Bangladesh Standard

Specification for Skin Creams
(Third Revision)

ICS 71.100.70

BANGLADESH STANDARDS AND TESTING INSTITUTION
MINISTRY OF INDUSTRIES
MAAN BHABAN, 116-A, TEJGAON INDUSTRIAL AREA
DHAKA-1208, BANGLADESH

Constitution of the Cosmetics and Related Products Sectional Committee, CSC-10

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Bangladesh Standard

Specification for Skin Creams (Third Revision)

Foreword

This Bangladesh Standard was adopted by the Bangladesh Standards and Testing Institution on 16-06-2019 after the draft finalized by the Cosmetics and Related Products Sectional Committee and approved by the Chemical Divisional Committee.

This standard was first published in 1992 (Reaffirmed 2006) and subsequently revised in 2011 and 2015. Due to its growing demand the sectional committee decided to revise this standard. In revising this standard the committee gave due attention to views of the consumers, manufacturers, trade bodies and other stakeholders. Also the standard committee has been decided to revise this standard as per BDS 1924:2017 -Guideline for Cosmetic Products in Bangladesh are as follows:

General purpose cream: such as vanishing cream, cold cream, cleansing creams, moisturizing cream, foundation creams, hand creams, emollient creams and general purpose creams are included in this standard.

Specialized cream: such as antiperspirant creams, acne creams, whitening cream, sun screen/block cream, anti-suntan cream, spot cream and special purposes cream are included in this standard.

Therapeutic Cream: such as hormone creams, steroid creams, hydroquinone cream, antiseptic/antibacterial cream etc. which have an effect on the physiological functions of the body or for which therapeutic/medicated claims are generally made, are not included in this standard.

It is also necessary that the raw materials used are such that at concentrations in which they would be present in skin creams and after interaction with the other raw materials, these are free from harmful effects. It shall be the responsibility of the manufacture to ensure the physiological and dermatological safety of this product.

This third revision cancels and replaces the second revision (BDS 1382:2015). The main changes compared to the previous revision are as follows:

a) pH value changed from 4.0-9.0 to 4.5-9.0.

b) Determination of Hydroquinone test method-1, Annex-H has been deleted and Annex-H Method-2 changed to Annex-G.

c) Marking clause has been modified.

d) A new clause herbal ingredient has been included.

In the formulation of this standard considerable assistance has been derived from the following publication:

IS 6608: 2004 Skin Creams - Specification (Second Revision); Bureau of Indian Standards. SLS 743 Specification for Skin Creams and lotion; and Published Cosmetics Journal has been used.

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 BDS 103.

Bangladesh Standard

Specification for Skin Creams (Third Revision)

1.0 Scope

This standard prescribes the requirements and the methods of sampling and test for skin creams.

It does not cover creams for which therapeutic claims are made.

2.0 Normative references

The following standards are necessary adjuncts to this standard. For undated reference latest edition may be used. All references shall be mandatory for safety of the finished cosmetics products.

BDS 37	Hydrochloric acid
BDS 833	Water for laboratory use
BDS 1277	Methods of sampling of cosmetics
BDS 1333	Determination of Arsenic
BDS 1340 (Part-1)	Classification of cosmetic raw materials and adjuncts:
	Part 1: Dyes, colour and pigments
BDS1340 (Part-2)	Classification of cosmetic raw materials and adjuncts:
	Part 2: Ingredients other than dyes, colour and pigments
BDS 1824	Methods of test for safety evaluation of cosmetics
BDS 1869	Methods of test for microbiological examination of cosmetics
BDS 1420	Hair cream.
BDS 1765	Methods of random sampling.
ISO 24153	Random sampling and randomization procedure.
ISO/TR17276	Cosmetics-Analytical approach for screening and quantification methods for heavy metals in cosmetics.

3.0 Requirements

3.1 Description

The skin cream shall be in the form of a thick emulsion or unctuous mass with a pleasant odour. It shall be white or pigmented or of uniform colour.

3.2 Ingredients

Unless specified otherwise, all the raw materials used in the manufacture of skin creams shall conform to the requirements prescribed in the relevant Bangladesh Standards where such standards exist. In those cases where Bangladesh Standards are not available, the raw materials shall conform to the requirements of B.P/U.S.P, other ingredients not found in B.P/U.S.P or any individual Bangladesh Standards but used, if any, shall conform to the provisions of BDS 1340 part 2.

