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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

होम्योपैथी में प्रयोग हेतु डिजिटलिस पर्पूरिया एल. हाइड्रो-अल्कोहोलिक अर्क — विशिष्टि

Draft Indian Standard

Digitalis purpurea L. Hydro-alcoholic Extract for Use in Homoeopathy — Specification

Homoeopathy Sectional Committee, AYD 07 **Last Date of Comments: 06-02-2025**

FOREWORD

(Formal clauses would be added later)

Digitalis purpurea hydro-alcoholic extract or mother tincture (Ø) is prepared from the leaves of *Digitalis purpurea* L. In homoeopathy, this is used as a starting material for homoeopathic dilutions or potencies. It is also used for the preparation of other dosage forms.

Digitalis purpurea L. is a biennial, sometime perennial herb, deciduous with branched tap root. It is native to Western Europe, Mediterranean region and northwest Africa; naturalized in Asia, South America, New Zealand, Canada, and much of the United States. *Digitalis purpurea* commonly known as Digitalis and having synonyms foxglove or purple foxglove *(*English); *Gant de Notre Dame* (French); *Fingerhu* (German). Some of the regional names are *Tilpuspi, Digitalis* (Hindi), *Hritpatri, Tilapushpi,* (Sanskrit).

The detailed specifications for the whole plant of Digitalis are prescribed in AYD/07/26948.

The standard is one of the series of standards being brought out on specifications of hydro-alcoholic extract for the use of researchers, academicians, students, clinical practitioners, and drug manufacturers.

In the formulation of this standard, significant assistance has been derived from Homoeopathic Pharmacopoeia of India, Vol. I, 1971; Vol. VI, 1990 published by the Ministry of Ayush, Government of India. Inputs have also been derived from the information available in the public domain in print and electronic media, including authoritative books. Also, due consideration has been given to the provisions of the *Drugs and Cosmetics Act*, 1940 and the Rules 1945 framed thereunder, including the latest amendments. In case of any disparity, this standard is subject to the restrictions imposed under these Rules and Regulations, wherever applicable.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft Indian Standard

DIGITALIS PURPUREA L. HYDRO-ALCOHOLIC EXTRACT FOR USE IN HOMOEOPATHY — SPECIFICATION

1 SCOPE

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of Digitalis purpurea prepared from the leaves of *Digitalis purpurea* L. (Family Scrophulariaceae).

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute the provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

IS No.	***Title***
IS 1070 : 2023	Reagent grade water — Specification (*fourth revision*)
IS 6911 : 2017	Stainless steel plate, sheet, and strip ― specifications (*second revision*)
AYD/07/26948	Digitalis Purpurea L. Leaves for Use in Traditional Medicine - Specification
IS 18977 : 2024	Millefolium (*Achillea millefolium* L.) Hydro-Alcoholic Extract for Use in Homoeopathy — Specification
IS 19085 : 2024	Glass Containers for Homoeopathic Pharmaceutical Preparations — Specification

3 REQUIREMENTS

3.1 Digitalis Purpurea leaves

3.1.1 *Description*

Fresh two-year-old leaves of *Digitalis purpurea* L shall be used. The *Macroscopic, microscopic, and powder* specifications of these leaves shall comply with the provisions as prescribed in AYD/07/26948.

3.1.2 *General Specifications*

Digitalis Purpurea leaves shall be free from extraneous/foreign matter and shall comply with the physical, chemical, and microbiological specifications as prescribed in AYD/07/26948.

3.2 Preparation of *Digitalis Purpurea* hydro-alcoholic extract

3.2.1 To prepare one thousand milliliters with strength 1/10:

a)	*Digitalis Purpurea* in moderately coarse powder	—	100 g
b)	Purified Water	—	567 ml
c)	Strong Alcohol (94.7 to 95.2 percent *v/v*)	—	468 ml

3.2.2 *General Specifications of hydro-alcoholic extract (Finished Product)*

a)	*Appearance*	—	Brownish
b)	*Alcohol content*	—	41 to 45 percent v/v
c)	*Wt. per ml*	—	0.930 g to 0.950 g
d)	*Total solids*	—	Not less than 3.0 percent w/v
e)	*TLC*	—	Should comply as prescribed in Table 1 (Sl. No. 7(ii)) of AYD/07/26948
f)	*UV absorbance λ max*	—	270 nm

3.2.3 *Identification Tests*

a) Test-A

Solution S: To 10 ml of the hydro-alcoholic extract, add 20 mL of water and 10 mL of lead acetate solution (10 % w/v solution of lead acetate in carbon dioxide free water). Shake, leave to stand for 5 min and filter. Shake the filtrate with 2x 15 mL portions of ethyl acetate and evaporate the combined organic phases to dryness under reduced pressure at a temperature not exceeding 50˚. Dissolve the residue in 1 mL of a mixture of equal volumes of ethyl acetate and methanol (stock solution), with which the following tests are to be performed.

i. Carefully evaporate 0.2 mL of stock solution to dryness on water bath. Dissolve the residue in 0.2 mL of *dinitrobenzoic acid* solution (2% w/v solution of *dinitrobenzoic acid* in ethanol 95%) and add 0.2 mL of dilute sodium hydroxide solution. A reddish violet colour is produced.

ii. Carefully evaporate 0.1 mL of stock solution to dryness on water bath and add 0.3 mL of mixture of 2 mL of *acetic anhydride* and add 0.3 mL of *sulphuric acid*. A yellow colour and then a muddy green colour is produced.

b) Test-B

Carry out Co-TLC with *digitonin* using *n-butanol: acetic acid: water (4:1:1 v/v)* as mobile phase and *antimony trichloride* as spray reagent. Spot corresponding to Digitonin appears.

NOTE — Quality of reagent
1. Reagents, including pure chemicals used, shall be of analytical grade.
2. Reagent-grade water for laboratory use shall be as per IS 1070.
3. Pure chemicals shall mean chemicals that do not contain impurities that affect the analysis results.

4 PACKING, STORAGE AND MARKING

4.1 Packing

Digitalis Purpurea hydro-alcoholic extract shall be packed in an amber coloured bottle of Type 3 glass or better (IS 19085) that prevents contamination, effects of light and humidity, with a seal that guarantees the inviolability of the product. The packing material shall be free from any fungal or insect infestation and not impart any foreign smell. Each container shall be securely closed and sealed.

4.2 Storage

Digitalis Purpurea hydro-alcoholic extract shall be stored in an amber-coloured bottle of Type 3 glass or better (IS 19085) or in a stainless steel container of SS316 type (IS 6911) that prevents contamination and effects of light and humidity, with a seal or security seal that guarantees the inviolability of the product.

4.3 Marking

The following particulars shall be legibly and indelibly marked or labeled on each pack of *Digitalis Purpurea* hydro-alcoholic extract:

a) Name of the hydro-alcoholic extract/mother tincture;
b) Name and address of the manufacturer or packer, including contact details;
c) Manufacturer’s license no.;
d) Batch number;
e) Net quantity when packed;
f) Date of Manufacturing;
g) Date of packing (MM/YYYY);
h) Date of expiry (MM/YYYY);
j) QR Code for Authentication (optional); and
k) Any other information requested by the buyer.

5 SAMPLING

5.1 Representative material samples shall be drawn as prescribed in Annex B of IS 18977.

5.2 The samples of *Digitalis purpurea* hydro-alcoholic extract shall be tested to ascertain the material's conformity to the requirements as per the specifications for the finished product in **3.2.2** and **3.2.3**.

6 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016*, and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.