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# GALENIC LABORATORY: STATE OF THE ART – A SCIENTIFIC AND TECHNOLOGICAL DISCIPLINE -INNOVATION AND MANAGEMENT

The semplified normative rules ( NBP NORME DI BUONA PREPARAZIONE) ) in Italy : An Useful tools also for non advanced country

The innovative 3D Printing system technology for cps and tablets .

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KEYWORDS

Physiology ,Galenic lab , magistral formula, clinical pharmacy , pharmaceutical care , personalized pharmacy, drug shortage ,NBP , semplified rules, official pharmacopeia, control process, quality management system, Rare disease, 3d PRINTING systems, management.

**CHAPTHER 1 ABSTRACT**

The term galenic imply a scientific and technical matter but also an art.

Related the hospital practice the future of pharmacy pass trought the innovation of the galenic lab.

Observing the today hospital practice HP in many countries and the international literature involved it is clear How clinical pharmacy is linked to the galenic lab practice LP.

Today more then recent past due to the various kinds of magistral formula requested by the clinicians

It is necessary that the clinical pharmacist CP perpesctive must to be added to the classic GALENIC lab competencies : this make possible to complete the profile of efficacy and safety of this fundamental and crucial Drugs like the magistral formula and officinal and their use .

Aim of this ancient discipline and art is today to provide efficacy and safe drugs for the need of single patient when it is not possibile to use the industrial product.

The clinical galenic activity can be divided into sterile and Non sterile .

( Total parenteral nutrition TPN bags, Pain therapy, oncological parenteral drugs lab UFA , radio drugs and diagnostics and non the sterile galenics) .

Aim of this work is to deeply investigate this relevant link ( CLINICAL PHARMACY CP with LAB PRACTICE LP) in order to get the really best clinical results for the patiens and healthcare org need.

Clinical pharmacy CP principle , PHARMACEUTICAL care PC , the managerial competencies and personalized pharmacy added to the best knowledge and competencies in the galenic lab. make the difference in order to obtain the right final clinical results.

The same in this work are submitted to the international pharmacy practioner , directors , researcher or students the Normatives rules operating in an advanced country like Italy : the semplified NBP ( NORME DI BUONA PREPARAZIONE) , example that can be applied also in the non advanced nations.

In italy pharmacist can follow or the full NBP ( NORME DI BUONA PREPARAZIONE) rules of the official pharmacopeia or the semplified according DM Salute 18.nov.2003. ( related the kind of galenic formula prepared if sterile or not).

The NBP ( NORME DI BUONA PREPARAZIONE) ( good manifacturing rules) introduce an QUALITY CQ SYSTEM MANAGEMENT.

The full NBP ( NORME DI BUONA PREPARAZIONE) are more used in more complex labs in ex. involved in specialistic products (Like oncologic or radio drugs, sterile colliria and other ).

This rules guarantee the quality, security and the efficacy of a drug prepared in galenic lab.

This are based on the resonsability principles, plan, documentation of all activity.( QUALITY SYSTEM OF INSURANCE CQ ).

All the phases of the preparation are under the responsability of the pharmacist.

The final quality of the products depends on the correct use of API and eccipients, on the right calculations operation, right volume measure or weight operation and the Check on the final products:

-following of the procedure , aspects, pakaging and closing system and other request by ITALIAN FU related the specific pharmaceutical form.

According NBP ( NORME DI BUONA PREPARAZIONE) the lab. must to be separated (or it must to be separable ) form the rest of 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 striclty enviromental condition required normative rules by to make possible to prepare in safety way drugs.

And it is mandatory to follow the written procedure : instrument verify, training of the pharmacists

Cleaning procedure, sanifications.

For Raw materials: it is needed to have certifications, technical sheet , safety sheet, data of the first use , expiry data

Working sheet is mandatory to testify the operations.

The pharmacist can follow this 2 option related the kind of drugs produced and the characteristic of the lab.

It is not the main focus of this work to produce a literal translation of the DM 18/nov /2003 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 other non advanced countries.

In order to make more interesting this book some useful concepts of physiology of the stomach and GI tract are reported .

The same some relevant pharmaceutical concepts and technique with a focus on the capsules CPS as pharmaceutical form ( gastro resistance, delayed release), some oral suspension , gels and other few preparation.

This work is produced whit a non conventional approach : it is not a book of pharmaceutical technique .

Innovation and management of the system make possible to increase the power of the galenic laboratories

In the hospital or in private pharmacy.

This work is produced only for international purpose.

**CHAPTHER 2 INTRODUCTION**

in hystory to treat the humans pathology great contribute was obtained with the introduction of GALENIC principle and methods.

From GALENUS form Pergamon ( Greek) 129 dc – 201 comes the word GALENIC art of the pharmacist to produce drugs inside in the pharmacy .

Fig. n 1 Galenus form Perganom

He codified the preparation of drugs using multiple kinds of ingredients. ( active principle API added with excipients).

For many times (centuries) this methods was used in the lab to produce remedy to treat many human pathology .

Federico II of Svevia 1194 – 1250 knowed as " STUPOR MUNDI " related his open mind concepts introduced

Fig. n 2 Federico II Svevia

In europe and in italy the need to have specific rules for regulation the activity of drugs production in the pharmacy lab. This In separate way from the prescription activity of the physicians.

All in order to avoid risk of conflic of interest between the prescrictive funtion from the pharmacy practice

this produced the mandatory separation between the medicine and the pharmacy discipline : to the physicians - role in prescription of drugs and therapy and – to the pharmacyst the production and sell of the drugs .

But during the illuministic period , in the industrial revolution , the succes of medicinal chemistry MC since 1800 - 1900 make possible to shift the drugs production form the pharmacy to the more complex industry.

During all this periods many FORMULARY and then PHARMACOPEIA in various countries was introduced and adopted To make possible to get the adeguate quality of drugs produced, safety , reproducibility of the procedure. ( monography, methods of analisys ,table et other reported ).

This texts becomes mandatory by healthcare normative law in the various contests ( FU italian, FU european, USP, BP and many other examples ).

Also the competencies of who was involved in remedy preparation increased during the various centuries :

from botanic experties ( SCUOLA SALERNITANA in the VII -VIII century ) to the IATROCHEMISTRY principle

( PARACELSUS in XVI century ) since last 2 century with the born of the modern pharmacy and medicinal chemistry.

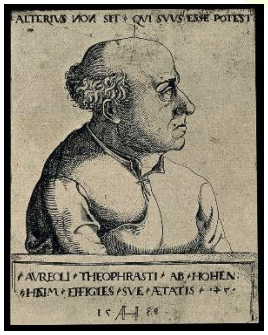



Fig. n 3 Paracelsus

Before the pharmacists, apothecaries that worked alongside with priests and physicians in regard to the patient care.

