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Non sterile clinical Galenic Laboratory : a scientific discipline Between laboratory practice clinical pharmacy and personalized pharmacological therapy. The simplified normative rules NBP in Italy

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Abstract

Observing the today hospital practice in many countries and the international literature involved it is clear

How clinical pharmacy is linked to the galenic laboratory practice. Today more than recent past due to the various kind of magistral formula request by the clinicians It is necessary that the clinical pharmacist perspective must to be added to the classic Galenic laboratory competencies : this make possible to complete the profile of efficacy and safety of this fundamental Drugs. The clinical galenic activity is divided in sterile and Non sterile . (Total parenteral nutrition bags, Pain therapy, oncological parenteral drugs laboratory, radio drugs and diagnostics , non-sterile galenic) . Aim of this work is to deeply investigate this crucial link (Clinical Pharmacy with Laboratory Practice) in order to get the really best clinical results for the patient. Clinical pharmacy principle, Pharmaceutical care, managerial competencies and personalized pharmacy added to the best knowledge and competencies in galenic laboratory make the difference in order to obtain the right final clinical results. The same in this work are submitted to international pharmacy practitioner , directors and researcher the Normative rules operating in an advanced country : the simplified NBP , example that can be applied also in non-advanced nations. In Italy pharmacist can follow or the full NBP of the official pharmacopeia or the simplified according DM Salute 18.11.2003. (related the kind of galenic formula if sterile or not) The NBP (good manufacturing rules) introduce an Quality System Management.

The full NBP are more used in more complex laboratory in example involved in specialistic products Like oncologic or radiopharmaceutical and other. Aim of this rules is to guarantee quality, security and efficacy of a drug prepared in galenic lab. This are based on responsibility principles, plan, documentation of all activity. (Quality System of Insurance). All phases of the preparation are under the responsibility of the pharmacist. The final quality depends on the correct use of API and excipients, right calculations operation, right volume or weight operation, procedure following. Check on the final products: following of the procedure , aspects, packaging and its closure. According NBP the laboratory must to be separated (or it must to be separable) form the pharmacy and a second pharmacist (that is different form the pharmacist that prepare) must to check the final preparation. The locals must to be according strictly environmental condition to make possible to prepare in safety way the drugs. And it is mandatory must to be followed written procedure. (instrument verify, training of the pharmacist Cleaning procedure, signification). Raw material certifications, technical sheet , safety sheet. Working sheet is mandatory. The pharmacist can follow this two option related the kind of drugs produced and the characteristic of the laboratory. It is not the main focus of this work to produce a literal translation of DM 18/11/03 only to submit its general meanings. This can be considered for the authors useful to be added also to the normative rules in force in non-advanced countries.

Keywords: Galenic laboratory; Magistral Formula; Clinical Pharmacy; Pharmaceutical care; Personalized pharmacy; Medicine shortage; NBP; Simplified Rules; Official Pharmacopeia; Control Process; Quality Management System; Rare disease; 3d Printing systems

Abbreviations: PC: Pharmaceutical Care; MD: Medical Devices; DC: Developing Countries; GL: Galenic Laboratories; UFF: Universidad Federal Fluminense; PD: Pediatric Diseases; CP: Community Pharmacies; FD: Fused-deposition

Introduction

Starting from the consideration that in history of the remedy for the pathology of humans great contribute was obtained with the introduction of Galenic principle and methods. From Galenus form Pergamon (Greek) 129 dc – 201 comes the term Galenic art of the pharmacist to produce drugs inside in the pharmacy . He codified the preparation of drugs using multiple kinds of ingredients. (active principle added with excipients). For many centuries this methods was used in the laboratory to produce remedy to treat many human pathology [1]. Federico II Svevia 1194 – 1250 known as "Stupor Mundi " related his open mind concepts introduced In Europe and in Italy the need to have specific rules for regulation the activity of drugs production in the pharmacy laboratory from the prescription activity of the physicians. This in order to avoid conflict of interest between this prescriptive function form the pharmacy practice : this produced the mandatory separation between medicine and pharmacy .: to the physicians the role in therapy and for pharmacist the production and sell of the drugs [2]. But during the illusionistic period , the industrial revolution , the success of medicinal chemistry since 1800 and 1900 many forces make possible to shift the drugs production form the pharmacy to the more complex industry. During all this periods many Formulary and then Pharmacopoeia in various countries was introduced and adopted To make possible to get adequate quality of the drugs produced, safety and reproducibility of the procedure. (monography, methods of analysis ,table et other).

