

# AN EVALUATION OF THE RULES OF GOOD PRACTICE IN MANUFACTURING COSMETIC AND DERMATO-COSMETIC PRODUCTS AT S.C. FARMEC S.A. CLUJ-NAPOCA

MONICA VUSCAN<sup>1</sup>, MARIUS BOJIȚĂ<sup>2</sup>

<sup>1</sup>S.C. Farmec S.A., Cluj-Napoca

<sup>2</sup>University of Medicine and Pharmacy "Iuliu Hațieganu"

## Abstract

*S.C. FARMEC S.A., the largest manufacturer of cosmetics in Romania has recently implemented, the rules of good manufacturing practice in the production of cosmetics and dermato-cosmetics. These rules, as part of Quality Assurance System, ensure that products are manufactured and controlled according to quality standards appropriate to their use, stipulated in the product specification and authorization Holder. Good Manufacturing Practice rules apply to both product and quality control. The paper analyzes how the Good Manufacturing Practice rules are applied within the Farmec Company in Cluj-Napoca.*

**Keywords:** rules of good manufacturing practice, manufacturing flow, cosmetics and dermato-cosmetics.

## O EVALUARE A APLICĂRII REGULILOR DE BUNĂ PRACTICĂ DE FABRICAȚIE A PRODUSELOR COSMETICE ȘI DERMATO-COSMETICE LA S.C. FARMEC S.A. CLUJ- NAPOCA

## Rezumat

*SC FARMEC S.A., cel mai mare producător de cosmetice din România și-a implementat, de curând, Regulile de Bună Practică de Fabricație în producția de cosmetice și dermato-cosmetice. Aceste reguli, ca parte a Sistemului de Asigurare a Calității, garantează că produsele sunt fabricate și controlate după standardele de calitate adecvate utilizării lor, prevăzute de specificația produsului și autorizația de punere pe piață. Regulile de Bună Practică de Fabricație se aplică atât produsului, cât și controlului calității. Lucrarea analizează modul în care sunt aplicate Regulile de Bună Practică de Fabricație la compania Farmec din Cluj-Napoca.*

**Cuvinte cheie:** Regulile de Bună Practică de Fabricație, flux de fabricație, produse cosmetice și dermato-cosmetice.

## Introduction

S.C. FARMEC S.A. Cluj-Napoca produce and sell cosmetics, medicinal products and products for house maintenance. It is the largest manufacturer of cosmetics in Romania, providing over 60% of Romanian production of cosmetics.

The production of the Farmec Company is achieved while respecting their principles of good practice regarding cosmetic manufacture. These principles are contained in the Guide to the principles of good manufacturing practice for cosmetics, approved by European standard

EN ISO 22716:2007, as a component of the rules of good manufacturing practice. In order to adapt the production of Farmec Company to these demands it was built a new and modern section, with a manufacturing flow that guarantees quality products under the conditions of hygiene, use of advanced technologies and the protection of the environment and personnel.

## Materials and methods

"The guide on the principles of good manufacturing practice of cosmetic products" developed by Farmec Company and approved by European standard EN ISO 22716:2007 was used as study material. The comparative method and logical analysis were used as working methods. Research has studied how to apply the main

Articol intrat la redacție în data de: 30.12.2009

Acceptat în data de: 05.01.2010

Adresa pentru corespondență: monicavuscan2002@yahoo.com

objectives of the Rules of Good Manufacturing Practice: quality management, premises and equipment, personnel, documentation, production, quality control, complaints and selfinspection in the Farmec Company .

### Results and discussion

#### 1. Quality Management

To manage product quality, Farmec Company, has established a quality assurance department, subordinated to the General Manager, that is responsible for all quality issues. Quality policy holds the highest rank in the hierarchy of quality documents and includes the general objectives and commitments of the managerial staff. Quality assurance department has introduced a system of Quality Assurance (QA) which is well designed, properly put into practice, and works in two directions: applying rules of good manufacturing practice (GMP) which guarantees the product manufacture and control according to quality standards required by product specification and the second direction is the quality control (QC) which entails sampling, laboratory testing, drafting specifications, organizational procedures, documentation and release [1,2].