The history of pharmaceutical industry is well knowed starting form the introduction of the first SULFAMIDICS since the Actual last antivirals drugs ( for c-19 treatement).

But , related the last industrial pharmaceutical revolution ,various problem arosed :

not all pharmaceuticals industries produce drgus for all kind of subpopulation ( pediatric patients , swallowing problems in geriatrics, drug shortages).

So There is a needs for personalized dosages or personalized pharmaceutical form PPP ( for pediatric or geriatric patients) or to produce officinal formula: various reason are involved.

needs to introduce drugs in enteral nutrition NE

drugs not available form national or foreign producers ( in example due by national or international shortcomings )

some orphan drugs OD for some rare disease RD

specific needs of specific dermatologic products ( not produced by industry, not in the market )

Emergency products : in example lat gel , calcium gel, cardioactive oral suspension stokes for pediatry

cannabis preparates : CBD,THC ( various formulations)

some disinfectants and antiseptics formula

some antidothes ( galenics) , in ex Activated charcoal AC, calcium gel, KI cps and other

galenics and magistral for pediatry : Phenobarbital bs , caffeina bs, cardioactive and other API ( cps, oral suspension or bs ).

galenics for the metabolic urgencies in pediatry, rare disease .

some lab. reagents and solutions , buffers

some contrast agents for radiology ( sodium bicarbonate cps , citric acid )

odontoiatric galenics : like ipoclorite solutions, toluidin solutions

otorino solutions : lidocaine solutions , alcool boric solutions

solution used in ginecologic ambulatory : acetic acid 5% and strong lugol

and many other useful products.

Due to the failure of industry to cover all this situation the galenic lab. Is crucial and real opportunity.

Today also many pharmaceutical industry PI not like more to produce classic drugs as many cardioactive products and other registered drugs and the magistral product make possible to overcome this problem.

( expecially today whit actual economic crisis some producers are no more interested to produce registered drugs if the price is highly reduced for various kind of reason ) .

Also a great number of galenic formula GF are in use and currently in the hospital or in private pharmacy: corrosive products for dermatologist,, lugol, acetic acid solutions, alcool solution for lab, various reactives , phytotherapic derivates and so on .

Galenic Pharmacy GP also provides educational, scientific and research activities in the profile discipline – pharmaceutical technology to the pharmacy students or under specilization programs course SPC.

But observing international literature IL it is possible to see that the best clinical results are obtained when the lab. activity in production magistral formula by the phyicians is completed when available the clinical pharmacist and managerial competecies in the same team.

Galenics is the lab.process that turns an active ingredient (API) into a ready-to-use medicine that can be dosed as required for the various kinds of patients .

This to optimise their absorption.

It is knowed as the discipline (or science) of the dosage form design.

According Review

Braz. J. Pharm. Sci. 56 2020 https://doi.org/10.1590/s2175-97902019000418358

Preparation of extemporaneous oral liquid in the hospital pharmacy

Márcio Robert ,M. da Silva ,L.Pereira Dysars, E.Pereira dos Santos, E. Ricci Júnior

"At the hospital, the pharmacist is constantly challenged to prepare the extemporaneous solutions ES from tablets, capsules or drug powder DP for patients unable to swallow, Like as pediatric, elderly or patients that use nasoenteric NE or nasogastric tubes. The preparation of extemporaneous solutions ES from capsules, tablets and drug powder requires stability studies analysis"

Figure n 4 manual encapsulator

## SIZE OF CAPSULES

| Size | Volume in ml | Size in mm |
|---|---|---|
| 000 | 1.37 | 26.3 |
| 00 | 0.95 | 23.7 |
| 0 | 0.68 | 21.8 |
| 1 | 0.50 | 19.2 |
| 2 | 0.37 | 18.3 |
| 3 | 0.30 | 15.3 |
| 4 | 0.21 | 14.7 |
| 5 | 0.15 | 11.9 |

Fig. n 5 Fig. n 5 from j Mallik ,useful table to verify the volume for filling a capsula


| Size | Overall Capsule Lenght (in) | Average Mg Capacity | Volume Capacity |
|---|---|---|---|
| 000 | 1.029 | 800 -1600 mg | 1.37 ml |
| 00E | 0.996 | 600 - 1200 mg | 0.90 ml |
| 00 | 0.921 | 600 - 1100 mg | 1.00 ml |
| 0E | 0.909 | 462 - 924 mg | 0.78 ml |
| 0 | 0.85 | 400 - 800 mg | 0.68 ml |
| 1 | 0.764 | 300 - 600 mg | 0.48 ml |
| 2 | 0.693 | 200 - 400 mg | 0.36 ml |
| 3 | 0.618 | 162 - 324 mg | 0.27 ml |
| 4 | 0.563 | 120 - 240 mg | 0.20 ml |

Fig n. 6 usefultable to choose what size is to be used accordin amount of API is to be filled inside.