This texts becomes mandatory by healthcare law in the various contests (FU Italian, FU European, US pharmacopeia and many other examples). Also the competencies of who was involved in remedy preparation increased during centuries : from botanic expertise (Scuola Salientian VII e VIII century) to the Iatrochemistry principle (Paracelsus from XVI century). Before the pharmacists, apothecaries that worked alongside priests and physicians in regard to the patient care. The history of pharmaceutical history is well known form introduction of the first Sulfamidics since the Actual last antivirals (for covid-19 treatment). But , related the last industrial pharmaceutical revolution ,some problem arose : not all pharmaceutical industries produce drugs for all subpopulation (pediatric patients , swallowing problems in geriatrics). There is the needs of personalized dosages or personalized pharmaceutical form (for pediatric or geriatric patients) needs to introduce drugs in enteral nutrition drugs not available form national or foreign producers (national or international shortcomings) orphan drugs for some rare disease dermatologic products cannabis preparate some disinfectants band antiseptics formula some antidotes (galenic) some laboratory reagents and solutions some contrast agents odontiasis galenic and many other So due to this failure of industry to cover all this situation the galenic laboratory is a real opportunity [3,4].

Today also many pharmaceutical industry not like more to produce classic drugs as many cardioactive products and other and the magistral product make possible to overcome this problem. (especially today whit actual economic crisis) . Also a great number of galenic formula are in use commonly in the hospital : corrosive products for dermatologist, alcohol solution for laboratory, various reactions, phytotherapy derivates and so on [5]. Galenic Pharmacy also provides educational, scientific and research activities in the profile discipline – pharmaceutical technology to the pharmacy student or under specialization programs.

But observing international literature it is possible to see that the best clinical results are obtained when the laboratory activity in production magistral formula by the physician is completed when available the clinical pharmacist and managerial competencies in the same team. Galenic is the laboratory process that turns an active ingredient (API) into a ready-to-use medicine that can be dosed as required for the various patients. This to optimize their absorption. It the discipline (or science) of dosage form design.

According Review

At the hospital, the pharmacist is constantly challenged to prepare extemporaneous solutions ES from tablets, capsules or drug powder for patients unable to swallow, Like as pediatric, elderly and patients that use mesenteric and nasogastric tubes. The preparation of extemporaneous solutions ES from capsules, tablets and drug powder requires stability studies analysis (Figure 1&2).

Material and Methods

With and observational point of view an review of relevant article related the topics of this work is performed. It is produced the meaning translation of an Italian normative rule DM 18 Nov 2003 An practical experimental study is reported with results from 2008 to 2023. Finally a global conclusion is submitted to the researcher related also innovations in fields of Galenic laboratory (Figure 3).

Results

From Literature

When COVID-19 pandemic started, the Italian hospital pharmacists faced multiple challenges and change their work practices. The aim of this study work was to describe the impact of the C-19 emergency on pharmaceutical care (PC) provided by pharmacists during the first wave of the pandemic. Issues related to pharmacist's involvement in the pandemic management PM were: changes in activities, support received by authorities and pharmacists' own perceived role in the Health System HS . A cross-sectional study world based on a web survey was conducted between May and June 2020 collecting information from pharmacists, members of Italian Society of Clinical Pharmacy and Therapeutics SCPT. 113 (11.4%) completed the questionnaire. The cohort was divided in two arms: pharmacists who worked in severely C-19 affected areas (High Spread Regions) and those

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employed in the less affected areas (Low Spread Regions). The changes in the pharmacy work settings PWS reflected the increase of logistics area and non-sterile clinical galenic, and reduction of clinical tasks. The most demanding challenge was referred to shortages of medical devices MD and drugs, 61/113 pharmacists reported difficulty in obtaining products compliant to quality standards. National Institutions and the Regional Governments provided a greater perceived support. More than about 50% of participants felt that their role did not change if compared to other healthcare professionals.

Figure 1: Manual Encapsulator.

Figure 2: Galenic Laboratory.

