

الدليل التنظيمي الخاص بتحليل مستحضرات التجميل

1. مقدمة:

هذا الدليل يخص القواعد والإجراءات المنظمة لتحليل مستحضرات التجميل الحاصلة على رقم إدراج.

2. متطلبات تحليل مستحضرات التجميل بنظام الإدراج:

تنقسم مستحضرات التجميل الحاصلة على رقم إدراج والواردة للتحليل بالإدارة المركزية للرقابة الدوائية الي قسمين:

أولاً: أول رسالة واردة /تشغيله بعد الإدراج -اول تشغيله بعد حصول المستحضر على موافقة متغيرات من الإدارة المركزية للمستحضرات الصيدلانية تستلزم التحليل.

وذلك على أن تكون الاجراءات كالاتي:

I. تقوم الشركة بتقديم شهادة تحليل من المصنع تحتوي على الاختبارات الالزامية الموضحة بجدول (1) .

II. تقوم الشركة بتقديم عينات للتحليل بمعامل الإدارة المركزية للرقابة الدوائية أو شهادة تحليل من أحد المعامل المعتمدة نتائج تحاليلها من خلال الإدارة المركزية للرقابة الدوائية وذلك للدراسة والتقييم الفني واصدار تقرير المعامل.

III. يتم تطبيق الاختبارات المطلوبة على مرحلتين:

• المرحلة الاولى: تبدأ المرحلة مع بداية تطبيق منظومة الإدراج وتشمل الاختبارات الموضحة بالجدول رقم (1) .

• المرحلة الثانية: تبدأ المرحلة بقرار تنفيذي من رئيس الإدارة المركزية للرقابة الدوائية بعد ستة أشهر من بدء منظومة الإدراج وبعده اقصي اثنا عشر شهراً وتشمل الاختبارات الموضحة بالجدول رقم (2).

ثانياً: السحب العشوائي (In market control):

يتم سحب عينات عن طريق الإدارة المركزية للعمليات وتشمل المستحضرات الحاصلة على رقم إدراج لأول مرة والمستحضرات المسجلة سابقاً وحاصلة على إخطار تسجيل مستحضر تجميل ويتم تحاليلها بمعامل مستحضرات التجميل بالإدارة المركزية للرقابة الدوائية طبقاً للقواعد الاسترشادية الأوروبية وتحديثاتها (جدول 3).

3. الاختبارات:

I - الاختبارات الالزامية (جدول 1):

Type of test	REQUIRED TEST	category
Physical tests	<ul style="list-style-type: none"> appearance/package integrity pH if applicable according to European guidelines 	All cosmetic products
Microbiological tests	<ul style="list-style-type: none"> Total microbial count Pathogenicity 	All cosmetic products

II - اختبارات الأمان (جدول 2)

Type of test	REQUIRED TEST	category
Physical tests	appearance/package integrity	All cosmetic products
	PH	pH if applicable according to European guidelines
	Heavy metals by AAS/ICP	All cosmetic products
	SPF	sunbathing products

Chemical test	Free Formaldehyde By GC/UV	1-Products for waving, straightening, and fixing 2- Kids fingers paint and kids face painting
	1,4 DIOXANE by GC	1 -Cleansing products (lotions, powders, shampoos) 2- Anti-dandruff shampoo 3- products for external intimate hygiene
	Hydrogen Peroxide by titration	1- products for care of the teeth and the mouth 2- products for nail care and nail lacquer
	Methanol by GC	Any cosmetic products containing high percent of ethanol or isopropanol
Microbiologic al tests	Total microbial count	All cosmetic products
	Pathogenicity	All cosmetic products

III- الإختبارات الخاصة بمستحضرات التجميل طبقا للقواعد الاسترشادية الأوروبية والحدود المسموح بها ويتم تحديثها بشكل دوري:

ويتم سحب العينات من الأسواق أو عند ورود شكوى من عيوب خطيرة في المستحضر

i- الإختبارات الخاصة بمستحضرات التجميل

1-PHYSICAL TESTS:

Type of test	REQUIRED TEST	category
Physical tests	<ul style="list-style-type: none"> appearance/package integrity pH if applicable according to European guidelines 	All cosmetic products

2-CHEMICAL TESTS:

Product	Required tests	Equipment
I-Skin Care products (hand, face, body)		
1. Creams, emulsions, lotions, gels, and oils for the skin (hands, face, feet, etc.)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
2. Face masks (except for peeling products)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
3. peeling products	Heavy Metals	ICP/AAS
	Salicylic acid	Titration/HPLC
	Preservatives	HPLC
	Hydroquinone	HPLC
4. Tinted bases (liquids, pastes, and powders).	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Asbestos in talc powder	XRD
5. Make up powders, after bath powders, hygienic powders, etc.	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Asbestos in talc powder	XRD
6. Medicated soaps, deodorant soaps, etc.	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	1,4 Dioxane	GC
7. Bath and shower preparations (salts, foams, oils, gels, etc.)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	1,4 Dioxane	GC
8. Depilatories	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Thioglycolic acid	Titration
9. sunbathing products	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	SPF	
	UV filter	HPLC
10. products for tanning without sun	Heavy Metals	ICP/AAS
	Preservatives	HPLC
11. whitening products	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Hydroquinone	HPLC
	Kojic acid	HPLC