Figure n 7 cilinder use to measure volumes

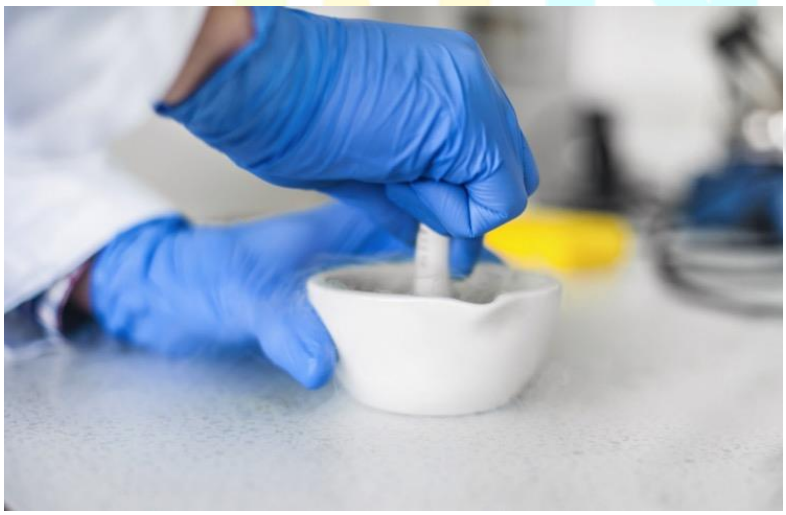


Fig. n 8 mortar and pestel

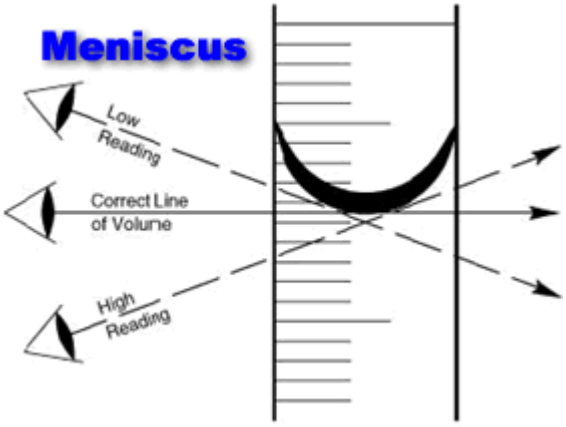



Fig. n 9 right method for measure of volume ( liquids) with cilinder

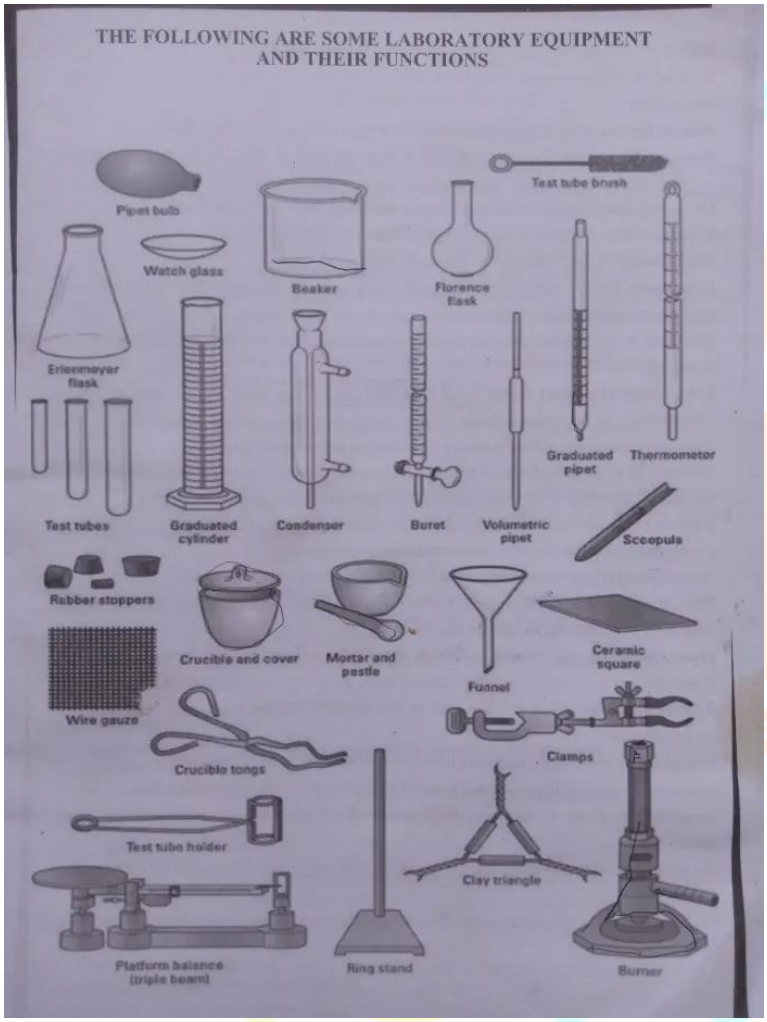



Fig. n 10 instruments and glases for galenic lab.

Fig. n 11

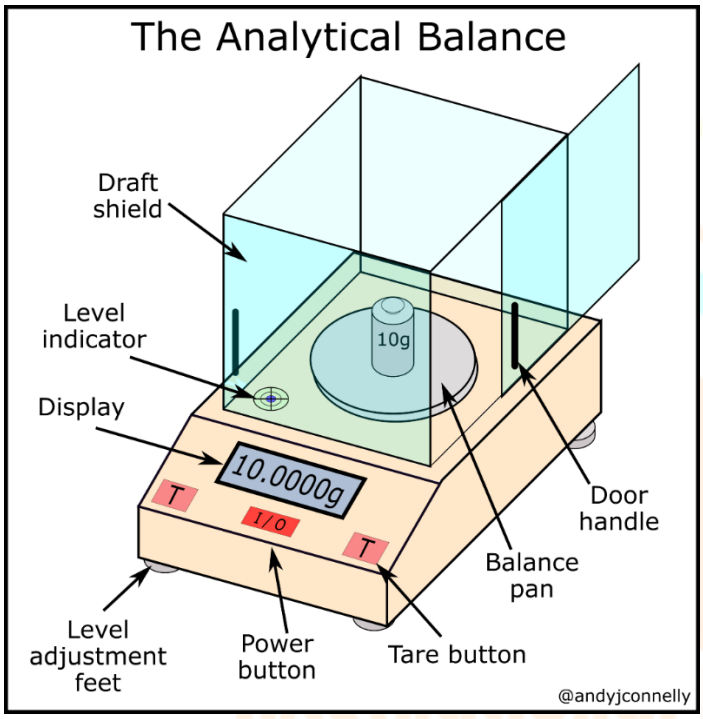



Fig. n 12

**The measure are crucial for API and eccipients :**

In example if tecnical Balance with sensibility 2 mg and admitted error 5% the minimum amount that can be measured :

2x100/5= 40 mg

**Aliquot Weighted method :** for measure of API under the precision level of the instrument :

1) Choose a multiple of the powder to be measured
2) Diluite with inert eccipient
3) Measure an aliquot of the diluited API + Eccipient

In example if needed 15 mg to be weighted:

15 mg x 20 = 300 mg ( multiplied for factor 20 )

Mix with eccipient 19 x 300 mg = 5700 gr

The global mixture is = 6000 mg

So it is necessary to weight a measure of 1/20 =300 mg that contain 15 mg of API

**CHAPTHER 3 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: Decreto M 18 NOV 2003

And are then reported some innovation in galenic field .

Finally a global conclusioni is submitted to the researcher related also innovations .

**CHAPTHER 4 RESULTS**

FROM LITERATURE

J Pharm Pract. 2021 Jun 15;8971900211023643. doi: 10.1177/08971900211023643.

Hospital Pharmacy Response to Covid-19 Pandemic in Italy: What We Learned From the First Outbreak Wave

Vera Damuzzo , Riccardo Bertin , D. Mengato , M. Chiumente , M. Rivano , A. Claudio Palozzo

DOI: 10.1177/08971900211023643

“ When C-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 the pharmaceutical care (PC) provided by pharmacists during the 1 th 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 care System HS .

A cross-sectional study work based on a web survey was conducted between May - Jun 2020 collecting information from the pharmacists, members of the Italian Soc. of Clinical Pharmacy and Therapeutics SCPT. 113 (11.4%) completed the questionnaire. The cohort was divided in 2 arms: pharmacists who worked in severely C-19 affected areas (High Spread Regions) and those 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 NSG, 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 Instit. and 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 HP .