Despite some limitations related to their clinical activity, pharmacists played a relevant l role in supplying personal protective equipment, medical devices MD and medications to improve health outcomes during this emergency. The results may guide pharmacists in future actions to improve the management of the pandemic [6]. Aid Progress Pharmacist Agreement Project: aims in developing countries Aid Progress Pharmacist Agreement (A.P.P.A.®) is a non-profit NP association based on a voluntary work and its main activity is the A.P.P.A.® Project. The Project started in the 2005 as a result of the cooperation between the Pharmacy Faculty of Turin (TO) and Italian community pharmacists. Its main task is the establishment of galenic laboratories (GLs) in hospitals of developing countries (DCs) according to the principles of international health cooperation.

Aims of the Project

Establishing GLs in DCs with the aim of preparing medicinal products MP that comply with quality requirements, first of all to fight the widespread counterfeiting of medicines in DCs; tailoring the dosages and pharmaceutical forms PF according to the actual patient needs; employing the local staff, teaching them a "new job," and opening a suitable school; minimizing the costs necessary to prepare these medicines. There are relevant and important reasons why galenic should be used:

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a. a low cost of the production system and simple operative procedures;

b. the possibility to adapt the dosages and pharmaceutical forms PF to the patients' needs and medical prescriptions;

c. reduction in the use of counterfeit medicines CM in the settings where the GL is located [7].

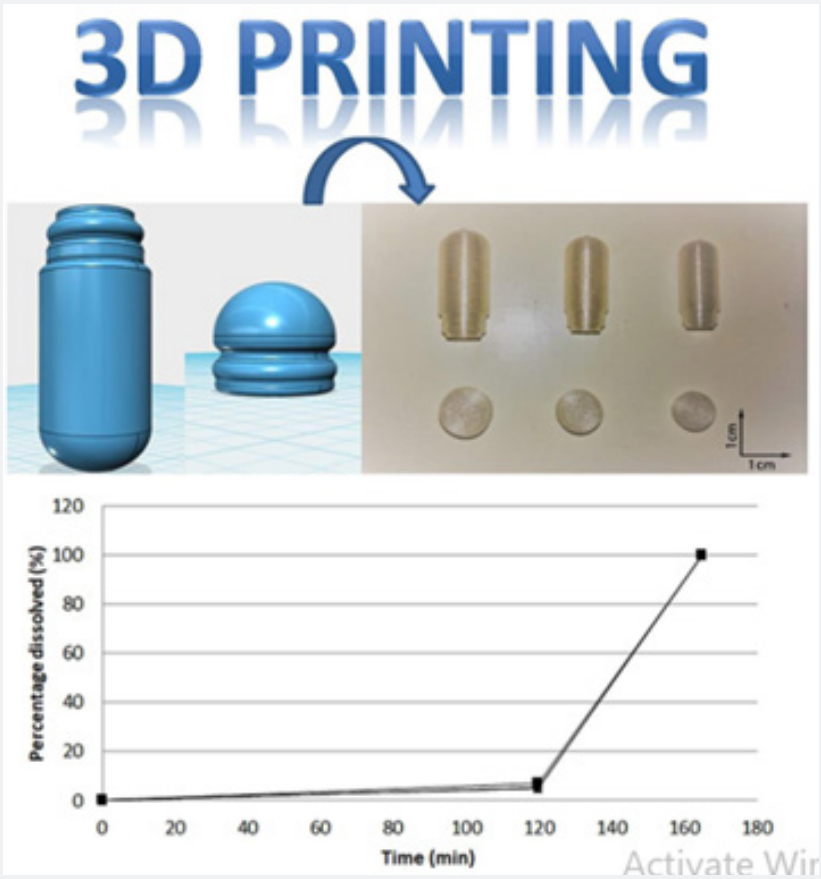

Figure 3: Feasibility study into the potential use of fused-deposition modeling to manufacture 3D-printed enteric capsules in compounding pharmacies.

