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Plastics infant feeding bottles

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Foreword

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This African Standard was prepared by ARSO/TC 14, Food packaging and labelling.

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Plastics infant feedingbottles

1 Scope

This standard prescribes the requirements and methods of sampling and test for infant plastic feeding bottles and receptacles.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 472, *Plastics — Vocabulary*

ISO 21067-1, *Packaging — Vocabulary — Part 1: General terms*

ISO 16770, *Plastics — Determination of environmental stress cracking (ESC) of polyethylene — Full-notch creep test (FNCT)*

ASTM D6247-18, *Standard Test Method for Determination of Elemental Content of Polyolefins by Wavelength Dispersive X-ray Fluorescence Spectrometry*

ISO 13106, *Plastics — Blow-moulded polypropylene containers for packaging of liquid foodstuffs*

ISO 13468-2, *Plastics — Determination of the total luminous transmittance of transparent materials — Part 2: Double-beam instrument*

3 Terms and definitions

For the purpose of this standard the terms and definitions given in ISO 472,ISO 21067-1and the following definitions apply.

3.1
accessories
supplementary items added to feeding bottle t including the hood, disc/stopper, teat and cap ring to make it efficient

3.2
drinking accessory
device other than a feeding teat which permits a child to obtain fluid from a container, for example feeding spout and straw

3.3
feeding bottle
container which is capable of holding a fluid and incorporates a graduated scale suitable for visual measurement and is intended for feeding a child through a feeding teat or drinking accessory.

3.4
locking ring
component used to secure a feeding teat or drinking accessory to the container.

3.5
sealing disc
component used to create a seal between the container and the locking ring.

3.6
protective cover
component as safety shield to cover a feeding teat or drinking accessory.

3.7
matched components
components defined above which are used together whilst feeding a child.

3.8
nominal capacity
volume of fluid expected to be filled in the bottles at 27 ± 2°C.

3.9
brimful capacity
volume of fuid held by the container when filled to the point of overflowing while standing on a flat horizontal level with all closures removed, at 27 ± 2°C.

3.10
re-usable
component intended to be used again after first use.

3.11
numbered graduations
numbered markings which indicate the volume of fluid within the feeding bottle.

3.12
Single-use drinking accessory or container
item of drinking equipment sold for single-use.

3.13
protrusions
drinking accessory, feeding teat or spoon, excluding straws or anything extruding from physical contour of the feeding device.

3.14
receptacles
container used for holding or storing drinking equipment.

3.15
fluid
liquid that can be fed to infants with a feeding bottle, for example, water, milk or liquidised food.

4 Materials

4.1 The material used for plastics feeding bottles and accessories excluding teats shall be of any food-contact approved polymer or other raw material as given in Annex A for manufacture of plastic feeding bottle. The materials used should be of no health hazards to babies and shall not contain Bisphenol A (BPA) or Polyvinyl chloride (PVC) or Polyethylene terephthalate (PET).

4.2 Teats shall conform toARS(This standard needs to be developed. REFERENCE: IS 3565: 2018 Teats for Feeding Bottles — Specification)

5 Requirements

5.1 General requirements

5.1.1 *Design*

5.1.1.1 The feeding bottle shall be of suitable design, shape and required dimensions as agreed to between the purchaser and the supplier.

5.1.1.2 The shape shall be such that it is easily cleanable and does not permit the fluid remnants to remain stuck inside the feeding bottles**.**

5.1.1.3 Figures C1 and C2illustrate typical examples of different items of drinking equipment and their design features.

NOTE Figures 1 and 2 are illustrative and for information only.

5.1.2 *Manufacture, Workmanship, Finish and Appearance*

5.1.2.1 The bottles and accessories shall be manufactured by a suitable process adhering to Good Manufacturing Practice (GMP).

5.1.2.2 The body of the bottle shall be smooth, both internally and externally, free from any visual defects like cavities, crevices, hooks, embedded foreign matters, detrimental bubbles, streaks, flaws and stains.
5.1.2.3 Neck shall be smooth from inside.

5.1.2.4 All components of plastic feeding bottle when assembled for use shall be free from sharp points and edges and any harmful extrusions**,** which are likely to cause injury.

5.1.2.5 Any parts that can be detached (e.g. cleaning) shall not be able to fit inside the bottle without compression**.**

5.1.3 **Dimensions**

Plastic infants feeding bottles shall comply with the dimensional requirements given in ISO 13106 when measured in accordance with the methods specified therein.

5.1.4 *Capacity*

5.1.4.1 The bottles shall be manufactured in nominal capacity of 125 ml, 150 ml and 250 ml or any othercapacity as agreed to between the purchaser and the supplier.

5.1.4.2 The brimful capacity shall exceed the nominal capacity by a minimum of 15 percent when tested in accordance with ISO 13106, Annex B.

5.1.4.3 *Capacity scale*
All feeding bottles shall be marked with graduations at least in millilitres. The feeding bottles shall be provided with the following capacity scale:

a) If the feeding bottle is unprinted, then capacity scale shall be engraved on the bottle and if the bottle is printed then the capacity scale shall be clearly printed.
b) The scale interval and the maximum indicating scale mark shall be as agreed to between the purchaser and the supplier. However, the minimum scale mark and interval marking shall be
c) not more than 20 percent of the maximum scale indicating mark.
d) The scale marks and the indicating numerical values shall be clear and shall not be affected byhigh temperature sterilizing treatment

5.2 Chemical Requirements

5.2.1 *Specificmigration of Certain Elements*

When tested in accordance with the ASTM D6247-18 or any equivalent spectrophotometric test method, heavy metals in plastic components of infant feeding bottlesshall not exceed the limits given in Table 1.

Table 1 Permissible Levels of Heavy Metals in Plastic infant feeding bottle

SNo.	Heavy Metals	Maximum .imit mg/kg*Max*
i)	Antimony	15
ii)	Arsenic	10
iii)	Chromium	10
iv)	Mercury	10
v)	Cadmium	20
vi)	Lead	25
vii)	Barium	100
viii)	Selenium	100

5.2.2 *Overall migration*

When tested in accordance with Annex D the maximum extraction values for the container material shall not exceed 10 mg/dm^2 or 60 mg/l.