Despite some limitations related to their clinical activity, pharmacists played a crucial role in supplying personal protective equipment PE, 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)

Croat Med J. 2014 Dec; doi: 10.3325/cmj.2014.55.662

Establishment of galenic laboratories in developing countries to produce high quality medicines: results of Aid Progress Pharmacist Agreement (A.P.P.A.®) Project

Francesca Baratta, A. Germano, G. Di Lascio, Richard Petieau,and Paola Brusa

"Aid Progress Pharmacist Agreement Project: aims in developing countries

Aid Progress Pharmacist Agreement 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 Turin and Italian community pharmacists. Its main task is the establishment of galenic laboratories (GLs) in hospitals of developing countries according to the principles of international health cooperation.

Aims of this Project:

- establishing GLs in DCs with the aim of preparing medicinal products MP that comply with the 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 PN;

-employing the local staff, teaching them a kind of a "new job," and opening a suitable school;

-minimizing the costs necessary to prepare these medicines formula MF

There are various relevant and important reasons why galenics should be used:

i) a low cost of the production system and simple kind of operative procedures OP;

ii) the possibility to adapt the dosages and pharmaceutical forms PF to the patients' needs and medical prescriptions;

iii) reduction in use of counterfeit medicines CM in the settings where the GL is located. "(7)

Study protocol 08 January 2018

Impact of collaborative pharmaceutical care on in-patients' medication safety: study protocol for a stepped wedge cluster randomized trial (MEDREV study)

Géraldine Leguelinel-Blache, C. Castelli, C.Roux-Marson, S. Bouvet, S. Andrieu, Philippe Cestac, Rémy Collomp, Paul Landais, B. Loulière, C. Mouchoux, R Varin, B. Allenet, P. Bedouch & Jean-Marie Kinowski

"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 MH , the clinical status CS , and the therapeutic adherence .

( change of galenic form due to swallowing problem, dose adjustment to the renal function RF ). After the collaborative meeting, the clinical pharmacist will check whether the prescriber has accepted his suggestions and modified the AMO. All the pharmaceutical interventions, the medication errors ME detected and the pharmaceutical suggestions of order kind of modification, will be collected and characterized in a standardized form according to the French Society of Clinical Pharmacy FSCP " (8)

JDDG: Journal der Deutschen Dermatologischen Gesellschaft

Topical preparations and their use in dermatology

J. Wohlrab 23 November 2016 https://doi.org/10.1111/ddg.13151

"The choice of a pharmaceutical (galenic) concept is primarily based on the requirements of the physico-chemical properties PCP of the active ingredient API to be applied.

The fixed combination of API in topical preparations is suitable for only a limited numb. of clinical treatment scenarios." (9)

Hospital Pharmacology. 2015;

Information on the Quality of Substance for the Preparation of Pharmaceutical Drugs in Terms of

Hospital Pharmacy M. Dj. Jovović , M. M. Ribar

"Compliance with the national legislation, like as establishing compliance prescribed by the

Eu legislation EL in the field of drug development is binding.

All manufacturers of drugs and/or API must apply quality standards prescribed by the European Pharm. 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 the harmonizing national legislation NL in order to improve conditions for

the preparation and production of galenic drugs GD in terms of inpatient health institutions HI

performed in a manner that is prescribed by international regulations IR . 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)

ORIGINAL ARTICLE

DOI: 10.1016/j.rppede.2016.02.012

Magistral drugs in hospitalized newborns and children

Medicamentos magistrais em recém-nascidos e crianças hospitalizados

A. Cabral de Souza Pereira, Elaine S. Miranda, S. Rodrigues de Castilho, D. Omena Futuro, Lenise Arneiro Teixeira, G. 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 forthis such preparations as a pediatric therapeutic alternative PTA in this hospital."(11)

Dooms, M., Carvalho, M. Compounded medication for patients with rare diseases. Orphanet J Rare Dis 13, 1 (2018). https://doi.org/10.1186/s13023-017-0741-y

04 January 2018

"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 needed."(12)

Pharmaceutics. 2021 Apr;

2021 Mar 26. doi: 10.3390/pharmaceutics13040448

Medicine Shortages in Serbia: Pharmacists' Standpoint and Potential Solutions for a Non-EU Country

Nataša J. Lješković, A. J. Galović, S. Stojkov,Nikola Jojić, S. Gigov

Umberto Musazzi

“Backup manufacturing on a small scale (magistral and galenical) could be a good way to overcome some kind of drugs shortages.”(13)

Pharmaceuticals (Basel). 2022 Jan

Mini-Tablets: A Valid Strategy to Combine Efficacy and Safety in Pediatrics

Guendalina Zuccari , Silvana Alfei , D. Marimpietri , V. Iurilli , Paola Barabino , L. Marchitto

DOI: 10.3390/ph15010108

“In treatment of pediatric diseases PD , mass-produced dosage forms are often not suitable for children. Commercially available medicines CAM are commonly manipulated- mixed with food by caregivers at home, or extemporaneous kinds of medications are routinely compounded in the hospital pharmacies HP to treat 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 relevance . For these kind of scope solid formulations SF 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 research work deals with the different approaches that may be applied to develop mini-tablets MT intended for pediatrics with a focus on safety of the excipients. Alongside the various conventional method of compression, 3D printing system 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)

Volume 174, July 2021

Advanced Drug Delivery Reviews

Translating 3D printed pharmaceuticals: From hype to real-world clinical applications

Seoane-Viaño , S. J. Trenfield , A. W. Basit , A. Goyanes

https://doi.org/10.1016/j.addr.2021.05.003

“Three-dimensional (3D) printing offers the potential to revolutionise 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 the patient needs . By using a 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 personalised dosages PD , drug combinations , geometries and release characteristics ; a concept which is currently unattainable and cost inefficient with conventional manufacturing technologies CMT ( tabletting, encapsulation). This kind of technology has been forecast to disrupt a wide range of pharma applications, ranging from expediting the drug development process DDP and providing benefits for pharmaceutical manufacture, to on demand printing of personalised medicines PM on the front-line and in hard-to-reach areas . “(15)

International Journal of Pharmaceutics

Volume 569, 5 October 2019

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

Christoph Nober , G. Manini , Emeric Carlier , Jean-Marie Raquez , S. Benali , P.Dubois , K.Amighi , J. Goole

https://doi.org/10.1016/j.ijpharm.2019.118581

“The purpose of this research sudy work was to investigate the feasibility to manufacture enteric capsules EC, which could be used in compounding pharmacies CP , 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 system 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 HME was used to make printable enteric filaments. They were made of the enteric polymer, a plasticizer and a thermoplastic polymer: Eudragit® L100-55, PEG 400 and polylactic acid, respectively.