The clinical pharmacist CP will have a collaborative meeting with both the prescriber and the nurse in order to notify any possible medication errors ME and suggest any proposals to optimize the AMO according to the medical history, the clinical status CS, and the therapeutic adherence. (change of galenic form due to swallowing problem, dose adjustment to renal function RF). After the collaborative meeting, the clinical pharmacist will check whether the prescriber has accepted his/her suggestion(s) and modified the AMO. All the pharmaceutical interventions, the medication errors ME detected and the pharmaceutical suggestions of order modification, will be collected and characterized in a standardized form according to the French Society of Clinical Pharmacy FSCP [8]. The choice of a pharmaceutical (galenic) concept is primarily based on the requirements of the physico-chemical properties PCP of the active ingredient to be applied. The fixed combination of active pharmaceutical ingredients API in topical preparations is suitable for only a limited number of clinical treatment scenarios [9]. Compliance with national legislation, like as establishing compliance prescribed by the European legislation EL in the field of drug development is binding. All manufacturers of drugs and/or active pharmaceutical ingredients PI must apply quality standards prescribed by the European Pharmacopoeia EP in order to develop, manufacture and sales of medicines. When it comes to the quality of pharmaceutical ingredients PI for the production of drugs in the pharmacy, pharmacies especially in residential institutions in our country is permanently done by harmonizing national legislation NL in order to improve conditions for the preparation and production of galenic drugs GD in terms of inpatient health institutions performed in a manner that is prescribed by international regulations. Th is requires the adaptation of institutions, including the fundamental changes in competence as national professional and administrative and regulatory rules that apply to state- and private sectors [10].

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Magistral drugs in hospitalized newborns and children Medicamentos magistrais em recém-nascidos e crianças hospitalizados Agueda Cabral de Souza Pereira, Elaine Silva Miranda, S. Rodrigues de Castilho, Débora Omena Futuro, Lenise Arneiro Teixeira, Geraldo Renato de Paula Universidade Federal Fluminense (UFF), Niterói, RJ, Brazil "The constant consumption of magistral oral solutions MOS and suspensions by newborns and children of the assessed hospital indicates the need for such preparations as a pediatric therapeutic alternative in this hospital [11]. When there is no on-label or even no off-label treatment for the patients with rare diseases RD pharmacists have to compound the medication [12]. Backup manufacturing on a small scale (magistral and galenical) could be a good way to overcome some kind of shortages [13].

In the treatment of pediatric diseases PD , mass-produced dosage forms are often not suitable for children. Commercially available medicines CAM are commonly manipulated and mixed with food by caregivers at home, or extemporaneous kinds of medications are routinely compounded in the hospital pharmacies HP to treat the hospitalized children. Despite considerable efforts by regulatory agencies RA, the pediatric population is still exposed to questionable and potentially harmful practices. When designing medicines for children, the ability to fine-tune the dosage while ensuring safety of the ingredients is of paramount and crucial importance. For these kind of scope solid formulations may represent a valid alternative to liquid formulations for their simpler formula and more stability, and, to overcome the problem of swelling ability, mini-tablets could be a practicable option. This review work deals with the different approaches that may be applied to develop mini-tablets intended for pediatrics with a focus on safety of the excipients. Alongside the various conventional method of compression, 3D printing appeared particularly appealing, as it allows to reduce the number of ingredients and to avoid both the mixing of powders and intermediate steps like as granulation. this technique could be well adaptable to the daily galenic preparations of a hospital pharmacy HP, thus leading to a reduction of the common practice of off-label preparations [14].

"Three-dimensional (3D) printing offers the potential to revolutionize the production of pharmaceuticals targeted to the gastrointestinal GI tract by offering a flexible drug product manufacturing platform that can adapt readily to changing market and patient needs . By using digital computer-aided design software to produce medicines in a layer-by-layer manner, 3D printing enables the on-demand production of drug products DP with personalized dosages PD, drug combinations , geometries and release characteristics ; a concept which is currently unattainable and cost inefficient with conventional manufacturing technologies (tableting and encapsulation). This technology has been forecast to disrupt a wide range of pharmaceutical applications, ranging from expediting the drug development process DDP and providing benefits for pharmaceutical manufacture, to on demand printing of personalized medicines PM on the front-line and in hard-to-reach areas [15].

The purpose of this research work was to investigate the feasibility to manufacture enteric capsules, which could be used in compounding pharmacies, by fused-deposition modeling. It is well-known that conventional enteric dip coating of capsules CPS in community pharmacies CP or hospitals is a time-consuming process which is characterized by an erratic efficacy. Fused-deposition FD modeling was selected as a potential 3D printing method due its ease and low-cost implementation LCI . Before starting to print the capsules CPS, an effective sealing system was designed via a computer-aided design program. Hot melt extrusion was used to make printable enteric filaments. They were made of the enteric polymer, a plasticizer and a thermoplastic polymer, namely Eudragit® L100-55, polyethylene glycol 400 and polylactic acid, respectively. Riboflavine-5′-phosphate was selected as a colored drug model to compare the efficacy of the 3D printed capsules to that of enteric dip coated capsules as they are currently produced in community pharmacies and hospitals HP . Different parameters of fabrication which could influence the dissolution profile of the model drug, such as the layer thickness or post-processing step, were studied. It was demonstrated that our 3D printed enteric capsules did not release the drug for 2h in acid medium (pH 1.2). They completely dissolved within 45 min at pH 6.8 which allowed the release of a minimal amount of 85% w/w of drug as it was recommended by the European Pharmacopoeia EP 9th Edition for enteric products [16].