5.2.3 Pigments and colourants

Examples of permitted pigments and colourants to be used on hermetic bags are as listed in Annex E.
The limits and tolerances of the pigments andcolourants used in the printing shallcomply with the requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Limits for heavy metals and aromatic amines in plastic infant feeding bottles

S/N	Heavy metals and aromatic amines	Limits, %by mass, max.	Test method
i.	Lead, %by mass, max.	0.01	ASTM D6247-18 or any equivalent spectrophotometric analysis
ii.	Arsenic, %by mass, max.	0.005	
iii.	Mercury, (soluble in N/10 HCl), %by mass, max.	0.005	
iv.	Cadmium, %by mass, max.	0.010	
v.	Zinc, %by mass, max.	0.05	
vi.	Selenium, %by mass, max.	0.01	
vii.	Barium, %by mass, max.	0.01	
viii.	Chromium, %by mass, max.	0.025	
ix.	Antimony,%by mass, max.	0.025	
x.	Polychlorinated bsphenyl reported as decachloro biphenyl, mg/kg, max.	25	Annex I
xi.	Total primary aromatic amines (calculated as aniline equivalent),%by mass, max.	0.05	Annex J

xii.	Sulphonated aromatic amines (calculated as aniline sulphonic acid), %by mass, max.	0.05	
xiii.	Carcinogenic amines listed in Annex H, mg/kg, max.		Annex J

5.3 Performance Requirements

In addition to the performance requirements specified in ISO 13106, the plastic infant feeding bottles shall comply with the requirements specified in 5.3.

5.3.1 *Environmental stress-crack resistance*

The bottles shall be tested in accordance withISO 16770and shall show no evidence of stress cracking or leakage after being kept in oven for 48 h.

5.3.2 *Transparency*

The transparency of a plastics feeding bottle shall not be less than 70 percent in any light source transmittance when tested in accordance with the method described in ISO 13468-2.

5.3.3 *Ageingresistance*

Immerse the bottles into the boiling water for 20 min, then immediately into water at 4°C for 20 min alternately and repeat it 3 times. At the end of the test, the change in the capacity of bottles shall not be more than 1 percent and also there shall be no defective changes in the bottle. There shall be no significant changes in appearance when the accessories are tested in accordance with the method indicated above.

5.3.4 *Compressive deformation resistance*

The bottles shall not get deformed by more than 10 percent in diameter in compressive direction at the compressive load of 19.6 N when tested in accordance with the method described in Annex G.

5.3.5 *Ink adhesion test for printed containers*

The printed bottles when tested in accordance with the method described in Annex F (see if Annex K in ISO 13106 can apply)shall not show any significant removal of the print from the bottle surface and the print shall be legible to the naked eye after the test.

6 Sampling

6.1 ***Sampling and criterion for conformity***

The samples of the bottles shall be drawn and the criteria for conformity determined as prescribed in ISO 13106.

6.2 *Samplepreparation*

The sample preparation applies to all tests except migration test given in**ASTM D6247-18.**

6.2.1 Samples from re-usable products shall be immersed in boiling water for 10 min without touching the walls of the container.

NOTE — This is to remove the surface coating arising from the manufacturing processes and ensure that the materials used are stable in boiling water.

6.2.2 New samples, preferably from the same batch, shall be used for each test.

6.2.3 Samples and test portions shall only be handled with suitable (non-rubber or plastic) gloves and shall only be stored in securely fastened, migration-free (glass) containers and protected from light.

7 Packing and Marking

7.1 Packing

The bottles shall be packed as agreed to between the purchaser and the supplier.

7.2 Marking

7.2.1 Each bottle shall be permanently marked with scale mark.

7.2.2 Each carton containing the bottle shall be permanently marked with the following:

a) name of manufacturer and trade-mark, or the company responsible for placing the product in the market, if any;
b) physical locational address of the manufacturer;
c) name of product;
d) nominal capacity;
e) batch No. and Code No.;
f) month and year of manufacture;
g) type of plastics used;
h) country of origin;
i) made from plastics materials meant for food contact applications indicating material used;and
j) instructions for use and hygienic care of the product shall be printed in English/National language and may be included in a separate leaflet placed in or/on the product as given in **8.2.3.**

8.2.3 *Instructions for Use*

8.2.3.1 The following information shall be provided:
a) Information for the safe use of the product; and
b) Information on unsuitable common methods of heating which might damage the product.

8.2.3.2 For re-usable products the following additional instructions shall be provided:
a) At least one method of cleaning;
b) Before first use, clean the product; and
c) Information on unsuitable common methods
of cleaning, storage and use which might damage the product.

8.2.3.3 For products with feeding accessories the following 'WARNINGS'shall be provided in the form given:
For your child's safety and health

WARNING
a) Always use this product with adult supervision.
b) Always check food temperature before feeding.
c) Keep all components not in use out of the reach of children.

NOTE — It is recommended that the supplier of drinking equipment include informative literature to explain the reasons and background for these warnings.

8.2.3.4 Heating in a microwave oven may produce localised high temperatures.

For products where microwave heating is recommended as a suitable method of food preparation the following instructions shall be provided although alternative wording is permitted:
Take extra care when microwave heating. Always stir heated food to ensure even heat distribution and test the temperature before serving.

Annex A
(informative)

List of material for manufacture of plastic feeding bottles

(Based on Malaysian Standard, MS 735 and US FDA Regulations) (1)(i) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

A.1 21 CFR 177.1520 (a)(3)(i)

Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

(i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:

(a) (1) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;

(2) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 shall contain not less than 80 but not more than 90 weight percent of polymer units derived from ethylene.

(3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.

(4) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.

(b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight percent of polymer units derived from ethylene;

(c) (1) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4- trimethylpentene-1 shall contain not less than 85 weight percent of polymer units derived from ethylene and/or propylene;

(2) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and butene-1 shall contain greater than 15 but not greater than 35 weight percent of polymer units derived from butene-1 with the remainder being propylene.

(d) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.

(e) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1, or ethylene, octene-1, and either hexene-1, butene-1, propylene, or 4- methylpentene-1 shall contain not less than 80 weight percent of polymer units derived from ethylene.