Riboflavine-5′-phosphate was selected like as a coloured drug model to compare the efficacy of the 3D printed cps 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 EC did not release the drug for 2 hours 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 Eur.Pharmacopoeia EP 9th Edition for enteric products.”(16)

Examples of some pharmacetucial forms prepared in pharmacy galenic lab ( non sterile ):

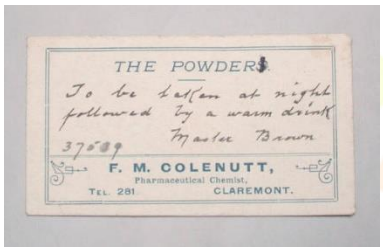



Fig. n 13 envelope of prescripetd powders

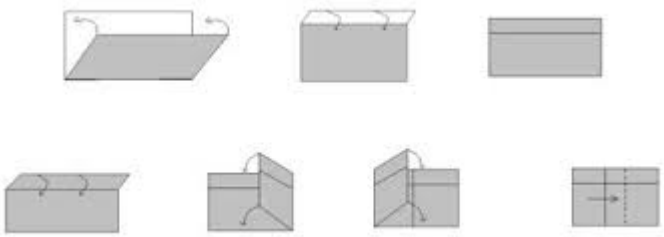


Fig. n 14 cartine-ENVELOPE containing a dose of drug ( as pharmaceutical form)


Fig. n 15 Phb ( pediatric envelopes)

Preparation ( only for registered pharmacist): calculate the API needed for requested number of envelopes add with the eccipient needed.

Mixing well ( with geometric diluition methods )in mortar with pestel for the time needed to get a really mixed powder ( it can be used a little part of alimetar colour to veryfy the procedure).

The divide into the all encelopes : weighing every single one.

Verify also watching the all envelope before close : to verify the amount in visual method.

Close the envelope, label, add the prases : narcotics, and put at distance form children.

Other kinds of preparation:

Powders :Activated charcoal sachets 30 gr -5 gr -1 gr as antidothes for emergiencies department.

Procedure : weight the AC for single sachets , fill, close , label

Other example : caffeine envelopes for newborn

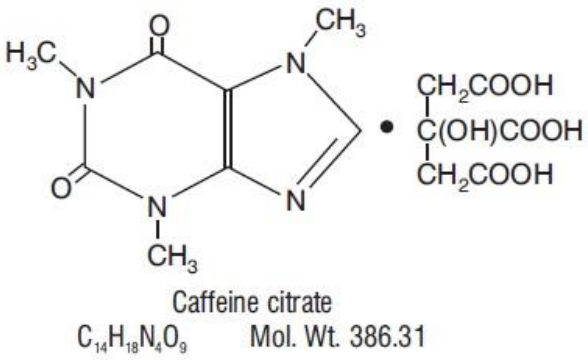



Fig n 16

Paediatr Drugs. 2001;doi: 10.2165/00128072-200103010-00005.

Caffeine citrate: a review of its use in apnoea of prematurity

A M Comer , C M Perry, D P Figgitt

"Caffeine citrate was generally well tolerated by neonates in clinical trials and it decreased the incidence of apnoea of prematurity compared with placebo. It has demonstrated similar efficacy to theophylline, but is generally better tolerated and has a wider therapeutic index TI . Caffeine citrate should, therefore, be considered the drug of choice when pharmacological treatment of apnoea of prematurity is required"

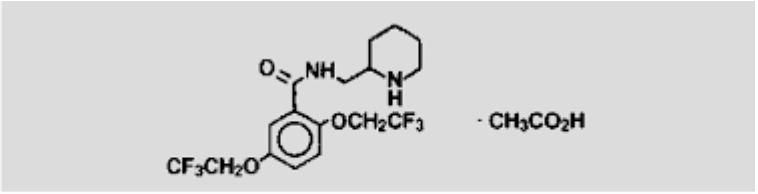


Figure 1. Graphic formula of flecainide acetate.

Fig. n 17 example of cps Flecainide pediatry

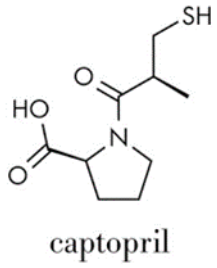



Fig. 18 pediatric cps or oral solution


Fig. n 19 oral solution

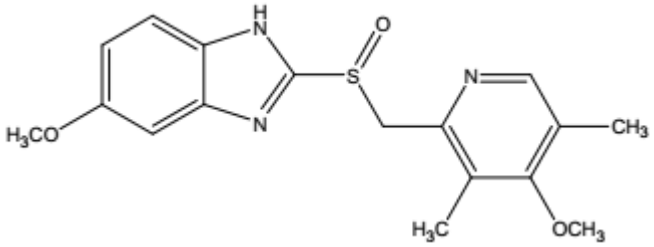



Fig. n 20 Omeprazole

**Of interest the profile related PPI : related the gastroresistance needed:**

Omeprazole

Neal Shah; W. Gossman. Feb 7, 2023.

Continuing Education Activity

"Omeprazole should be ingested 30 to 60 minutes before meals. It may be taken with an antacids. When taken twice daily, the first dose should be before breakfast and the 2nd dose before dinner. The cps and tablet should be swallowed whole, not crushed or chewed."

Related stomach Physiology it is of interest to read :

Neurogastroenterol Motil. 2019 Apr doi: 10.1111/nmo.13546

Advances in the physiology of gastric emptying

Raj K. Goyal, Y. Guo, H. Mashimo

"GASTRIC EMPTYING IN THE INTER-DIGESTIVE PERIOD

In the inter-digestive (fasting) period, gastric motility designed to clear the stomach of undigestible residues. It is characterized by a cyclical motor activity called the migrating motor complex (MMC). The MMC is divided into 4 phases. Phase 1 lasts approximately 45-60 minutes, during which the peristaltic pump exhibits electrical slow waves that are not associated with the muscle contractions. Motor quiescence is due to tonic inhibition of the motor activity. Phase 2 is associated with slow waves associated with frequent phasic contractions. Phase 3 (also called "activity front") is characterized by a front of large amplitude contractions, lasting 5-15 minutes that march toward the pyloric sphincter. The phase III of the MMC is neurally mediated and is independent of the slow waves."

**GASTRO -RESISTANCE rigid capsules and DELAY RELEASE**

Some API are gastro lesive ( fans) and some other are inactivated at PH gastric ( omeprazol and other PPI, pancreatin).

Budesonide for example need an intestinal release.

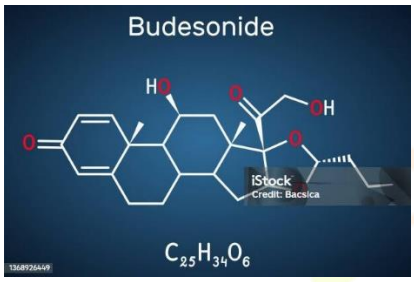



Fig. n 21

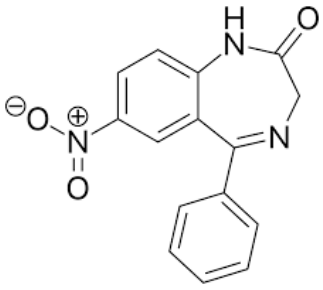


Fig. n 22 nitrazepam pediatric cps

**Related the Capsule as pharmaceutical form in pharmacy :**

very used in galenic labs , this can mask odour and taste of various API

This can dissolve themselves in GI tract , and can be easlity prepared in pharmacy also with manual ecapsulators.( low cost even if imply pharmacist time to produce) .