#### 2. Premises and equipment

The premises and equipment are built, adapted and maintained to be suitable for the operations that are carried out. Their location and design minimize risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, the deposit of dust and dirt, and generally, any undesirable effect on product quality.

The premises ensure protection against insects, rodents, intruders, etc. and provide sufficient space for carrying out technological operations efficiently [1,2,3,4,5].

The department of manufacture for cosmetics and dermato-cosmetics of the Farmec Company consists of the following areas. Production areas: room for melting solid materials and heating liquid materials, operations that are performed in melters equipped with a cushion duplicators stirring system; preparation room where there is preparation equipment (mixers) with cape, blending and mixing systems, timers for blending and mixing times, temperature and pressure control devices, vacuum pumps; fillig and packing area where the automatic filling and labelling machines are; pure water preparation room where there is an installation of obtaining purified water by reverse osmosis; room for washing utensils. Storage areas: quarantine storage room for semi-finished products; storage and slicing raw materials room; clean utensils storage room; process control room; storage room for production samples; quarantine room for finished products; packaging materials warehouse; finished products warehouse. Quality control sections: Laboratory of physico-chemical analysis; microbiological analysis laboratory; laboratory for Quality control of packaging and materials used in packaging. Annex areas: mechanical workshop; locker room for street

clothes; dressing room for work clothes; office and lock chamber areas leading to the manufacturing area.

All these rooms are equipped with treatment plants and air filtration and their walls are made of sandwich panels with zinc coated steel front, paint applied in electrostatic field. The final layer is polyurethane varnish. The floor is made of epoxy resin.

#### 3. Staff

In the production sector there is properly qualified staff and individual responsibilities are clearly contained in job descriptions. The entire personnel knows the specific job GMP principles through initial training, as well as through continuous training, which includes proper hygiene in relation to the kind of work performed (preparation, conditioning etc.).

Department staff consists of section head, a chemical engineer, supervisors, laboratory assistants, office workers, administrators, operators, mechanics, electricians and unskilled workers. Key personnel shall consist of the section chief and head of quality control.

#### 4. Documentation

Documentation of production department includes: documents regarding the operation section of cosmetics and dermato-cosmetics (operating authorization and metrological authorization, ISCIR); documents for reception of raw materials and packaging; documents for preparation; documents for lab control of semi-finished and finished products; documents relating to the completion of charges; procedures to ensure hygiene in the production process; the general rules for the operation section.

The entire documentation is written clearly to avoid errors that are inherent in verbal communication and allow the history of the series restoration. Specifications, manufacturing formulas, manufacturing and packaging instructions, procedures and records for all manufacturing operations are prepared daily.

#### 5. Production

To get quality products all production operations are clearly defined, in accordance with the GMP principles. For the manufacturing of cosmetics and dermato-cosmetics class D of cleaning the environment at the operational level is required.

Conditions imposed by this class of cleaning are provided by arranging for special filters, HEPA type, mounted in the ceiling of the chamber, which provide air flow to laminar flow.

Access to production areas is allowed only to authorized personnel and is made through two lock chambers: one for staff and one for equipment and materials. At every stage of processing, all materials, bulk containers, the most important parts of the equipment are labelled with all information necessary to identify the product status, using specific colors (in quarantine, accepted, rejected, clean etc.).

**Prevention of cross contamination in production** has always been one of the main concerns of the company. Any contamination of raw materials or product by another material or product must be ruled out. Cross contamination has been avoided by taking technical and organizational measures: installation of lock chambers and air extraction systems; minimizing the risk of contamination caused by recirculation or entering of untreated air or inadequately treated air; using cleaning and decontamination procedures with known efficiency as cleaning equipment failure is a regular source of cross contamination; verifying the absence of residues and using labels on the clean equipment.

Measures to prevent cross contamination and their effectiveness are regularly checked in accordance with established procedures [1,2,4,5].

**Raw materials:** are purchased from accredited suppliers that have implemented GMP. The stored raw materials are properly labelled. Production uses only materials that have been accepted by quality control and are valid.

#### **During processing operations:**

- **Intermediate and bulk products** are stored in appropriate conditions, in the quarantine storage room for semi-finished products. The necessary process control analyses (pH, viscosity, stability etc.), and those of environment (temperature, humidity, air pressure) are performed and recorded.