3.2.1 The dyes, colours (pigments, lakes etc.) if used in the manufacture of skin creams shall comply with BDS 1340 (Part 1).

3.2.2 Other ingredients shall comply with the provision of BDS 1340 (Part 2).

3.2.3 Fragrance - The fragrance of the skin creams shall be mild, distinct and pleasant.

3.2.4 Herbal ingredients - Herbal ingredients having no harmful effects may be incorporated in cream formulation. Manufacturer shall guarantee safety of herbal ingredients.

4.0 Specific requirements

4.1 Safety-When used in the normal manner, the skin cream shall not bring about any other harmful effect to the body in general. For the determination of the dermatological safety, reference shall be made to BDS1824.

4.1.1 The product shall not be manufactured from any carcinogenic ingredients.

4.2 Heavy metals- calculated as lead (Pb), arsenic (as As_2O_3) and mercury (as Hg) shall not exceed 20 ppm, 2 ppm and 1 ppm respectively when tested by the respective method prescribed in the relevant Bangladesh Standards and authorized/validated test method .

4.3 The material shall also comply with the requirements given in Table 1 when tested as prescribed in column 4 of the Table 1.

Table 1 Requirements for Skin Creams

(*Clause 4.3*)

Sl. No. (1)	Characteristics (2)	Requirements (3)	Method of test, Ref. to (4)
i)	Thermal stability	To pass the test	A
ii)	pH	4.5 - 9.0	B
iii)	Total Fatty Substance Content, percent, by mass, Min	5	C
iv)	Total residue, percent by mass, Min	10.0	D
v)	Heavy metals (as Pb), parts per million, Max	20	E
vi)	Arsenic (as As_2O_3), parts per million, Max	2	BDS 1333
vii)	Mercury (as Hg), parts per million, Below	1	F
viii)	Hydroquinone, parts per million, Below	5.0	G
ix)	Microbial content / limit (a) Total viable count cfu/g (b) Gram negative pathogens	 Not more than 1000 Less than 10	BDS 1869
For creams based on beeswax and borax, the pH shall be between 5.0 -10.0			

5.0 Packing and marking

5.2 Packing

The material shall be packed in suitable well-closed containers.

5.3 Marking

The containers shall be legibly marked with the following information:

a) Name of the material;

b) Name and address of the manufacturer/distributor (including the country of origin);

c) Brand name or registered trade mark, if any;

d) Net mass, in grams, of the material;

e) List of the ingredients (Specifically dyes, colours and preservatives);

f) Batch number/lot number;

g) Date of manufacture;

h) Use best before/date of expiry;

i) Maximum retail price; and

j) pH value.

5.2.1 The containers may also be marked with the BSTI Certification Mark

NOTE: The use of the BSTI Certification Mark is governed by the provisions of the Bangladesh Standards and Testing Institution Act, 2018 and the Rules and Regulations made there under, Details of conditions be under which a license for the use of the BSTI Certification Mark may granted to manufacturers or processors, may be obtained from the Bangladesh Standards and Testing Institution.

6.0 Sampling

6.1 Representative samples of the material shall be drawn as prescribed in BDS 1277.

6.2 Tests for all the characteristics shall be carried out on the composite sample as per methods referred under col. 4 of table 1.

6.3 The material shall be taken to have conformed to the standard if the composite sample passes all the tests.

7.0 Quality of reagents

Unless specified otherwise, pure chemicals and distilled water (BDS 833) shall be employed in tests.

NOTE - 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

Annex A

[Table 1 Sl. No.(i)]

Test for thermal stability

A - 1.0 Apparatus

A - 1.1 A humidity chamber / incubator controlled at 60 to 70 percent relative humidity and 45 ± 1°C.

A - 1.2 Clear glass bottles of around 30 mL capacity with plug and screw on cap for proper closure.

A - 2.0 Procedure

With the help of spatula, insert the cream into glass bottle and tap it to settle to the bottom. Fill up to two-third capacity of bottle and insert plug and tighten the cap. Keep the filled bottle erect in side the incubator at 45 ± 1°C for 48 hours.

The sample shall be taken to have passed the test, if on removal from the incubator shows no oil separation or any other phase separation.