A.2 21 CFR 177.1520 (b)

(b) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

A.3 CFR 177.1520 (c) Specifications

Item	Olefin polymers	Density	Melting Point (MP) or softening point (SP) in °C	Maximum extractable fraction (expressed as percent by weight of the polymer) in n-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
(1)	(2)	(3)	(4)	(5)	(6)
1.1a	Polypropylene described in paragraph(a)(1)(i) of this section	0.880 – 0.913	MP: 160-180°C	6.4 percent at reflux temperature	9.8 percent at 25°C
3.1a	Olefin copolymers described in paragraph (a)(3)(i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking; except olefin copolymers described in paragraph (a)(3)(i)(a)(3) of this section and listed in item 3.1c of this table and olefin copolymers describedin paragraph (a)(3)(i)(e) of this section and listed in item 3.1b of this table	0.85 – 1.00		5.5 percent at 50°C	30 percent at 25°C

Annex B
(normative)

Test for permanency of pigment

B-1 General
This test is meant only for those feeding bottles which have a printed scale and graduations.

B-2 Reagents

B-2.1 Sodium Bichromate,

B-2.2 Concentrated Sulphuric Acid, relative density – 1.834 approximately.

B-3 Procedure

B-3.1 Weight about 20 g of sodium dichromate and dissolve in 1 500 ml of concentrated sulphuric acid and dilute to 2 500 ml with water. Immerse the bottles in the solution at room temperature for 15 min. Rinse the samples with water and dry.

B-3.1.1 The bottles shall be taken as having satisfied the requirements of the test, if the printed impressions do not become illegible.

Annex C
(informative)

Typical examples of different items of drinking equipment and their design features.

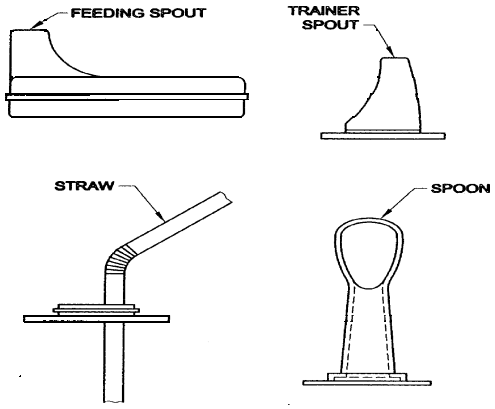

Figure C1– example of drinking accessories

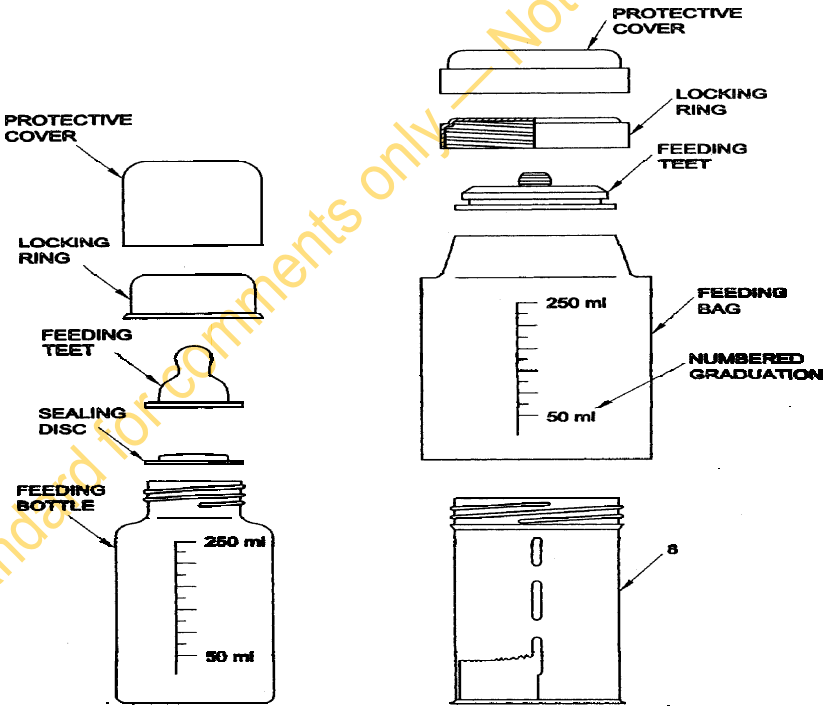

Figure C2 – examples of containers with feeding teats

Annex D

(normative)

Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs – Method of analysis

D.1Types of simulants

The determination of migration in simulants is to be carried out using the simulants laid down:

a) Simulant 'A' - distilled water or water of equivalent quality.

b) Simulant 'B' - 3 percent acetic acid (w/v) in aqueous solution (using the simulant 'A')

D.2 Selection of standard test conditions and simulants for different foodstuffs

D.2.1 The choice of simulating solvents and test conditions (time-temperature) depends on the type of foodtuff and its condition of use. Food products have been classified into seven major groups suitable simulants to be used for different types of foods as per Table D.1.

Table D.1—Classification of foods and selection of simulant

S/N	Type of food	Description	Examples	Simulant
i.	I	Aqueous, non-acidic foods without fat (pH > 5)	Honey, mineral water, sugar syrups molasses, skimmed milk, rusgulla, infusions, murabba, yeast, paste etc yeast paste etc	'A'
ii.	II	Aqueous. acidic foods without fat (pH ≤ 5 5)	Fruit juices, squashes, fruit chunks or puree or paste, vinegar, jams, jellies, carbonated beverages. lemonade, processed vegetables, rennet, preparations of soups, broths, sauces, RTS beverages etc	'B'

D.2.2 Table D.2 lists test conditions (time-temperature) for extractability studies to be carried out as above depending on conditions of use of the food.

Table D.2— Test conditions of temperature and time

S/N	Conditions of use	Water (time- temperature)
i.	High temperature heat sterilized (Retorting)	121°C, 2h
ii.	Hot filled or pasteurized above 66°C, 100°C	100°C, 2h
iii.	Hot filled or pasteurized below 66°C	70°C, 2h
iv.	Room temperature filled and stored (no thermal treatment in container) and also in refrigerated and frozen condition	40°C, 10 days

D.3 Apparatus

D.3.1 Electric oven/water bath, equipped with thermostat to maintain the desired temperature within ± 1 ºC accuracy

D.3.2 Electric hot plate, with temperature control regulator

D.3.3 Analytical balance, with a sensitivity of 0.1 mg

D.3.4 Glass beakers, Pyrex of 1 000 ml capacity or equivalent

D.3.5 Stainless steel evaporating dish of 100 ml capacity

D.3.6 Stainless steel tongs

D.4 Selection of Sample

Minimum triplicate samples representing the lot/batch have to be selected. The films representative sample shall be of sufficient size to convert into two pouches of size 125 mm width and 200 mm length (inner dimension excluding seal area) with 1 000 cm^2 surface area coming in contact.