About in 15 minutes the hard gelatine capsule dissolves in the stomach.

There are 3 kinds of gelatine cps : hard cps, gastro resistence cps, prolonged or delayed release cps.

There are cps of gelatin or idrossipropilmetilcellulose (HPMC = ipromellosa) (V-caps), plus colorant and mattifying.

This can be filled with API and eccipient particle acido resistance coated or covering the capsules after filling the API+ eccipient with specific acido resistance treatement.

In every way It is necessary to consider that :

acido resistance cps are not gastro resistance , because the acido resistence cps dissolve themseves in about 30 minutes at PH acid like the stomach.

Delay release capslues are diffrent from gastro resistance .

For this reason it is necessary to consider some concept:

**In the GI tract there are various PH environment :**

gastric PH 1-3

duodenum 5,6-8

Small intestine 7,2-7,5

Colon 7,9-8,5

In article : Dan Med Bull. 1999 Jun

Intraluminal pH of the human gastrointestinal tract

J Fallingborg

Is reported :

“The intraluminal pH is rapidly changed from highly acid into the stomach to about pH 6 into duodenum. The pH gradually increases in the small intestine from a pH 6 to about pH 7.4 in the terminal ileum. The pH drops to 5.7 in the caecum, but again gradually increases, reaching a pH 6.7 in rectum.”

So the ACIDO RESITENCE caps are not to be considered as gastro resistence because in 30 minutes this start to realese API in gastric environment .

**The italian pharmacopea for gastro resistance require AT LEAST 1 hour of integrity in HCL 0,1 N solution under mixing.**

Then in phosfate buffer at 6,8 ph they must to disaggregate in 1 hour.

The classic hard gelatine capsule start to disaggregate in 15 minutes about.

**For preparation of gastro resistance capsules can be used according National italy tariffary in use** :

a) capsule in other capsules method : prepare normal gelatin capsules with inside API and eccipients then put inside this into other acido resistance capsules of superior measure

CPS acido resistance HPMC : 30 minutes resistance in acid environent + 15 minutes normal resistance of hard gelatine = tot 45 minutes

There are experimental proof about efficacy of this method

b) Prepare a normal gelatin capsule with API and eccipient inside and then, after closing threat with cellulose acetoftalate 8% in aceton ( there are instrument to do this . This proceure Must to be repeated at least 2 times : for 30-40 sec in the first step and 20 sec in the second then filtered with gauze ).

Doi: 10.4025/actascihealthsci.v35i2.14581

Acta Scientiarum. Health Sciences Maringá, July-Dec., 2013

The importance of coating standardization in gastro-resistant capsules produced in magistral pharmacy

Suelen Cristina Franco, Flávia Cristina da Silva, Marcela Maria Baracat, Rúbia Casagrande

Janice Aparecida Rafael and Daniela Cristina de Medeiros

“it was observed that the cps coated with cellulose acetate phthalate 10% complied with the pharmacopeia’s disintegration specifications required”

Fig n 23 from Santarelli E.

Other interesting method:

using an ACIDO RESITANCE capusle but using as eccipient METOLOSE 90SH hydroxipropil metil cellulose HPMC at high viscosity ( at 10%) in order to increase the global acido resistance ( see Bettiol) or metilcellulose with similar viscosity.

This because in the acido resistence cps the closing system is not able to stop the acid entrance in the capsule.

And in article : Enteric Dissolution Enhancement of Engineered Gastro Resistant Omeprazole Tablets usingHydroxypropyl Methylcellulose Acetate Succinate 2021
Sagar Kumar Mohapatra , Rudra Narayan Sahoo, S.Mallick , Rajaram Mohapatra : is reported

“Omeprazole gets degraded in the stomach;to prevent this enteric coating was done employing
HPMC. This formulatory approach can be transferred to the local pharmaceutical industries.”

dealyed release capules : is used EUDRAGIT type RL to cover capsules produced.

In article : Study of a delayed-release system for hard and soft capsules coated with eudragit® s100 acrylic polymers

Luciana Arantes , Soares Eduardo Crema Universidade Federal do Triângulo Mineiro, Brasil

Acta Scientiarum. Health Sciences, vol. 42, 2020

Is reported :"The findings demonstrate the pharmaceutical application of the Eudragit. S100 in the modification of the coating and the preparation of a delayed-release system of hard and soft capsules, thus enabling ileal release of active ingredients."

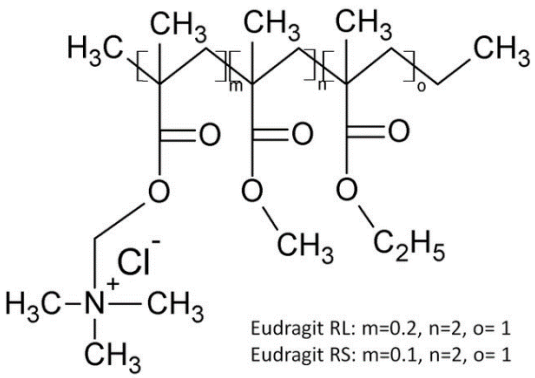



Fig. n 24 From T.QUINTEN

Pancreatin cps : is needed gastroresistance to avoid inactivation of the API

(Units for gr)

**Other kind of cps** : Veg caps , for consumers that have dietary restrictions against the consumption of animal byproducts

**Procedure to prepare hard cps in galenic lab** ( only for registerd pharmacist ) :

according the amount of API in one single cps use the righy size of cps , verify if needed a normal hard gelatine cps or gastro resistance or delay release based on the API .

Calculate the global API neded for all the cps required , Based on the number of cps asked by physician

Using the volume method : volume filling for 1 cps X total n. cps to be prepared ( V TOTAL)

Add eccipients ( in example cellulose microcristalline or other ) to the API since volume total with a cilinder .

Mix very well for the time needed.

Using encapsulator , after charging the empty gelatin cps , open and fill the cps with the really mixed powder ( API + eccipients): use the method at fall.

Verify all cps are equally filled then close them according the procedure .

Perform the quality control required by pharmacopeia : number of dosis forme, mass units uniformity and all required , then label.