Annex B

[*Table1 Sl. No.(ii)*]

Determination of pH

B - 1.0 Apparatus

A pH meter, preferably equipped with a glass electrode

B - 2.0 Procedure

B - 2.1 For oil-in-water emulsion creams

Weigh accurately 5 ± 0.01 g of the cream in a 100 mL beaker. Add 45 mL of water and disperse the cream in it. Determine the pH of the suspension at 27°C using the pH meter.

B - 2.2 For water in oil emulsion creams

Weigh 10 g of the cream to the nearest 0.1 g. Add 90 mL of rectified spirit previously adjusted to pH 6.5 to 7.0. Warm, if necessary to 45°C and stir thoroughly for 15 minutes. Filter the alcoholic layer through a filter paper and measure the pH of the filtrate at 27°C using the pH meter.

Annex C

[Table 1 Sl. No. (iii)]

Determination of total fatty substance content

C - 0.0 Principle of the method

The emulsion is broken with dilute mineral acid and the fatty matter is extracted with petroleum ether. It is weighed after removal of the solvent.

C - 1.0 Reagents

C - 1.1 Dilute hydrochloric acid -1:1 (v/v).

C - 1.2 Petroleum ether (60- 80°C).

C - 1.3 Methyl Orange Indicator Solution - Dissolve 0.1 g of methyl orange in 100 mL of water.

C - 1.4 Sodium sulphate - desiccated.

C - 2.0 Procedure

Weigh accurately 2 g of the material into a conical flask, add 25 mL of dilute hydrochloric acid, fit a reflux condenser into the flask and boil the contents until the solution is perfectly clear. Pour the contents of the flask into a 300 mL separating funnel and allow it to cool to room temperature. Rinse the conical flask with 50 mL of petroleum ether in portions of 10 mL. Pour the petroleum ether rinsing into the separating funnel, shake the separating funnel well and leave until the layers separate. Separate out the aqueous phase and shake it out with 50 mL portions of petroleum ether twice.

Combine all the ether extracts and wash them with water until free of acid (when tested with methyl orange indicator solution). Filter the petroleum ether extracts through a filter paper containing sodium sulphate into a conical flask which has been previously dried at a temperature of 90 ± 2°C and then weighed. Wash the sodium sulphate on the filter with petroleum ether and combine the washings with filtrate. Distil off the petroleum ether and dry the material remaining in the flask at a temperature 90 ± 2°C of to constant mass.

C - 3.0 Calculation

Total fatty substance, per cent by mass = $100 \frac{M_1}{M_2}$

where,

M_1 = Mass in g of the residue, and

M_2 = Mass in g of the material taken for the test.

Annex D

[Table 1 Sl. No. (iv)]

Determination of residue

D - 1.0 Procedure

D - 1.1 Weigh accurately about 5 g of the material in a weighed, clean and dry squat form weighing bottle and dry to a constant mass at 105 ± 1°C. Cool in a desiccator and weigh.

D - 1.2 Calculation

Residue, per cent by mass = $100 \frac{M_1}{M_2}$

where,

M_1 = Mass in g of the residue, and

M_2 = Mass in g of the material taken for test.

Annex E

[Table 1 Sl. No.(v)]

Test for heavy metals

E - 1.0 Outline of the method

The colour produced with hydrogen sulphide solution is matched against that obtained with standard lead solution.

E - 2.0 Apparatus

E - 2.1 Nessler cylinders - 50 mL capacity**.**

E - 3 Reagents

E - 3.1 Dilute hydrochloric acid - approximately 5M
E - 3.2 Dilute acetic acid - approximately 1M
E - 3.3 Dilute ammonium hydroxide - approximately 5M
E - 3.4 Hydrogen sulphide solution - standard

E - 3.5 Standard lead solution - Dissolve 1.600 g of lead nitrate in water and make up the solution to 1000 mL. Pipette out 10 mL of the solution and dilute again to 1000 mL with water. One millilitre of this solution contain 0.01mg of lead (as Pb).

E - 4.0 Procedure

Weigh accurately about 2.000 g of the material in a crucible and heat on a hot plate and then in a muffle furnace to ignite it at 600^{o}C to constant mass. Add 3 mL of dilute hydrochloric acid, warm (wait till no more dissolution occurs) and make up the volume to 100mL. Filter the solution. Transfer 25 mL of the filtrate into a Nessler's cylinder. In the second Nessler's cylinder, add 2 mL of dilute acetic acid, 1.0 mL of standard lead solution and make up the volume with water to 25 mL.