D.5 Preparation of the test specimen

The containers/pouches used shall be carefully rinsed with water (25-30°C) to remove extraneous materials prior to actual migration test.

D.6 Simulant Quantity

Equal to nominal filling capacity or at least 1 ml/cm^2 of contact area.

NOTE Glassware, laboratory apparatus which come into contact with simulants and/or the sample during the test shall be thoroughly washed and dried prior to test.

D.7 Procedure

Fill the container/pouch to their filled capacity with preheated simulant at test temperature and close it. In case of pouches, exclude air as much as possible before sealing and expose the filled container/pouch to specified temperature maintained in oven/water bath/pressure cooker/autoclave for the specified duration of time. After exposure for the specified duration, remove the container/pouch and transfer the contents immediately into a clean Pyrex beaker along with three washings of the specimen with small quantity of the fresh simulant.

D.8 Determination of Amount of Extractive

D.8.1 Evaporate/distil the contents in Pyrex beaker to about 50-60mL and transfer into a clean tared stainless steel dish along with 3 washings of Pyrex beaker with small quantity of fresh simulant and further evaporate the concentrate in the dish to dryness in an oven at 100 °C ± 5 °C. Cool the dish with extractive in a desiccator for 30 minutes and weigh to nearest 0.1mg till constant weight of residue is obtained. Calculate the extractives in mg/dm^2 and mg/kg or mg/L or ppm of the foodstuff with respect to the capacity of container/pouch to be used. Blank shall also be carried out without the sample.

D.8.2 Calculate the amount of extractive in ppm for the particular size of container being tested.

Amount of extractive (Ex) = $\frac{M}{V}$x1000 mg/kg or mg/l

or Ex= $\frac{M}{A}$x100 mg/dm^2

where

M = mass of residue in mg minus blank value;

A= surface area in cm^2 exposed in each replicate;

V = volume of the container in ml in a replicate in actual use.

NOTE 1 For irregular shaped containers, nearest surface area is obtained by superimposing the graph sheet on the container and getting the surface area by increments in each segment.

NOTE 2 In case of heptane as solvent divide EX by a factor of five in arriving at the extractivity for a food product.

Annex E
(informative)

List of colourants and pigments for use in plastics in contact with foodstuffs and pharmaceuticals

E.1 Principle

E.1.1 This annex provides a list of permitted pigments and colourants for use in plastics intended to come in contact with foodstuffs and pharmaceuticals.

E.1.2 Pigments and colourants used shall not show visible bleeding or migration from the dried food products and shall show no signs of instability or degradation during processing.

E.2 List of pigments and colourants for use in plastics that come into direct contact with foodstuffs and pharmaceuticals

E.2.1 Organic pigments

List of organic pigments and colourants are listed in Table E1.

Table E1 — Organic pigments

Sl No.	CAS No.	C.I. No	C.I. Name
1.	2512-29-0	11680	Pigment yellow 1
2.	6486-23-3	11710	Pigment yellow 3
3.	5979-28-2	20040	Pigment yellow 16
4.	6370-75-8	65405	C.I. Vat yellow 12
5.	12286-66-7	13940	Pigment yellow 62
6.	5580-58-5	20038	Pigment yellow 94
7.	5280-80-8	20034	Pigment yellow 95
8.	5590-18-1	56280	Pigment yellow 110
9.	29920-31-8	11738	Pigment yellow 120
10.	79953-85-8	20037	Pigment yellow 128
11.	30125-47-4	56300	Pigment yellow 138
12.	36888-99-0	56298	Pigment yellow 139
13.	71832-85-4	13960	Pigment yellow 168
14.	96352-23-7	56160	Pigment yellow 173
15.	77804-81-0	21290	Pigment yellow 180
16.	74441-05-7	11777	Pigment yellow 181
17.	67906-31-4	12830	Pigment yellow 182
18.	65212-77-3	18792	Pigment yellow 183
19.	129433-54-7	18795	Pigment yellow 191
20.	3627-47-2	65410	Vat Yellow 26
21.	12236-62-3	11780	Pigment Orange 36
22.	4424-06-0	71105	Pigment. Orange 43
23.	40716-47-0	11265	Pigment Orange 61
24.	72102-84-2	12760	Pigment Orange 64
25.	35869-64-8	20060	Pigment Brown 23

26.	68516-75-6	□	Pigment Brown 41
27.	6041-94-7	12310	Pigment Red 2
28.	2425-85-6	12120	Pigment Red 3
29.	2814-77-9	12085	Pigment Red 4
30.	6410-41-9	12490	Pigment Red 5
31.	6471-51-8	12420	Pigment Red 7
32.	6410-30-6	12335	Pigment Red 8
33.	6410-38-4	12460	Pigment Red 9
34.	6410-35-1	12440	Pigment Red 10
35.	6410-32-8	12385	Pigment Red 12
36.	3564-22-5	12350	Pigment Red 18
37.	6883-91-6	21205	Pigment Red 37
38.	6358-87-8	21120	Pigment Red 38
39.	7023-61-2	15865:2	Pigment Red 48:2
40.	15782-05-5	15865:3	Pigment Red 48:3
41.	1103-39-5	15630:2	Pigment Red 49:2
42.	17852-99-2	15860:1	Pigment Red 52:1
43.	4/9/5281	15850:1	Pigment Red 57:1
44.	6417-83-0	15880:1	Pigment Red 63:1
45.	5850-80-6	15525	Pigment Red 68
46.	72-48-0	58000:1	Pigment Red 83
47.	14295-43-3	73312	Pigment Red 88
48.	6409-74-1	60745	Pigment Red 89
49.	6535-46-2	12370	Pigment Red 112
50.	980-26-7	73915	Pigment Red 122
51.	5280-78-4	20735	Pigment Red 144
52.	5280-68-2	12485	Pigment Red 146
53.	4948-15-6	71137	Pigment Red 149
54.	56396-10-2	12290	Pigment Red 150
55.	3905-19-9	20730	Pigment Red 166
56.	2786-76-7	12475	Pigment Red 170
57.	4051-63-2	65300	Pigment Red 177
58.	5521-31-3	71130	Pigment Red 179
59.	77804-81-0	21290	Pigment Red 180
60.	2379-74-0	73360	Pigment Red 181
61.	59847-23-9	12486	Pigment Red 187
62.	3089-17-6	73907	Pigment red 202
63.	31778-10-6	12514	Pigment red 208
64.	1/1/3573	73905	Pigment red 209
65.	40618-31-3	20066	Pigment red 214
66.	68259-05-2	20055	Pigment red 220
67.	71566-54-6	20065	Pigment red 221
68.	52238-92-3	20067	Pigment red 242
69.	43035-18-3	15915	Pigment red 247
70.	84632-65-5	56110	Pigment Red 254