In is important to **SIEVING of the powders :** API and eccipients, in order to avoid aggregates

For Volume tipe 0 cps = 0,68 ml for 1 cps 100 cps = 68 ml capacity

**Mix THE POWDERS**: mortar and pestel, V type automatic mixer, Container shaked manually

Between the **Eccipients for  hard gelatin capsules** :is is possible to see :

diluents
glidants
lubrificants
disgregants
tensioactives

for igroscopic API (  es ammonio clorure ) it is used colloidal silice

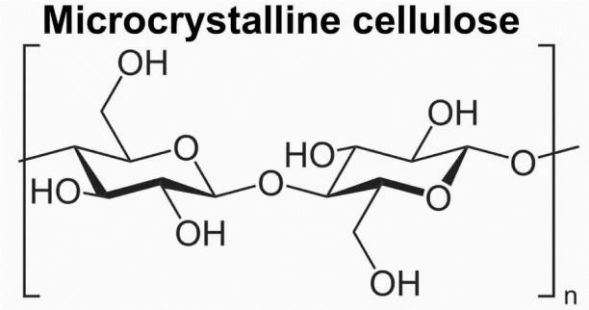



Fig .n 25 eccipient

**Right MIXING  procedure of the powders** : API and eccipients : using the geometric method diluition

Mortar and pestle or mechanical powder automatic systems  ( 3D type or  V typer o other )

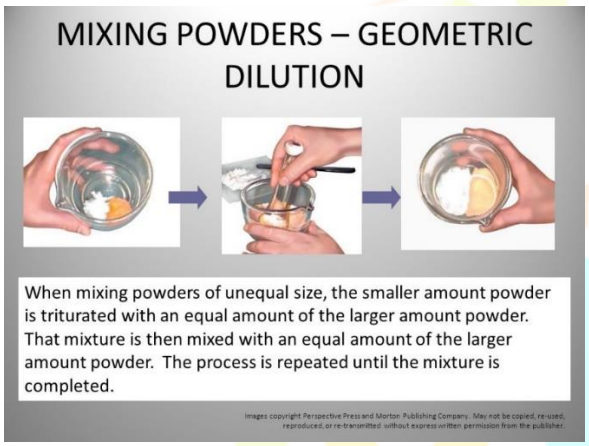



Fig n  26


Fig n 27

Use of alimentar colour to chek the level of mixing

**Filling procedure of cps** : to be used the volume methods (or weight method if already validated).

This because the variuos powders and API used have different apparent density.

It is needed to beat the cilinder with the powder three time before read the level.

**Saggi previsti dalla FU XII edizione**
**Capsule**

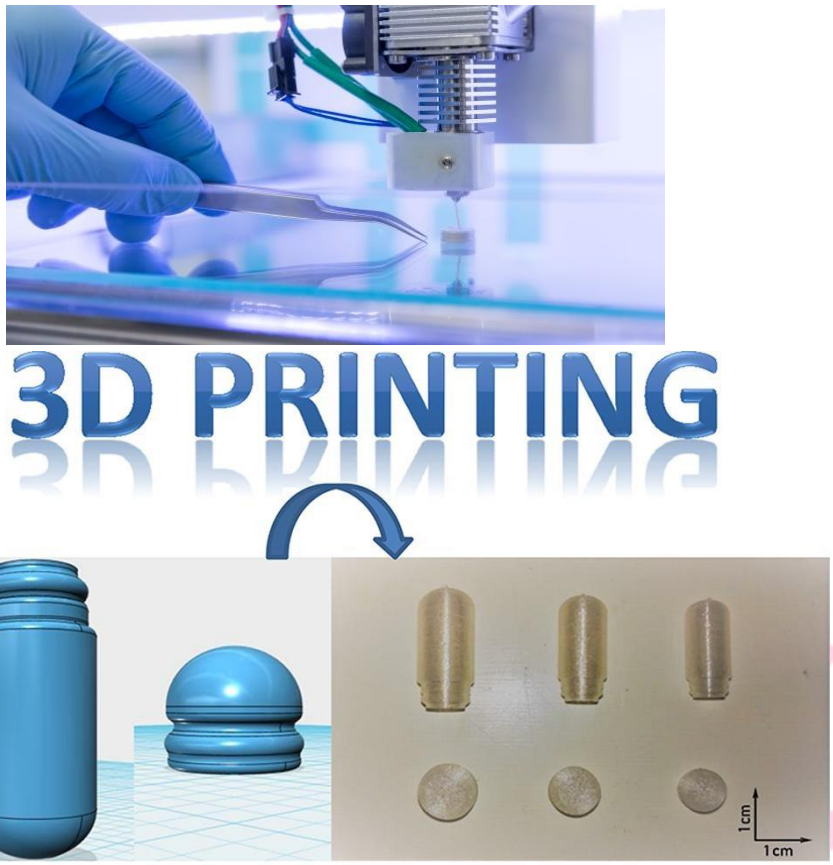
Uniformità delle unità di dosaggio 2.9.40
Uniformità di contenuto 2.9.6
Uniformità di massa 2.9.5
Dissoluzione 2.9.3
Disaggregazione 2.9.1

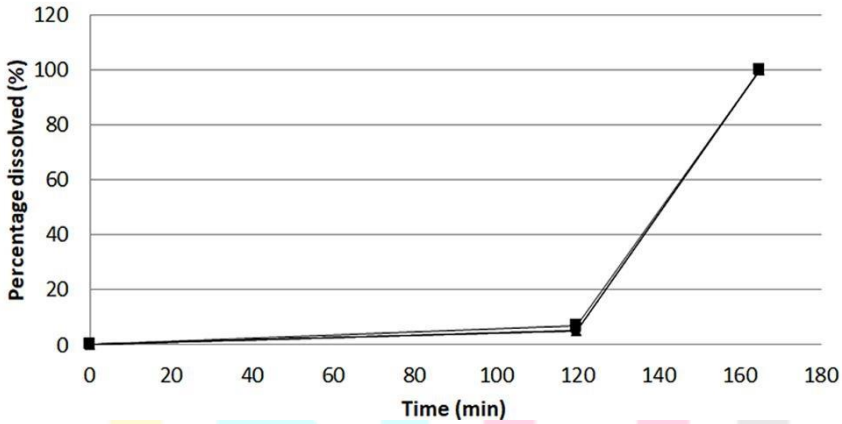
**Conservation of the cps** : in dry and fresh environment , no more then 30 grades

Other examples of cps for radiology : cps of sodium bicarbonate and cps of citric acid as MDC.

**Spatolated cp:** in example sildenafil 25 mg , API is first accurately mixed with a specific base , then moistened with other specific product then spatolated into the apposite instrument.