Add 10 mL of hydrogen sulphide solution to each Nessler's cylinder and make up the volume with water to 50 mL. Mix and allow to stand for 10 minutes. Compare the colour produced in the two Nessler's cylinders. Blank determination without samples are recommended to avoid errors arising out of the reagents.

E - 5.0 Results

The sample may be taken to have passed the test, if the colour developed in the sample solution is less than that of standard solution.

Annex F

[Table 1 Sl. No. (vii)]

Determination of Mercury

by Atomic Absorption Spectrephotometric method

(Mercury vaporizer unit)

F - 1.0 Principle - Digested mercury react with reducing agent to form elemental mercury.

F - 1.1 Nitric acid - See BDS 34
F - 1.2 Distilled water - See BDS 833
F - 1.3 Potassium permanganate solution
F - 1.4 Sulphuric acid - see BDS 38
F - 1.5 Hydrocloric acid - see BDS 37
F - 1.6 Reductant - 10% $SnCl_2$ stabilized in 22 HCl mL

F - 2.0 Quality of Reagents

F - 2.1 Unless specified otherwise, pure chemicals and distilled waters (See BDS 833) shall be used in tests.

NOTE - `Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

F - 2.3 Apparatus/Equipments

F - 3.1 Volumetric flasks - 50 mL, 100 mL.
F - 3.2 Beaker - 400 mL
F - 3.3 Centrifuge machine

F - 3.4 Method of sample preparation - Weigh approximately about 2.0 g of the sample into a 400 mL beaker and then add 5-10 mL of distilled water. Digest with 2.5 mL nitric acid by heating on a water bath at 70-80^{o}C about 1 hour and evaporate to dryness. Cool the sample to room temperature and mix a small amount of distilled water and centrifuge at 400-500 rpm for 10-15 minutes and filter the solution through a filter paper (No. 41).

Transfer the filtrate into a volumetric flask and make up the volume up to the mark (50 mL or 100 mL) with distilled water.

F - 4.0 Blank preparation - 2.5 mL concentrated nitric acid and volume up to mark (50 mL or 100 mL) with distilled water.

F - 4.1 Instrumental parameters / Conditions

Method name - Cold Vapor Atomic Absorption Spectroscopy (CVAAS).

F - 4.2 Spectrometer parameters

F - 4.3 Wavelength - 253.7 nm
F - 4.4 Background correction - D2

Calculation :

$$\text{Mercury content (ppm)} = \frac{\text{Absorbance} \times \text{Total volume}}{\text{Weight of sample} \times 1000}$$

Annex G

[Table 1 Sl. No. (viii)]

Determination of Hydroquinone by HPLC method

G - 1.0 Application - Applicable to skin creams.

G - 2.0 Reagents and materials

G - 2.1 Methanol LiChrosoiv (R) Grade: Traceable (Merck product number 1060072500 or equivalent)
[Caution: Highly flammable, toxic by inhalation and if swallowed]

G - 2.2 Water LiChrosolv (R) Grade: Traceable (Merck product number 1153332500 or equivalent)

G - 2.3 Hydroquinone >99.0%: CAS number 123-31-9, Sigma - Aldrich Reagent Plus (R) Cat no: H9003

G - 2.4 Diluent : 50:50 water/methanol (v/v)

Mix 500 mL of methanol (2.1) with 500 mL of water in a glass bottle with screw lid (2.2).

G - 3.0 Apparatus and equipment

G - 3.1 HPLC with UV-Vis detector - Agilent 1260 or equivalent

G - 3.2 C18 Reverse phase column - Zorbax ODS, 250 mm × 4.6 mm, 5 µm or equivalent

G - 3.3 0.45 µm Nylon syringe filter - Merck millipore millex (r) - HN, cat number-SLHN033NB

G - 3.4 Standard laboratory glassware

G - 3.5 Water bath maintained at 60°C

G - 3.6 A four decimal place analytical balance

G - 4.0 Sampling technique

G - 4.1 If the sample is packed in a tube, discard initial few centimeters of product and weigh directly into the flask.

G - 4.2 Use disposable syringe to weigh the sample, if the sample is not packed in a tube.