71.	120500-90-5	561050	Pigment red 257
72.	70833-37-3	56270	Pigment red 256
73.	88949-33-1	561300	Pigment Red 264
74.	1047-16-1	73900	Pigment Violet 19
75.	6358-30-1	51319	Pigment Violet 23
76.	81-33-4	71129	Pigment Violet 29
77.	5462-29-3	73385	Pigment Violet 36
78.	2379-75-1	73395	Pigment Violet 38
79.	147-14-8	74160	Pigment Blue 15:X
80.	574-93-6	74100	Pigment Blue 16
81.	1328-50-3	74140	Vat Blue 29
82.	81-77-6	69800	Pigment Blue 60
83.	482-89-3	73000	Pigment Blue 66
84.	1328-53-6	74260	Pigment Green 7
85.	1330-37-6	74255	Pigment Green 37
86.	31837-42-0	13980	Pigment Yellow 151
87.	4118-16-5	60645	Pigment Yellow 147
88.	52238-92-3	20067	Pigment Red 242
89.	250640-08-5	□	Pigment Orange 79
90.	84632-66-6/ 61951-98-2	□	Pigment Red 272
91.	154946−66−4	18759:1	Pigment yellow 191:1

E.2. Dyestuffs

Sl No.	CASNo.	C.I.No	C.I.Name
1.	6370-85-0	66510	Vat Yellow 9
2.	6252-78-4	73860	Vat Red 45
3.	6492-68-8	73305	Vat Red 47
4.	482-89-3	73000	Vat Blue 1
5.	130-20-1	69825	Vat Blue 6
6.	1330-38-7	74180	Direct Blue 86
7.	128-80-3	61656	Solvent Green 3
8.	116-75-6	61568	Solvent Blue 104
9.	12236-03-2	61568	Disperse Orange 47
10.	17354-14-2	61554	Solvent Blue 35
11.	4702-90-3	48160	Solvent Yellow 93
12.	4851-50-7	625580	Solvent Green 28
13.	61969-44-6	615290	Solvent Blue 97
14.	6408-72-6	615290	Disperse Violet 26
15.	64696-98-6	48525	Solvent Brown 53
16.	6829-22-7	564150	Solvent Red 179
17.	61969-47-9/6925-69-5	564100	Solvent Orange 60
18.	75216-45-4/7576-65-0	47020	Solvent Yellow 114/ Disperse Yellow 54
19.	81-39-0	68210	Solvent Red 52

20.	81-48-1	60725	Solvent Violet 13
21.	83249-52-9	56280	Disperse Yellow 241
22.	80748-21-6/54079-53-7/17772-51-9	□	Disperse Yellow 201
23.	20749-68-2/71902-17-5	564120	Solvent Red 135
24.	12226-78-7/81457-65-0	□	Solvent Blue 67
25.	6408-72-6	62025	Solvent Violet 59
26.	72968-71-9	□	Solvent Red 195
27.	23552-74-1/37229-23-5	□	Solvent Blue 45

E.3 Inorganic pigments/alloys

Sl No.	CAS No.	C.I. No	C.I. Name
1.	7429-90-5	77000	Aluminium
2.	7440-50-6	77400	Copper
3.	7440-22-4	77820	Silver
4.	7440-57-5	77480	Gold
5.	7440-31-5	77860	Tin
6.	7440-06-4	77795	Platinum and platinum group metals
7.	7440-50-8	77400	Bronzes of copper
8.	471-341-1	77220	Whitening (calcium carbonate)
9.	10101-41-4	77231	Calciumsulphate(Gypsum,plasterofParis)
10.	1332-58-7	77005	Kaolin
11.	13463-67-7	77891	Titan White (titanium oxide)
12.	1344-28-1	77002	Alumina
13.	637-12-7	□	Aluminium stearate
14.	14807-96-6 and 8005-37-6	77718	Talc
15.	51274-00-1	77492	Yellow iron oxide
16.	1345-27-3	77491	Iron oxide
17.	57455-37-5	77007	Ultramarine blue (complex silicate of aluminium and sodium sulphurated)
18.	□	77437	Egyptian blue (double silicate of copper and calcium)
19.	1345-16-0	77346	Cobalt blue (cobalt aluminate)
20.	1333-86-4	77266	Carbon black
21.	7727-43-7	77120	Barytes (barium Sulphate)
22.	64294-91-3	77492	Sienna (natural ferric oxide)
23.	12769-96-9	77007	Pigment Violet 15
24.	1308-38-9	77288	Pigment Green 17
25.	1309-37-1	77491	Pigment Red 101
26.	1314-13-2	77975	Pigment White 4
27.	1314-98-3	77975	Pigment White 7
28.	1317-61-9	77499	Pigment Black 11
29.	57455-37-5/ 101357-30-6	77007	Pigment Blue 29
30.	68187-51-9	77496	Pigment Yellow 119
31.	7727-43-7	77120	Pigment white 21
32.	8007-18-9	77788	Pigment Yellow 53
33.	12001-26-2	77019	Pigment White 20
34.	18282-10-5	77861	□
35.	1344-28-1	□	□
36.	68186-90-3	77310	Pigment Brown 24
37.	1345-05-7	77115	Pigment White 5

