: NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)

b) Arsenic: NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)

c) Mercury: NMT 0.5 mg/kg or 0.5 mg/litre (0.5ppm)

d) Cadmium: NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)

4. **Disintegration Test** (for tablets, capsules and pills) shall be within the following prescribed limits

a) Uncoated tablets: NMT 30 minutes

b) Film-coated tablets: NMT 30 minutes

c) Sugar-coated tablets: NMT 60 minutes

d) Enteric-coated tablets: Does not disintegrate for 120 minutes in acid solution but to disintegrate within 60 minutes in buffer solution

e) Capsules : NMT 30 minutes

f) Pills : NMT 120 minutes

5. **Test for Uniformity of Weight tablets and capsules** only shall be conducted which shall be within the following prescribed limits.

i) Tablet

a)- For tablet with average weight of 130mg or less: Not more than 2 tablets differ from the average weight by more than 10% AND no tablets differ from the average weight by more than 20%

b)- For tablet with average weight between 130-324mg: Not more than 2 tablets differ from the average weight by more than 7.5% AND no tablet differs from the average weights by more than 15%

c)- For tablets with average weight more than 324mg: Not more than 2 tablets differ from the average

weight by more than 5% AND no tablet differs from the average weight by more than 10%

ii) Capsule

Individual weight of the capsule to be within the limit of 90-110% of the average weight.

6. Tests for Microbial Contamination shall be within the following prescribed limits as defined and tabulated for the various dosage forms.

1. Table 1: Finished product specifications template for a product containing a plant, plant material, alga, fungus or bacterium and/or their extracts or isolates +

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate	Macroscopic/organoleptic (not applicable to extracts and isolates)	Pharmacopoeial or other internationally recognized methods	Conforms to herbarium reference
	Microscopic (not applicable to extracts and isolates)	Any microscopy method	Conforms to herbarium reference
	Chemical identity (for extracts and isolates)	TLC, HPLC or other internationally recognized methods	Characteristic of the material
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally recognized methods	$< 1 X 10^4$ cfu/g or ml
	Total viable aerobic count	Pharmacopoeial or other internationally recognized methods	$< 1 X 10^5$ cfu/g or ml

Purity (Chemical)	*Escherichia coli*	Pharmacopoeial or other internationally recognized methods	< 1 X10^1 cfu/g for all internal use except for teas, decoctions, or topical dosage
	Salmonella spp.	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally recognized methods	For plant, plant material, alga, fungus or bacterium: < 1 X 10^2 cfu/ g or ml for all internal uses except for teas, decoctions, or topical dosage forms: < 1 X
	Pseudomonas aeruginosa (for liquids with	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Aflatoxins (for nuts and ginseng or their extracts and isolates or any substances derived from these)	Pharmacopoeial or other internationally recognized methods Internationally	Aflatoxins < 20 µg/kg (ppb) of substance Limits based
	Arsenic	Pharmacopoeial or other internationally recognized methods	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally recognized methods	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally recognized methods	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally recognized methods	< 0.29 µg/kg b.w./day
	Pesticides	Pharmacopoeial or other internationally recognized methods	Conforms to pharmacopoeial limits
	Solvent residues (for extracts and isolates)	Pharmacopoeial or ICH	Conforms to pharmacopoeial or ICH limits

Specification Templates.

	Other impurities (for extracts and isolates)	Pharmacopoeial	Conforms to pharmacopoeial limits
	Radioactivity (if suspected)	International Atomic Energy	600 Becquerel/Kg
Quantity/potency	Quantity tests	GC, HPLC or other internationally recognized methods	80 -120% of label claim
Performance tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60
	Antimicrobial Effectiveness***	USP <51>, Ph. Eur. 5.1.3 or equivalent	Meets pharmacopoeial requirement

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

c) *** Required for products containing preservatives, performed at the end of shelf-life (test on development batches). Not required on every batch.

2. Table 2: Finished product specifications template for a product containing a non-human animal material and/or their extracts or isolates +

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate	Macroscopic/organoleptic (not applicable to extracts and isolates)	Pharmacopoeial or other internationally recognized methods	Conforms to reference
	Microscopic (not applicable to extracts and isolates)	Any microscopy method	Conforms to reference
	Chemical identity (for extracts and isolates)	TLC, HPLC or other internationally recognized methods	Characteristic of the material
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally recognized methods	< 1 X 10^4 cfu/g or ml
	Total viable aerobic count	Pharmacopoeial or other internationally recognized methods	< 1 X 10^5 cfu/g or ml
	Escherichia coli	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with [illegible])	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally recognized methods	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally recognized methods	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally recognized methods	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally recognized methods	< 0.29 µg/kg b.w./day
	Pesticides	Pharmacopoeial or other internationally recognized methods	Conforms to pharmacopoeial limits