12. anti-wrinkle products	Heavy Metals	ICP/AAS
	Preservatives	HPLC
13. Deoderants and anti-perspirants	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Aluminum salts	Titration
<u>II-Hair care products</u>		
1-Hair Tents bleaches & hair dyes products	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Hydrogen peroxide	Titration
	Resorcinol	TLC
	Oxidation colorants (dyes)	TLC
	ammonia	Titration
2-Products for waving, straightening, and fixing	silver nitrate (for eye lashes/eyebrows)	ICP/AAS
	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Free sodium and potassium hydroxide	Titration
	Free formaldehyde	GC/UV
3-Setting products	Thioglycolic acid	Titration
	Heavy Metals	ICP/AAS
4-Cleansing products (lotions, powders, shampoos)	Preservatives	HPLC
	Heavy Metals	ICP/AAS
	Resorcinol	TLC
	1,4 Dioxane	GC
	Salicylic acid	Titration
5-Conditioning products (lotions, creams, oils)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Salicylic acid	Titration
6-Hairdressing products (lotions, lacquers, brilliantine" s)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
7-Anti-dandruff shampoos	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Resorcinol	TLC
	1,4 Dioxane	GC
	Selenium di sulphide	Titration
	Zn pyrithione	Titration

III- Shaving products (creams, foams, lotions, etc.)	Heavy Metals	ICP/AAS
	Preservatives	HPLC
IV- products for making up and removing makeup from the face and the eyes	Heavy Metals	ICP/AAS
	Preservatives	HPLC
V- products intended for application to the lips	Heavy Metals	ICP/AAS
	Preservatives	HPLC
VI- products for care of the teeth and the mouth	Heavy Metals	ICP/AAS
	Fluoride	Fluoride Potentiometry
	Preservatives	HPLC
	Chloroform	GC
	Hydrogen peroxide	Titration
	Free formaldehyde	GC/UV
VII- products for nail care and nail lacquer	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	Free sodium and potassium hydroxide	Titration
	Hydrogen peroxide	Titration
	Formaldehyde	GC/UV
VIII- products for external intimate hygiene	Heavy Metals	ICP/AAS
	Preservatives	HPLC
	1,4 Dioxane	GC
IX- Kids fingers paints, and kids face painting	Free formaldehyde	GC/UV
	Preservatives	HPLC
	Heavy metals	ICP/AAS
Any cosmetic products containing high percent of ethanol or isopropanol	Methanol	GC

3-Biological Tests: will be done according to risk assessment.

4-Microbiological Tests

All cosmetic products except the products used around the eyes, products used for infants under three years, and products used on mucous membranes	Total microbial count (T.M.C.)	N.M.T 10^3 CFU/ml or gm
	Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm
Products used around the eyes, products for infants under three years, and products used on mucous membranes	Total microbial count (T.M.C.)	N.M.T 10^2 CFU/ml or gm
	Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm

ii-الحدود الخاصة بالاختبارات

The PH of cosmetic product should be in the range (4-8) excluding hair colorant and excluding the product with PH mentioned in Annex 3 according to their composition ingredients as shown in the table*. Certain product which formulated with PH value outside this range are acceptable if they had evidence to demonstrate that the PH is necessary to achieve the required cosmetic effect and have a demonstrable safety report

Product category	pH
(1) Skin care products (a) Cleanser (b) Toner (c) Sunscreen (d) Moisturizers (e) Serum (f) AHA and BHA Exfoliants (g) Vitamin C products (h) Retinol products	(a) 4.5-7 (b) 5-7 (c) 5-7.5 (d) 5-7 (e) 4-6 (f) 3.7-5 (g) 3-4 (h) 3.7-5
(2) Hair care products (a) Shampoos for adults (b) Shampoo for babies (c) Hair dyes i. Black & brown shades ii. Other shades (d) Developer (e) *straightening products containing metal hydroxides (f) Some hair treatments products containing keratin & protein	(a) 5-8 (b) 5-7 (c) i. 9-11 ii. 6-11 (d) 1.8-4 (e) up to 12.7 (f) <4
(3) For products contain Thioglycolic acid and its salts as (a) *Hair products: for general or professional use (b) *Depilatories (c) Hair rinse-off products For products contain Thioglycolic acid esters (e) Hair waving or straightening products	(a) 7- 9.5 (b) 7 - 12.7 (c) up o 9.5 (e) 6 - 9.5
(4) Medicated soap (1% aqueous solution) Acidic Medicated soap	8-11 4-6