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Sl No.	CAS No.	C.I. No	C.I. Name
14.	14807-96-6 and 8005-37-6	77718	Talc
15.	51274-00-1	77492	Yellow iron oxide
16.	1345-27-3	77491	Iron oxide
17.	57455-37-5	77007	Ultramarine blue (complex silicate of aluminium and sodium sulphurated)
18.	□	77437	Egyptian blue (double silicate of copper and calcium)
19.	1345-16-0	77346	Cobalt blue (cobalt aluminate)
20.	1333-86-4	77266	Carbon black
21.	7727-43-7	77120	Barytes (barium Sulphate)
22.	64294-91-3	77492	Sienna (natural ferric oxide)
23.	12769-96-9	77007	Pigment Violet 15
24.	1308-38-9	77288	Pigment Green 17
25.	1309-37-1	77491	Pigment Red 101
26.	1314-13-2	77975	Pigment White 4
27.	1314-98-3	77975	Pigment White 7
28.	1317-61-9	77499	Pigment Black 11
29.	57455-37-5/ 101357-30-6	77007	Pigment Blue 29
30.	68187-51-9	77496	Pigment Yellow 119
31.	7727-43-7	77120	Pigment white 21
32.	8007-18-9	77788	Pigment Yellow 53
33.	12001-26-2	77019	Pigment White 20
34.	18282-10-5	77861	□
35.	1344-28-1	□	□
36.	68186-90-3	77310	Pigment Brown 24
37.	1345-05-7	77115	Pigment White 5

Annex F
(normative)

Test for permanency of pigment

F-1 GENERAL
This test is meant only for those feeding bottles which have a printed scale and graduations.

F-2 REAGENTS

F-2.1 Sodium Bichromate,

F-2.2 Concentrated Sulphuric Acid, relative density – 1.834 approximately

F-3 PROCEDURE

F-3.1 Weight about 20 g of sodium dichromate and dissolve in 1 500 ml of concentrated sulphuric acid and dilute to 2 500 ml with water. Immerse the bottles in the solution at room temperature for 15 min. Rinse the samples with water and dry.

F-3.1.1 The bottles shall be taken as having satisfied the requirements of the test, if the printed impressions do not become illegible.

Annex G
(normative)

Compressive Deformation Test

E.1 PROCEDURE

Apply the compressive load of 19.6 Nin the middle part of the body or to the part having the maximum diameterof a feeding bottle by the use of compression jig as shown in Fig. 5 Measure the deflection of the part atthat time, and calculate percentage deflection. Themeasurements shall be carried out at 27 ± 2 °C.

E-2 CALCULATION

Percentage deflection of diameter =

$$\frac{\text{outside diameter prior to test} - \text{outside diameter at the time of compression}}{\text{outside diameter prior to test}} X100$$

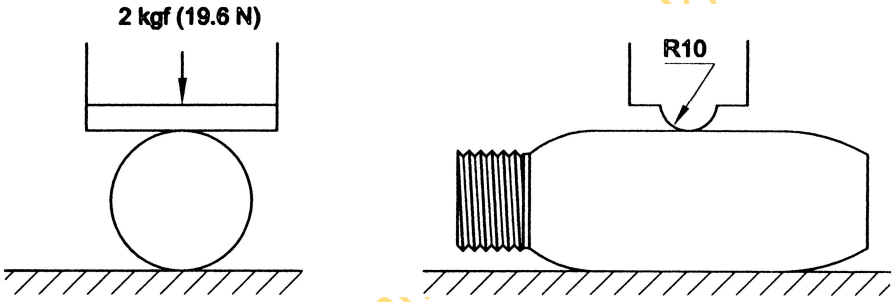

Figure G1— Compression Jig

Annex H
(normative)

List of carcinogenic amine

Sl No.	CAS No.	Substances
1.	92-67-1	4-Aminobiphenyl
2.	92-87-5	Benzidine
3.	95-69-2	4-Chloro-o-toluidine
4.	91-59-8	2-Naphthylamine
5.	97-56-3	o-Aminoazotoluene/ 4-Amino-2,3-dimethylazobenzene/ 4-o-Tolylazo-o-toluidine
6.	99-55-8	5-Nitro-o-toluidine
7.	106-47-8	p-Chloroaniline
8.	615-05-4	2,4-Diamino anisole
9.	101-77-9	4,4'-Methylenedianiline/ 4,4'-Diaminodiphenylmethane
10.	**91-94-1**	**3,3'-Dichlorobenzidine/** **3,3'-Dichlorobiphenyl-4,4'-xylendiamine**
11.	119-90-4	3,3'-Dimethoxybenzidine
12.	119-93-7	3,3'-Dimethylbenzidine/ 4,4'-Bi-o-toluidine
13.	838-88-0	3,3'-Dimethyl -4,4'-diaminodiphenylmethane
14.	120-71-8	6-Methoxy-m-toluidine-p-cresidine
15.	101-14-4	4,4'-Methylene-bis-(2-chloroaniline)/ 2,2'-Dichloro-4,4'-methylenedianiline
16.	101-80-4	4,4'-Oxydianiline
17.	139-65-1	4,4'-Thiodianiline
18.	95-53-4	o-Toluidine/ 2-Aminotoluene
19.	95-80-7	4-Methyl-m-phenylenediamine
20.	137-17-7	2,4,5-Trimethylaniline
21.	90-04-0	o-Anisidine-2-methoxyaniline
22.	60-09-3	4-Aminoazobenzene

Annex I
(normative)

Determination of polychlorinated biphenyl (PCB)

I.1 GENERAL

This method covers determination oftotal polychlorinatedbiphenyls(PCBs)contentincolourant materialbylowresolutiongaschromatographycoupled tohighresolutionmassspectrometer(LRGC-HRMS) usingElectronImpact(EI)mode.

ApplicationofLRGC-HRMSensuresseparation/ recognition of most PCB congeners are separatedor recognizableatdifferentretentiontimes.

NOTE—IncaseaspecificPCBistobereportedwhichisdifferentfromanycongenerdirectlyspecifiedbyinternalstandard, suitable care should be taken using external windowstandards for identification.

I.2 APPARATUS

I-2.1 Low Resolution Gas Chromatography Coupled to High Resolution Mass Spectrometer (LRGC-HRMS) Using Electron Impact (EI) Mode

I-2.2 Rotary Evaporator

I-2.3 Weighing Balance, nearest to 0.000 1 g.