	Solvent residues (for extracts and	Pharmacopoeial or ICH	Conforms to

			pharmacopoeial or ICH limits
	Other impurities (for extracts and isolates)	Pharmacopoeial	Conforms to pharmacopoeial limits
	Specific contaminants (PCDDs, PCDFs and PCBs in marine animal	As per CRN monograph****	As per CRN
	Radioactivity (if suspected)	International Atomic Energy	600 Becquerel/Kg
Quantity/potency	Quantity tests	GC, HPLC or other internationally recognized methods .	80 -120% of label claim
Performance tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60
	Antimicrobial Effectiveness***	USP <51>, Ph. Eur. 5.1.3 or equivalent	Meets pharmacopoeial requirement

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

c) *** Required for products containing preservatives, performed at the end of shelf-life (test on development batches). Not required on every batch.

3. Table 3: Finished product specifications template for a product containing enzymes +

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate test is	Physical description	Any appropriate method	Not applicable
	Chemical identity	HPLC, MS, gel electrophoresis, spectrophotometric methods, substrate specific or other appropriate assays.	Appropriate to identify Medicinal Ingredients
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally recognized methods	< 1 X 10^4 cfu/g or ml
	Total viable aerobic count	Pharmacopoeial or other internationally recognized methods	< 1 X 10^5 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with < 50% alcohol)	Pharmacopoeial or other internationally recognized methods	Not detectable per g or ml
	Enterobacteriaceae	Pharmacopoeial or other internationally recognized methods	< 1 X 10^2 cfu/g or ml
	Arsenic	Pharmacopoeial or other internationally recognized methods	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally recognized methods	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally recognized methods	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other	< 0.29 µg/kg

		internationally recognized methods	
	Antibiotic activity (for microbially derived	FAO/WHO or other internationally recognized methods	Not detectable
	Solvent residues	Pharmacopoeial or other internationally recognized methods	Conforms to pharmacopoeial or ICH limits
	Related impurities**	Pharmacopoeial	Conforms to pharmacopoeial limits
Quantity	Enzyme activity assay	Assay (substrate specific), HPLC or other internationally recognized	80%-150% of label claim
Performance tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60 min (plain coated
	Antimicrobial Effectiveness***	USP <51>, Ph. Eur. 5.1.3 or equivalent	Meets pharmacopoeial requirement

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients
from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

c) *** Required for products containing preservatives, performed at the end of shelf-life (test on development batches). Not required on every batch.

4. Table 4: Finished product specifications template for a product containing vitamins +

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate test	Physical description Chemical identity	Any appropriate method Pharmacopoeial or other internationally recognized methods	Not applicable Conforms to pharmacopoeial standard(if applicable)
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 3 X 10^2 cfu/g or mL
	Total viable aerobic Count	Pharmacopoeial or other internationally	< 3 X 10^3 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with < 50%	Pharmacopoeial or other internationally recognized	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Solvent residues	Pharmacopoeial or other internationally	Conforms to pharmacopoeial or ICH limits
	Related impurities**	Pharmacopoeial	Conforms to pharmacopoeial

Quantity/Potency	Quantity tests	Pharmacopoeial or other internationally recognized	Conforms to pharmacopoeial limits or, in their absence, 80
Performance tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60 min (plain coated
	Antimicrobial	USP <51>, Ph. Eur.	Meets pharmacopoeial

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

*** Required for products containing preservatives, performed at the end of shelf-life

c) (test on development batches). Not required on every batch.

5. Table 5: Finished product specifications template for a product containing amino acids +

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate test	Physical description Chemical identity	Any appropriate method Pharmacopoeial other internationally recognized methods	Not applicable Conforms to pharmacopoeial standard(if applicable)
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 3 X 10^2 cfu/g mL
	Total viable aerobic count	Pharmacopoeial or other internationally	< 3 X 10^3 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with < 50%	Pharmacopoeial or other internationally recognized	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
Purity (Chemical)	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Solvent residues	Pharmacopoeial or other internationally	Conforms to pharmacopoeial or ICH limits
	Other impurities **	Pharmacopoeial or other	Conforms to pharmacopoeial

		recognized	
Quantity/Potency	Quantity tests	Pharmacopoeial or other internationally recognized	Conforms to pharmacopoeial limits or 80 -120% of label claim
Performance tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60 min (plain coated
	Antimicrobial	USP <51>, Ph. Eur.	Meets pharmacopoeial

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

*** Required for products containing preservatives, performed at the end of shelf-life

c) (test on development batches). Not required on every batch.