Practical project

In this part are analyzed the Italian normative rules named NBP and simplified as DM Salute 18.11.2003 normed di buona preparation" applied by law as mandatory in the galenic laboratory setting inside the pharmacy (public or private - hospital and community). NBP or GMP good manufacturing practice The GMP philosophy are based on : documentation of the process , registrations, every phases of the process, activity and single operations.

i. Team must receive adequate training
ii. Responsibility clearly identified
iii. Quality of API and excipients
iv. Cleaning and sanitization procedure
v. Regular check of the instruments
vi. Process validation
vii. NC non conformity management

So In Italy by law the pharmacist that work in a galenic laboratory according DM 22/06/05 must to follow or the full NBP of Italian FU (more complex) or DM Salute 18.11.2003 (if not sterile magistral preparations or officinal reduced scale). The pharmacy

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that prepare non sterile magistral formula or officinal reduced scale can follow or full NBP or simplified NBP. Instead if prepared sterile products , or toxic properties , anticancer drugs and radio drugs, it must to be used biological hood : it is mandatory to follow full NBP. For non-sterile products it is possible in Italy to deviate from full NBP and to follow the simplified rules if it is possible to keep under control all the process , proving it. (quality efficacy , safety depends on organization and consistent control) . First NBP was introduced in (FU IX ed.) in 1989. In the chapter 795 USP, pharmaceutical compounding of non-sterile products , related the difficulty of the preparations, its stability , storage conditions, dosage form , complexity in calculations, systemic, topic use, risk level for pharmacist, damage risk for patients are classified 3 situations :simple compounding , moderate and complex compounding. It is request to produce the master formulation records and the compounding record. Like NBP the USP rules are based on the quality of final products and on the documentation of all process. Some preparations at high microbiological quality need to be prepared in zone with Hepa Filter . A translation of simplified NBP an its philosophy (DM Salute 18.11.2003) and their meaning are reported.

Results

Translation of the meaning of the NBP procedure simplified DM 18/11/2003 Application field :(non-sterile magistral and officinal forms reduced lots) for hospital and community pharmacy medical prescription for magistral formula and Pharmacopeia for Officinal reduced scale production) Preliminary evaluation about opportunity -possibility to prepare the galenic requested or needed definitions: magistral formula, officinal, reduced batch laboratory hygienic written procedure, frequency (provided by director of the pharmacy or lab. Responsible). lab area: it must to be adequate to the kind of galenic products produced, ceiling and walls washable it can be in a separate room separate or not separate inside the pharmacy. instruments: mandatory according Pharmacopeia off. Italian , the measure instrument must to be verified in regular way. The refrigerator must to be cleaned. Containers (and related certificate of conformity to pharmacopeia requirement of the primary containers). Raw material : chemical denomination, date of arrive in pharmacy , batch number , expiration date or date of reticulation, certificate of analysis signed by producer (according pharmacopeia quality requirement), conservation condition or use, date of first use. (necessary a register of raw materials , excipients and API, with a progressive numeration). The empty container of raw material must to be kept for 6 month after final use. Fulfillments (preventive and after setup) to the preparations . Prescription verify, normative requirement , sign of the physician, overdosages verify (according table n. 8 pharmacopeia Italy), Incompatibility verify , the possibility to prepare in lab. After setup: to be written on the prescription the progressive number of the preparation, date of the preparation, expiration date, excipients used, precautions and cautions, label must to be attached.