I-2.4 Micropipette, with disposable pipette tips.

I-2.5 Surgical Hand Gloves C-2.6 Glass Column

I-2.6.1 Column,30cmlong,18mmdiameterwith250 ml top reservoir.

I-2.6.2 Column,30cmlong,10mmdiameterwith 250 ml top reservoir.

I2.7 Magnetic Stirrer and Magnetic Bar

I-2.8 Ground Joint Conical Flask — 500 ml.

I.3 REAGENTS

I-3.1 Concentrated Sulphuric acid — Analyticalgrade.

I-3.2 n-Hexane — Analytical reagent grade.

I-3.3 DichloroMethane—Analyticalreagentgrade.

I-3.4 SilicaGel—Technicalgrade,poresize60Å, 70-230 mesh,63-200 μm

I-3.5 PCB Standard Solution (EC 4058) or Equivalent

I-3.6 n-Nonane

I-3.7 Celite 545 (CAS No. 68855-54-9)

I-3.8 Cesium Hydroxide

I-3.9 Silver Nitrate

I-3.10 Alumina (ICN Alumina B - Super I (Basic) (50-200 μm or Alternate)

I-3.11 Sodium Sulphate, anhydrous.

I-3.12 Toluene,analyticalreagentgrade.

I-3.13 Ethanol,analytical reagent grade.

I-4 WORK CONDITIONS

Dustfreeenvironmentwithpositivepressureinsidethe laboratorybyairhandlingunitandtemperaturetobe maintainedat22±2°C.

I-5 PROCEDURE

I-5.1 Preparation of test sample

I-5.1.1 Weighaccurately0.75-2.5gsampleintoa conicalflaskandadd0.5-0.9gethanoltowetthe colourantsurface.

I-5.1.2 Add100µlPCBstandard(5timesdilutedwith n-nonane).Add1-2gofphosphoricacidandsodium sulphateofapproximatelysameweightasofthesample. Add40gof92-96percentsulphuricacidtwice, carefullywithrepeatedshaking.Sonicatethemixturefor30-100minuntilhomogenousdarkreddisholive colour solution isobtained.

C-5.2 Liquid – LiquidExtraction

I-5.2.1 Extractsulphuricacidsolutionwith200ml n-hexaneandrapidlystirbyultra-sonicationforat least30min.Incaseofsamplesuspectedofunusually highimpuritycontent,amixtureof50mln-hexaneand 200mldichloromethanetobeused.

I-5.2.2 Transferthemixturetoaseparatingfunneland collecttheorganicphaseina500mlroundbottom flask.Repeattheextractionsteps2times(moreif necessary)andcombinealltheorganicphasesinaround bottomflask.Incase,ifpossible,decantorganiclayer directly.Incase,ifoilylayerfoundthenfollowthestep asgivenasI-5.2.3.Add1-2mln-nonaneinorganic phase and remove the solvent using rotaryevaporator. Reducethevolumeupto1-2mlinroundbottomflask. Followthecleanupprocedureusing1-2mlremaining solvent.

I**-5.2.3** Add50percentaqueouspotassiumhydroxide solutioninorganicphasetomakeitspH7-8,andshake outtheaqueouslayertwicewith100mln-hexane,in ordertocontrolthechangeoftemperatureduetoheat ofneutralization.AfterreachingpH8,transferthe solutionintotheseparationfunnel,rinsetheflaskwith 10mlofn-hexane.Combineallthecleanorganicphases inaroundbottomflaskanddrythembyadding0.5g ofanhydroussodiumsulphate.Add1-2mln-nonaneinorganicphaseandremovethesolventusing rotaryevaporator.Reducethevolumeupto1-2mlin roundbottomflask.Followthecleanupprocedureusing 1-2mlremainingsolvent.

I-5.3 Clean-up

I-5.3.1 Taketheneatandcleanglasscolumn(size30 cmlong,18mmdiameterwith250mltopreservoir). Filltheglasscolumnwithn-hexaneupto1/3oftop reservoir.Weighthechemicalsandtransfertocolumn infollowingsequence.Whileadditionofreagentshake thecolumnexternallytoavoidanyairbubblesleftin thecolumnforbetterefficiency.

Reagent/Chemicals	Mass(g)
Silica gel	5
Celite:Sulphuricacid(1:1mix)	30-33
Silica gel	5-6
Anhydrous sodium sulphate	5-7

Letn-hexanerununtiltoplayersreached.Thenpre- condition with 200 ml hexane: dichloromethane (4:1,v/v)andletrunofftothetoplayeragain.Discard theelute.

I-5.3.2 Transfer the analyte from round bottom flask tocolumnwithhelpoftransferpipetteandrinsethe roundbottomflaskfor5timeswithapproximately 5mlhexane:dichloromethane(4:1,v/v)andtransfer tomulti-

layercolumn.Addapproximately150ml n-hexane.Collectthesolventin500mlroundbottom flask.Recovertheexcessn-hexanebyrotaryevaporator until5-7mlsolutionisleft.

I-5.4 Alumina column

I-5.4.1 Taketheneatandcleanglasscolumn(size30cm long,10mmdiameterwith250mltopreservoir).Fillthe glasscolumnwithtolueneupto1/3rdoftopreservoir. Usageofn-hexaneinsteadoftolueneisalsopermissible. Weighthechemicalsandtransfertocolumninfollowing sequence.Whileadditionofreagentshakethecolumn externallytoavoidanyairbubblesleftinthecolumn.

Reagent/Chemicals	Mass(g)
Silicagel	0.3-0.5
Anhydrousalumina	12.5-13
Silicagel	0.3
Anhydroussodiumsulphate	3

I-5.4.2 Afterfillingofthecolumn,removethetoluene/n-hexaneupthejustabovethetoplayerofreagent.

Loadconcentration—Eluateofpreviousstepintothe column.Rinsetheflasktwice(2times3mltoluene/n hexane)andaddthesolventtothecolumn.

Pre-run—Eluteoffwith40mltolueneintoacalibratedcylinder in case of brominated sample matrix. Elute with hexane: dichloromethane (98 : 2, v/v), adding first 2 ml × 2 ml and finally 76 ml of the eluant and collectinto the same cylinder of the pre-run till reaching avolume of 120 ml.