G - 5.0 Procedure

G - 5.1 Preparation of calibration standard

G - A. Preparation of 1000 ppm hydroquinone standard

G - 5.1.1 Weigh accurately 100 ± 0.1mg of hydroquinone in a 100 mL volumetric flask and record the weight.

G - 5.1.2 Add 50 mL of diluent (2.4), dissolve and make up the volume with diluent (2.4).

G - B. Preparation of 100 ppm and 10 ppm hydroquinone standards

G - 5.1.3 Pipette out 10 mL of above solution (5.1.2) to a 100 mL volumetric flask and dilute up to the mark with diluent (2.4). Resulting solution will be equivalent to10 ppm of hydroquinone.

G - 5.1.4 Pipette out 10 mL of above solution (5.1.3) to a 100 mL volumetric flask and dilute up to the mark with diluent (2.4). Resulting solution will be equivalent to 10 ppm of hydroquinone.

G - C. Preparation of calibration solutions

G - 5.1.5 Pipette out 0.5 mL, 1 mL, 5 mL, 10 mL and 15 mL of the above solution (5.1.4) to 5 different 100 mL volumetric flasks and dilute up to the mark with diluent (2.4).This will yield 0.05, 0.1, 0.5,1.0 and 1.5 ppm of hydroquinone calibration standards respectively.

G - 5.2 Sample preparation

G - 5.2.1 Weigh accurately 1.0 ± 0.1 g (nearest to 0.001g) of skin cream sample directly into a 50 mL volumetric flask (refer section number - 4.1 and 4.2).

G - 5.2.2 Add 25 mL diluent (2.4), close the flask and shake vigorously until a homogenous suspension is obtained.

G - 5.2.3 Immerse the flask (5.2.2) in a water bath (3.5) maintained at 60±2°C for 5 minutes to enhance the extraction.

G - 5.2.4 Cool the solution to room temperature and make up to the volume (V_1) with diluent (2.4) and shake well.

G - 5.2.5 Filter the above solution through a 0.45 µm Nylon syringe filter (3.3).

G - 5.2.6 Discard initial few mL and collect the filtrate in a 2 mL vial.

G - 5.2.7 Perform the HPLC determination within 24 hours of preparing the extract.

G - 5.3 HPLC analysis

Analyse the blank, calibration standards and sample solutions using the below mentioned HPLC conditions.

G - 5.3.1 HPLC conditions

Mobile phase	:	Water: Methanol 95.5 (v/v) (Mix 950 mL of water (2.2) with 50 mL of Methanol (2.1).
Flow rate	:	1.5 mL/min
Wavelength	:	295 nm
Column temperature	:	36°C
HPLC Column	:	Zorbax ODS, 250 mm × 4.6 mm, 5 µm or Equivalent
Injection volume	:	10 µL
Run time	:	35 minutes

G - 5.3.2 Inject blank (2.4), calibration solutions (5.1.5) and note down the peak areas.

G - 5.3.3 Draw the calibration curve and calculate the slope.

G - 6.0 Calculation and expression of results:

G - 6.1 Calculate the Hydroquinone content from calibration curve

$$Y = mX + C$$

where,

m = Slope of calibration curve

C = Intercept

Y = Sample area

X = Concentration of Hydroquinone (ppm)

$$\text{Hydroquinone (ppm)} = \frac{\text{(Sample Area)} \times \text{Volume prepared } (V_1) \text{ in mL}}{\text{Slope of calibration} \times \text{Weight of Sample (g)}}$$

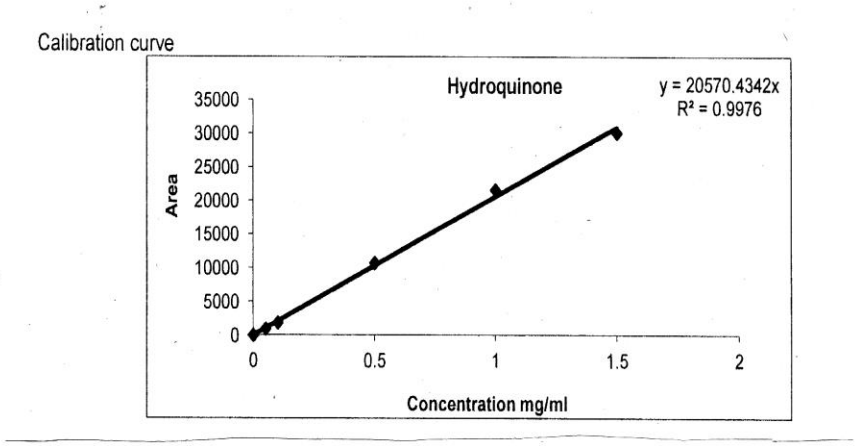


Fig.1: Determination of hydroquinone

Annex H

Hydroquinone conformity test by HPLC method

(Qualitative)

H - 1.0 Perform hydroquinone analysis as per the method in section 5.1 to 5.3 using Florescence detector and PDA detector to confirm the presence of the hydroquinone in the sample.