Sign of the pharmacist in the label, on the prescription or on the working sheet Labeling etichettatura – batch number and expiration date, composition qualitative quantitative, API Excipients , date limits for use, precautions, Price (community pharmacy) Documents storage -conservation documentation (time) , empty bottle . The written prescription must to be kipped in pharmacy for 6 month and the same working sheet. The prescription of narcotics must to be kept in pharmacy for the time required by normative rules. Quality control: right following of the procedure, organoleptic characteristics, control of the packaging, sealing of the container, right label compilation, mass uniformity ,acceptation limits A copy of the label must to be attached to the working sheet Documentation : of the working space, instruments, raw materials Expiration time of the drugs prepared : according FU requirement : 30 days that can be prolonged to 6 month according chemical -physical microbiological stability documented by official information's. Mandatory equipment and tools utensil in pharmacy.

a. balance sensitivity to the mg , scale = 0,001 g, loading capacity at least 500 g or in alternative way two different balances , one with sensitivity at the mg (d=0,001g) with loading capacity at least 50 g and the other with sensitivity at 0,50 g (d=0,50 g) with carry load at least of 2 kg.

b. Bain Marie or other equipment that can assure ,in heating , temperature since to 100 °C.

c. Fridge able to assure the right storage conditions according pharmacopeia requirement

d. Point of fusion equipment . (to test the raw material)

e. chemical glassware, also graduated sufficient for the execution of the preparation.

f. percolator at empty Concentrator [1].

g. encapsulate [2]

h. Tablet press [3].

i. powder Aspiration system [4].

j. molds or plastic valve for ovules and suppositories [5].

k. tools and devices necessary to guarantee sterility of the preparation [6]

l. Beyond the reported instruments , the pharmacy must have all other instruments, equipment, tools, Materials, Products and reactive adequate to the number end to the nature of the preparations usually performed and of suitable tools for their check to be done according the Pharmacopeia indications.

Pharmacy that execute injectable preparations must have also materials, equipment, and tools essential to this preparations and for all the control expected by pharmacopeia for this specific kind of preparation.

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Note:

a) Mandatory for pharmacy that prepare extracts . they must to be of marterials and adequate dimension to the volume and related the preparation to be executed.

b) Mandatory for the pharmacy that prepare capsules.

c) Mandatory for the pharmacy that prepare tablets.

d) Mandatory for pharmacy that prepare tablets, capsules , capsule, teas or sachets.

e) Mandatory for pharmacy that prepare suppositories and ova.

f) For pharmacy that prepare sterile products.

Experimental Project

In order to evaluate the application of reduced NBP in an hosp. galenic lab PC area are reported The all official non conformity registered from 2008 to 2023. (the internal production) Results : no major non conformity registered related the preparation activity. (for the non-sterile galenic activity), only 2 secondary-minor NC due by an excipient to be modified to increase solubility of an API and related a closing system for an oral power.

Discussion

As reported in this work are clear the advantages to produce some kinds of drugs in a galenic laboratory. Even the industrial epoca , with the pharmaceutical industry increase , the industrial production of drugs Was rapidly developed and so reduced or stopped the production in the galenic laboratory : this process was due to The complexity process to produce with high quality the finished drugs in the amount requested by the hospital and the patient. But the same some condition needed to maintain this procedure : for magistral prescription single patient based and for the production of disinfectants, reagents or other product. It must also to be remembered that during last COVID-19 pandemia one of the main producers of antiseptic gel hands and alcoholic solution was the hospital pharmacy in their lab as well as in the private pharmacy. The industry in this situation was not able to provide ready to use great amount of this product in few time as needed for the public safety [3]. The galenic hospital laboratory in the public hospital was able to guarantee this production and the safety of the patient and healthcare professional. The results of a practical experience reported show also in a specific settings the goodness of this rules NBP even if simplified .

The technological innovation make possible to better cover the need for drugs shortcomings. Comparing full NBP to the reduced DM 10 nov 2003 it is possible to verify that NBP require separate or separable locals , check by other pharmacist vs the one that prepare the drug in lab., and required as mandatory written procedures accreditation . For DM it is not mandatory complex quality check on the final products, no mandatory written procedure are needed (even if suggested). In this work it is also submitted a new technology useful in galenical laboratory : the 3D Printing System. As an innovation for quality and efficiency of the process.

Conclusion

As conclusion it is possible to say that observing the Italian Reduced NBP rules in an advanced countries can be applied also in non-advanced countries with great benefit for healthcare of the patients. Related the specific preparation requested by the clinicians. This rules report general behavior and procedure to be followed to be sure that the drugs produced are safe and useful for the patient. Not all laboratory in the world have the same instruments or complex laboratory , but in every laboratory It is crucial to know the responsibility as well as procedure adopted (quality control of raw material , active substantive, qualification of the pharmacist , traceability of the lots and other). For this reason it is opinion of the author that this rules must to be translated in their general meaning from Italian to English languages as reported in this work.

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