I-5.4.3 Transfer the extract solution quantitatively toa flask and evaporate to a volume of 500 µl, reduce toapproximately 200 µl by nitrogen blowing and transferto a standard 1.2 ml septum-sealed glass vial.The measuring solution is obtained by rinsing the flask2 times with 25 µl n-nonane and adding the volume tothe GC-vial.

I-5.5 Determination of analytes

Refer the instrument manual for operation and analysisof PCB by gas chromatography — MassSpectrometry (GCMS) using auto-sampler, injection volume shall be 3-10 µl.

NOTE — Perfluorotributylamine (PFTBA) tuning is performed every two months or according to instrument performance monitoring requirement.

I-5.6 Calculation and quantification procedure

I-5.6.1 Incase,ifpeaksarenotappearingindesirewindows then set the time accordingly.

IntegrationtheMpeaksinGC-quadrapoleshouldbe carriedoutmanuallyinthere-quantificationmode. Smallpeaksandespeciallythoselookingsignificant, butlackingevenanapproximateisotopicratioas predetermined for the Analyte, response is considered 100percent.Chemicallyandstructurallymostcongers aretoberatio-calculatedfromthecongenerstandard amount.Amountofeachdeterminedcongenerisdivided bythesampleweight.

C-5.6.2 Lower detection limit

PCBbelowtherangeof1ppmcannotbemeasuredby this method, since the internal relativestandard deviation(RSD)willapproach100percent.Reportthe sumofdecachlorobiphenyl(DeCB)equivalent(ppm) fromono-todeca-chlorobiphenylandapply correctionfactor,ifany,basedonthemeasurementof uncertainty.

C-5.6.3 Mass Conversion Factors

Degree of Chlorination	From CB to DeCB Equivalent	From DeCB to CB Equivalent
Mono-CB	2.649	0.377 50
Di-CB	2.244	0.445 64
Tri-CB	1.930	0.518 13
Tetra -CB	1.706	0.586 17
Penta -CB	1.528	0.654 45

Hexa-CB	1.391	0.718 91
Hepta-CB	1.264	0.791 14
Octa-CB	1.158	0.863 56
Nona-CB	1.073	0.931 97
Deca-CB(DeCB)	1.000	1.000 00

Annex J
(normative)

Determination of total primary aromatic amines

J.1 GENERAL

Analysisofprimaryaromaticamine(PAA)inorganic colourantstoascertainqualityforsafeuseinfood contactapplication.

J.2 APPARATUS

J-2.1 **Weighing Balance,** nearest to 0.000 1 g.

J-2.2 **Ultrasonic Bath**

J-2.3 **Centrifuge Capable** to 3 000 rpm

J-2.4 **HPLC System Equipped with Gradient Elution—DADdetectorandpump**.UVdetectorcan be use asoptional.

J-2.5 **Column—**250mm×4mm,5μmorequivalentHPLC column.

J.3 REAGENTS

J-3.1 Hydrochloric Acid Solution — 1N.

J-3.2 Sodium Hydroxide Solution — 5N.

J-3.3 HPLC grade methanol

J-3.4 pH Strips

J-3.5 Distilled Water

J-3.6 AnalyticalReferenceStandardsforAmines, to test appropriate individual colorant.

For example, 2,5-Dichroanilinemaybeusedasanalyticalreference standardforPigmentRed2.

J-3.7 Phosphoric Acid —Analytical grade.

J-3.8 Diammonium Hydrogen Phosphate —Analytical grade.

J.4 PROCEDURE

J-4.1 Sample Preparation

Weighaccurately0.5gsamplein250mlcapacityflask. Add20mlmethanoland60ml1Nhydrochloricacid. Apply sonication for 5 min in ultrasonic bath at37±2°Candsubsequentlystiritfor25minat200rpm and37±2°C.Transferthecontenttocentrifugetube andapplycentrifugefor5minat3000rpmanddecant clearlayerin250mlbeakerthroughfilterpaper.

Add30ml1Nhydrochloricacidincentrifugetubeand stirfor25minat200rpmand37±2°C.Centrifuge thisat3000rpmanddecantclearlayerin250mlbeaker through filter paper. Wash filter paper with approximately2ml1Nhydrochloricacidandcombine thefiltratewiththefirstaqueousphase.AdjustpHto7 using5Nsodiumhydroxidesolutionandtransferto200 mlvolumetricflask.Makeupthevolumeto200ml withdistilledwater.Inject10µlinHPLCdirectly.

J-4.2 Standard Preparation

Weigh,tothenearest0.1mg,10±1mgofeach aromaticamineintoa100mlvolumetricflask.Add methanol/water8:2(v/v).Placeitinanultrasonicbath for10mintoensurecompletedissolutiontomake standardsolutionsforcalibrationcurve.Thestability ofthemixedstockstandardsolutionshouldbechecked

regularly.Itshouldbestableforupto6monthswhen storedincoolanddarkplace(27°C).Calculatethe responsefactor(RF).Useminimumthreepoints calibrationcurve.

J-4.3 Instrument (HPLC) Set Up

Column : 250 mm × 4 mm, 5 ìmorequivalent HPLC column
Oven temperature : 40°C
Mobile phase

A :5mmolDiammoniumhydrogen phosphatebufferedtopH7with concentratedphosphoricacid
B :HPLC grade methanol

Gradient :90percent(v/v)A:10percent(v/v)B,in30min5percent(v/v)A and 95 percent (v/v) B
Flowrate : 0.9ml/min
Injection volume: 10 µl or higher depending uponlimit of detection.
Injection volume: suitable to ensure the limit ofdetection (LOD) (5–15 µl)
Runtime : 45min
Flow : 0.3ml/min
DADmode : 240 ± 20nm
DADrange : 200 to 800nm

J-4.4 Calculation of Response Factor for Each Concentration

$$\text{ResponseFactor(RF)} = \frac{\text{Area ofstandard}}{\text{Concentration of standard(ppm)}}$$

J-4.5 Calculation of Individual Primary Aromatic Amine

$$\text{Individual primary aromatic amine, in ppm} = \frac{\text{Sample are x dilution factor}}{\text{RFx weight of the sample (g)}}$$

Recalculatetoanilineequivalentincaseofallamines otherthanthoselistedinAnnexH.

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