6. Table 6: Finished product specifications template for a product containing essential fatty acids+

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate	Physical description Chemical identity	Any appropriate method Pharmacopoeial or other internationally recognized methods	Not applicable Characteristic of the material Appropriate to identify MI
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 1 X 10^4 cfu/g or mL
	Total viable aerobic count	Pharmacopoeial or other internationally	< 1 X 10^5 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Pseudomonas aeruginosa	Pharmacopoeial or other internationally	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Solvent residues	Pharmacopoeial or other internationally	Conforms to Pharmacopoeial or ICH limits
	Specific contaminants (PCDDs, PCDFs and PCBs if oils are of marine animal origin)	As per CRN monograph****	As per CRN monograph****

	Other impurities**	Pharmacopoeial or other internationally	Conforms to pharmacopoeial limits
Quantity	Quantity tests	Internationally recognized methods (GC,	80%-120% of label claim
Performance tests (where	Disintegration (for tablets and capsules) (Dissolution may be substituted for	Pharmacopoeial or other internationally recognized	NMT 45 min (uncoated tablet) NMT 60 min (plain coated tablet)
	Antimicrobial	USP <51>, Ph. Eur.	Meets pharmacopoeial

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients
from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

c) *** Required for products containing preservatives, performed at the end of shelf-life (test on development batches). Not required on every batch.

7. Table 7: Finished product specifications template for a product containing synthetic duplicates+

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate test	Physical description	Any appropriate method	Not applicable
	Chemical identity	Pharmacopoeial other internationally recognized methods	Appropriate to identify MI
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 3 X 10^2 cfu/g or mL
	Total viable aerobic count	Pharmacopoeial or other internationally	< 3 X 10^3 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with < 50%	Pharmacopoeial or other internationally recognized	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Solvent residues	Pharmacopoeial or other internationally	Conforms to Pharmacopoeial or ICH limits
	Other impurities**	Pharmacopoeial or other	Conforms to pharmacopoeial

		recognized methods	
Quantity	Quantity tests	Internationally recognized methods (GC,	80%-120% of label claim
Performanc e tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60 min (plain coated
	Antimicrobial	USP <51>, Ph. Eur.	Meets pharmacopoeial

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

*** Required for products containing preservatives, performed at the end of shelf-life

c) (test on development batches). Not required on every batch.

8. Table 8: Finished product specifications template for a product containing minerals+

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on raw material if no appropriate test	Physical description	Any appropriate method	Not applicable
	Chemical identity	Pharmacopoeial other internationally recognized methods	Appropriate to identify MI
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 3 X 10^2 cfu/g or mL
	Total viable aerobic count	Pharmacopoeial or other internationally	< 3 X 10^3 cfu/g or mL
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Pseudomonas aeruginosa (for liquids with < 50%	Pharmacopoeial or other internationally recognized	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Solvent residues	Pharmacopoeial or other internationally	Conforms to Pharmacopoeial or ICH limits
	Related impurities**	Pharmacopoeial	Conforms to pharmacopoeial

Quantity	Quantity tests	Pharmacopoeial or other internationally recognized	Conforms to Pharmacopoeial limits or, in their absence, 80
Performanc e tests (where applicable)	Disintegration (for tablets and capsules) (Dissolution may be substituted for disintegration)	Pharmacopoeial or other internationally recognized methods	NMT 45 min (uncoated tablet) NMT 60 min (plain coated
	Antimicrobial	USP <51>, Ph. Eur.	Meets pharmacopoeial

a) +- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

b) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

*** Required for products containing preservatives, performed at the end of shelf-life

c) (test on development batches). Not required on every batch.