The confirmatory tests mentioned below can be performed when there is any false positive peak or interference detected at the hydroquinone retention time while performing HPLC-UV Analysis.

H - 2.0 Fluorescence analysis:

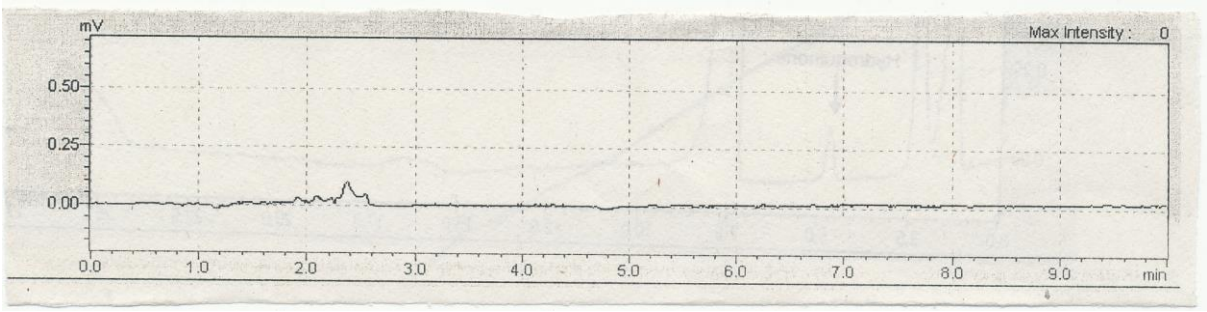
Perform the hydroquinone analysis as per section 5.1 to 5.3. Use Fluorescence detector with the below mentioned detector conditions. Excitation wavelength of 304 nm and emission wavelength of 338 nm.

H - 3.0 PDA analysis:

Perform the hydroquinone analysis as per the mentioned in section 5.1 to 5.3. Use PDA detector to analyze the sample and standards in the range 200-400nm.

H - 4.0 The above two test in addition to the HPLC-UV analysis can be conducted to confirm hydroquinone is present or absent, in case there is any interference or false positive peak detected at the retention of hydroquinone.

H - 5.0 Chromatogram of blank (Diluent 2.4)



H - 5.1 Standard hydroquinone chromatogram (0.1 ppm) equivalent to 5 ppm in finished product

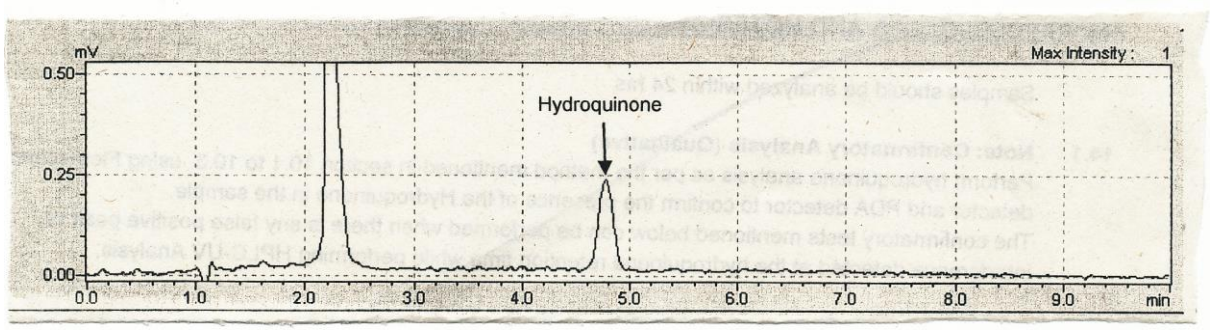


Fig.2 : Conformation of hydroquinone

NOTE - Samples should be analyzed within 24 hours.

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