- **Packaging materials** are treated with equal attention as raw materials. They are stored in appropriate secure conditions in the packaging materials warehouse, to prevent unauthorized access and avoid any mixing.

- **Filling and Packaging:** Before starting any packaging operation it is important to check if the packaging area, the filling lines, the printing machines and any other equipment is clean and free of products or previously used materials or documents. The filling line is labelled with the name and product series. The accuracy of the data printed on packaging materials (batch number, expiration date) is checked. Labelling is done after the primary packaging operation. Any remaining unused material is returned.

- **Finished products** are kept in quarantine in the quarantine room for finished products until final release of the series.

- **Rejected products** are reprocessed only in exceptional circumstances only if the quality of the finished product is not affected. Such operations are carried out in accordance with certain procedures that are defined and approved after assessing possible risks. Reprocessing is recorded.

#### **6. Quality Control**

Quality control is conducted in the area of quality control. Samples from the production area are brought to the control area. After they are inspected, specifications and issuing procedures are drawn up. These documents guarantee that all necessary and relevant tests were

performed. No product is released unless it meets quality requirements. The sector has other tasks such as determining, validating and implementing all quality control procedures, keeping production samples, verifying correct labelling of containers of materials and products, controlling product stability, participating in the investigation of complaints about product quality etc. All these operations are performed in accordance with written procedures and are recorded. The review by the filling line includes tests of: the quantity filled, the general appearance of packaging, proper use of products and packaging materials, printing accuracy and correct functioning of control devices on the line. The staff of the Quality control department has access to production areas for sampling and conducting the necessary investigations [5,6,7].

#### **7. Complaints**

There are written procedures describing the actions that need to be taken in case of a complaint about an allegedly defective product, up to a recall. Any complaint is registered with all original details and investigated very thoroughly. There is a person responsible for examining complaints who decides on appropriate measures and a person responsible for carrying out withdrawals.

#### **8. Selfinspection**

Selfinspections are done independently and rigorously by competent persons in the company. Also, independent audits are conducted by outside experts (clients). All selfinspections are recorded and contain measures for corrective actions.

Finally, it can be considered that cosmetic and dermato-cosmetic production in Farmec company fully respects GMP, the company obtaining the ISO certificate in 2003.

#### **Conclusions**

It was investigated how the rules of Good Manufacturing Practice (GMP) are applied in the Farmec Company in the preparation of cosmetics and dermato-cosmetics. Responsibility for quality assurance lies with the quality assurance department of the company.

The arrangements for the preparation of cosmetic products are seeking to create production areas, storage areas, quality control areas and annex areas. Bringing qualified staff in the cosmetics department, with clear individual responsibilities, helped to establish and maintain an appropriate system of quality assurance. Key personnel consists of the section chief and head of quality control.

Production operations follow clearly defined procedures, in accordance with the GMP principles to obtain required product quality.

Quality control deals with sampling, product testing, writing specifications, as well as the organization, documentation and procedures for issuing cosmetics.

To resolve complaints, there is a person in charge

of complaints and a person responsible for withdrawing defective products from the market.

Selfinspections are conducted independently and rigorously by competent persons in the company or outside the company, in order to verify the real situation and to propose appropriate corrective actions.

The results of the evaluation show that the production flow for cosmetics and dermato-cosmetics in the Farmec Company fully respects GMP.

### References

1. XXX nr.1058 Order in November 19, 2003, regarding the approval of the rules of good manufacturing practice for medicinal

products, Official Journal, Part 1 nr.63, January 26, 2004

2. XXX Rules of good manufacturing practice for medicinal products, Official Gazette, Part 1, nr.63 bis, January 26, 2004

3. XXX "Good Manufacturing Practice", proposals set out by the Federation of Perfumery Industries in cooperation with the authorities in France, in June 1992

4. XXX "Basic instructions for manufacturing cosmetics", IKW, Frankfurt am Main, June 1990.

5. XXX ISO 9001 "Quality assurance system-Model for Quality Assurance in design, development, production, installation and operation".

6. XXX ISO 9004 "Quality Management and quality assurance system elements-Regulations".

7. XXX ISO 8402 "Quality-vocabulary" (NF X 50-120).