9. Table 9: Finished product specifications template for a product containing probiotics+

Test	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity (Genus, epithet, strain) *May be performed on raw material if no appropriate test is available for MI	Physical description	Any appropriate	Not applicable
	Phenotyping	Microscopy or Gram stain reactions, or biochemical tests or culturing and growth conditions and strain number	Characteristic for genus/epithet/strain . Database comparison (e.g. API strips). Specify strain-specific culturing and growth conditions
	Genotyping (optional)	PCR/sequence analysis and restriction fragment length polymorphism (PFLP)	Characteristic of the bacterial strain
Purity (microbial)	Contaminating fungus (yeast and mould)	Pharmacopoeial or other internationally	< 1 X 10^4 cfu/g or ml
	Enterobacteriaceae	Pharmacopoeial or other internationally	< 1 X 10^2 cfu/g or ml
	Escherichia coli	Pharmacopoeial or other internationally	Not detectable per g or ml
	Salmonella spp.	Pharmacopoeial or other internationally	Not detectable per g or ml
	Staphylococcus aureus	Pharmacopoeial or other internationally	Not detectable per g or ml
	Arsenic	Pharmacopoeial or other internationally	< 0.14 µg/kg b.w./day
	Cadmium	Pharmacopoeial or other internationally	< 0.09 µg/kg b.w./day
	Lead	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Total mercury	Pharmacopoeial or other internationally	< 0.29 µg/kg b.w./day
	Related impurities**	Pharmacopoeial	Conforms to pharmacopoeial
Quantity	Total viable count	Internationally recognized	80%-300% of label claim
Performanc e tests	Disintegration (for tablets and capsules)	Pharmacopoeial or other	NMT 45 min (uncoated tablet)

applicable)	(Dissolution may be substituted for disintegration)	recognized methods	NMT 60 min (coated tablet)

+- The tolerance limits specified are applicable to products containing single or multi ingredients from this category

** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

10. Table 10: Specifications template for finished products containing synthetic duplicates for topical use

Test Parameters	Test	Method(s)	Tolerances
Physical description of finished	Organoleptic	Visual, olfactory	Color, shape
Identity of medicinal ingredients *May be performed on	Physical: specific rotation, refractive index (for a liquid), solubility in common solvents (e.g., water, alcohols), specific gravity, residue on ignition Chemical: molecular weight, MS, infrared absorption (IR), NMR, HPLC, GC, AA and/or any other	Pharmacopoeial	Conforms to pharmacopoeial standard (if applicable) Appropriate to identify MI
Physical description of finished	Organoleptic (such as colour, form, etc)	Appropriate method(s)	n/a
Purity (microbial)	Total Viable Aerobic Count*	Pharmacopoeial	< 3 X 10^3 microorganisms per g
	Contaminating fungus*	Pharmacopoeial	< 3 X 10^2 microorganisms per g
	Escherichia coli*	Pharmacopoeial	Not detectable per g or mL
	Salmonella*	Pharmacopoeial	Not detectable per g or mL
	*Staphylococcus aureus**	Pharmacopoeial	Not detectable per g or mL
	*Pseudomonas aeruginosa**	Pharmacopoeial	Not detectable per g or mL
	Total Heavy Metals**	Pharmacopoeial (e.g. USP	≤10 ppm (as Pb)
	Solvent residues**	Pharmacopoeial or other internationally recognized methods	Conforms to Pharmacopoeial or ICH limits
	Related impurities**	Pharmacopoeial	Conforms to pharmacopoeial
Quantity/potency	Quantitative tests	HPLC, GC etc. or other internationally recognized methods	conforms to relevant pharmacopoeial standard or in its absence, default of 80-120% of label claim
Performance tests	Disintegration (for tablets and capsules) (Dissolution may be	Pharmacopoeial or other	NMT 45 min (uncoated tablet)

	disintegration)	internationall y recognized methods	NMT 60 min (plain coated tablet)
	Antimicrobial Effectiveness***	USP <51>, Ph. Eur. 5.1.3 or equivalent	Meets pharmacopoeial requirement

a) May be tested in accordance with USP General Chapter <1112>
n/a- not applicable

a) ** Not required if impurities are tested in raw materials and the impurity is not a degradation product.

b) *** Required for products containing preservatives, performed at the end of shelf-life (test on development batches). Not required on every batch

APPENDIX 1: LIST OF UNSUITABLE DOSAGE FORMS*:

A number of dosage forms are unsuitable for application of specification templates as they require quality assessment.

Categories of dosage forms that is unsuitable for above specifications are :

a. metered;
b. combined, extended or delayed release;
c. patch, systemic release; or
d. liposomal formation

Specific dosage forms that are unsuitable are:

a. aerosol, metered-dose;
b. capsule, combined release;
c. capsule, delayed release;
d. capsule, extended release;
e. cream, liposomal;
f. gel, extended release;
g. granule, delayed release;
h. patch, extended release;
i. powder, delayed release;
j. powder for suspension, extended release;
k. powder, metered dose;
l. spray, metered dose;
m. suppository, extended release;
n. suspension, liposomal;
o. syrup, extended-release;
p. tablet, combined release;
q. tablet, delayed release;
r. tablet, extended release; and
s. enteric coated dosage forms

*Please note that this list is not exhaustive