	The chemical tests	Limit of Safety
1	Determination of 1,4 Dioxane (a) Shampoo, shower gel, cleansing product (b) Any products contain SLS, SLES, PEG	According to Annex III (a), (b) NMT 10 ppm
2	Determination of Thioglycolic acid and its salts and ester (a) Hair waving or straightening (b) Depilatories	According to Annex III (a) NMT 8 (general use) or* NMT 11%* (professional use) (b) NMT 5%* *Note: The above -mentioned percentages are calculated as thioglycolic acid
3	Determination of Methanol Products contain ethanol or isopropanol (e.g., body mist)	According to Annex III NMT 5% as % of Ethanol or Isopropanol
4	Determination of Hydroquinone (a) Artificial nail system (b) skin whitening, lightening, and brightening, especially contain Arbutin, Tocopherol and Tocopherol acetate	(a) NMT 0.02% (Annex III) (b) Not detected (Annex II)
5	Determination of Formaldehyde (a) Nail hardener (b) Oral product (toothpaste, mouth wash) (c) other products	According to Annex III (a) NMT 5% (b) NMT 0.1% (c) NMT 0.2%
6	Determination of P-Phenylenediamine Hair dyes	According to Annex III NMT 4%
7	Determination of Kojic acid Skin whitening, lightening, and brightening	According to Annex III NMT 1%
8	Determination of salicylic acid (a) as preservative in cosmetic product (b) Rinse off hair products (c) other products (Peeling products)	According to Annex III (a) NMT 0.5% (b) NMT 3% (c) NMT 2%
9	Determination of Ammonia or ammonium hydroxide Creams, emulsions, lotions, gels, and oils for the skin (hands, face, feet, etc.)	According to Annex III NMT 6% (as ammonia)
10	Determination of Hydrogen peroxide (a) Hair products (b) Skin products	According to Annex III (a) NMT 12 % (b) NMT 4 %

	(c) Nail hardening products (d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products (e) Tooth whitening or bleaching products (professional use) (f) Products intended for eyelashes	(c) NMT 2 % (d) ≤ 0.1 (e) $> 0.1 \% \leq 6 \%$ (f) NMT 2 % All % calculated as H ₂ O ₂ present or released
11	Determination of Silver nitrate Hair dyes (Only for coloring eyelashes and eyebrows)	According to Annex III (a) NMT 4%
12	Determination of Chloroform Toothpaste	According to Annex I Not detected
13	Determination of selenium disulfide and zinc Zinc pyrithione Antidandruff shampoos	According to Annex III NMT 1% (for both)
14	Determination of Resorcinol (a) Hair dye substance in oxidative hair dye products (b) Products intended for coloring eyelashes (c) Hair lotions and shampoos	According to Annex III (a) and (b): NMT 2.5% (c) NMT 0.5%
15	Determination of Aluminum salts (a) non-spray deodorants or non-spray antiperspirants (b) spray deodorants or spray antiperspirants (c) (Deodorant) Aluminum zirconium chloride hydroxide complexes and the Aluminum zirconium chloride hydroxide glycine complexes	According to Annex III (a) NMT 6.25% (as Aluminum conc) (b) NMT 10.6% (c) NMT 20% as anhydrous aluminum zirconium chloride hydroxide) NMT 5.4% as zirconium
16	Determination of preservatives (a) Ethyl and Methylparaben (b) Propylparaben and butylparaben	According to Annex VI (a) NMT 0.4% (for each), (b) NMT 0.19% (for each) NMT 0.8% for mixture of them
17	Determination of heavy metals (a) pb (b) As (c) Cd (d) Hg	(a) NMT 10 ppm (10 μ g/g) (b) NMT 3 ppm (c) NMT 3 ppm (d) NMT 3 ppm
18	Determination of fluoride Toothpaste	According to Annex III NMT 0.15% as fluoride
19	Determination of metal hydroxide (sodium, potassium) (a) Nail cuticle solvent	According to Annex III (a) NMT 5%

	(b) Hair straightener (c) depilatories -pH adjuster -Other uses: e.g. KOH as Callosity softener/remover	(b) NMT 2% (general use), (c)NMT 4.5% (professional use) - up to pH 12.7 - up to pH 11
20	Determination of UV filter For common UV filter (as example) Zn oxide Titanium dioxide Benzophenone -3 Avobenzone Ethyl hexyl methoxy cinnamate	Limit according to Annex VI NMT 25% NMT 25% NMT 6% NMT 5 % NMT 10 %

Microbiological tests for cosmetic products			
	Category of products	Type of test	Specification
1	All cosmetic products except the products used around the eyes, products used for infants under three years, and products used on mucous membranes	Total microbial count (T.M.C.)	N.M.T 10 ³ CFU/ml or gm
		Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm
2	Products used around the eyes, products for infants under three years, and products used on mucous membranes	Total microbial count (T.M.C.)	N.M.T 10 ² CFU/ml or gm
		Specified micro-organisms: a) Staphylococcus aureus b) Pseudomonas aeruginosa c) Candida albicans d) Escherichia coli	Absent in 1ml or 1gm