Innovations: the 3 D printing systems




c)

Fig n . 28 from https://doi.org/10.1016/j.ijpharm.2019.118581

Some lab glassware or instrument :

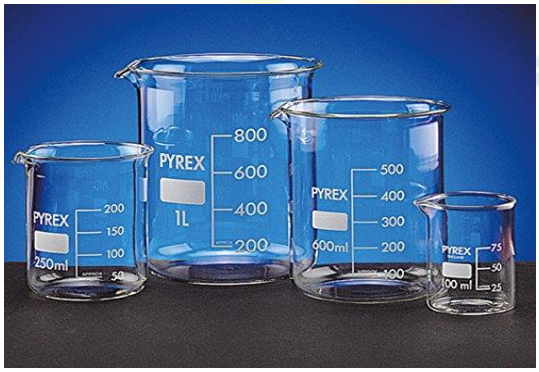



Fig. n 29 glass beker

Fig n 30 cilinder

Fig. n 31 graduated pipett

Fig. n 32 cream jar

Fig n 33 spatule for cream and ungents

Fig n 34 alluminion tube for gel

Fig n 35 suppositories moulds

Fig. n 36 sieves for powders

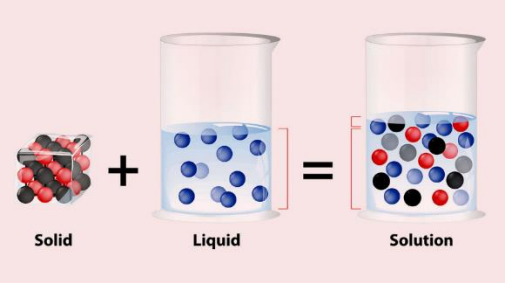



Fig n . 37 solutions

In example : acetic acid solution 5% for ginecologic ambulatory

Preparation : add the water then the acid needed , then mix well , fill the bottle and label

Write : external use, corrosive .

KOH solution and TCA solutions for dermatologic use

Boric alchool 3% in ETOH at 60%

In example DTT solution for trasfusional wards :

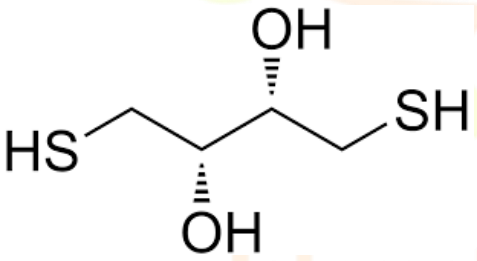



Fig n 38 ditio treitol

Preparation : PREPARE BEFORE pbs buffer with water required , then measure the amount of DTT necessary and add to the PBS buffer. Fill the bottle and label , to be stoked at 2-8 centigrades.

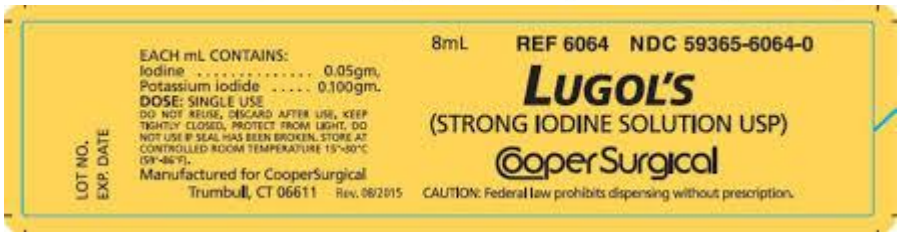



Fig n 39 strong lugol solutions

HO–OH

hydrogen peroxide

Fig. n 40 peroxide of hydrogen solution

Other example of solution preparation : Toluidin 1% solution for detect oral lesion, Ipoclorite solution in water for dentistry

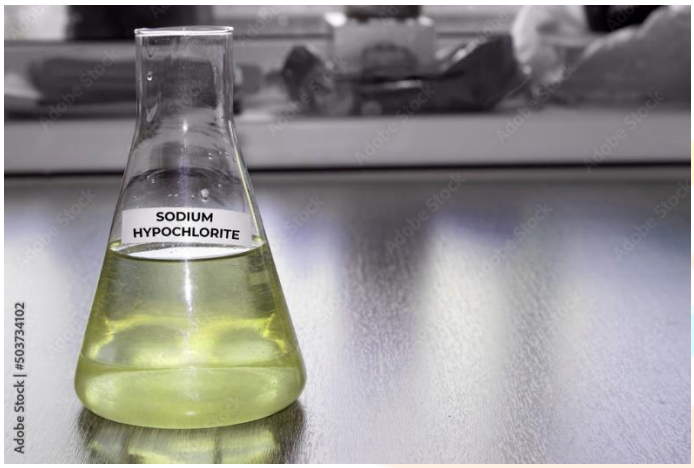



Fig n 41

JOULIE SOL ORAL: sodium fosfate bibasic dodecaidrate 17,04 gr , ac fosforic 85% 5,68 gr , water qb 100ml

For ipofosfatemia and ipercalcemia

TCA solution : tricloro acetic solution 50 % in dermatology

J Clin Pharm Ther. 1992 Jun;17(3):185-9. doi: 10.1111/j.1365-2710.1992.tb01291.x.

Stability of captopril in some aqueous systems

Y Pramar , V Das Gupta, C Bethea

"Captopril solution prepared in water using tablets was stable for about 20 days when stored at 5 degrees C, and that prepared using powder in water was stable for about 27 days."

Captopril 1 mg/mL Oral Solution

Amanda Ye, RPh, PharmD Medical Director–Health Professional Digital Education

Staten Island, New YorkUS Pharm. 2024;49(2):59-60.

FORMULA

**Captopril 1 mg/mL Oral Solution**

| Rx: | Ingredient | Quantity |
|---|---|---|
| | Captopril 50 mg | 2 tablets |
| | Ascorbic acid 500 mg | 1 tablet |
| | Purified water | qs to 100 mL |

"Stability: The USP default beyond-use date for preserved aqueous oral liquids is 35 days. However, according to captopril stability studies, this formulation is stable for 14 days at controlled room temperature and for 56 days when refrigerated."

**GTT :** in example nifedipin gtt


Fig. n 42 suspensions

**Suspension as pharmaceutical form :** dispersion of a solid (size from 0,5-1 to 100 micrometer ) in a liquid

( the solids particle are Insoluble).

This pharmaceutical form are easy to be swallowed, mask unpleasant taste , viscosity adeguate .

The oral suspension with API powders are mixed i mortar and pestes with an suspendig agent then added the acqueous phases ( with the rest of idrosoluble eccipients) to get the final volume .

In use Flocculants agents ( repulsion force ): elettrolites, tensioactives , polimers ( cellulose derivates, gomme adragante, arabica, gelatina)

Other eccipients used can be preservatives , antioxidants, aroma and edulcorants.

Are available ready for use basis for oral suspension whit right stability during time.

Crucial to label the preparation adding the phrase: " shake before the use "

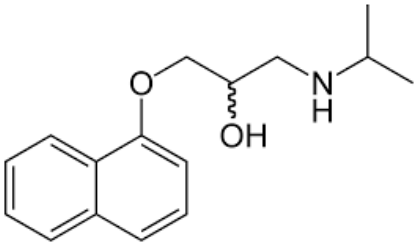



Fig. n 43 propranolol beta bloker - pediatric cps or oral suspension or solution

(It is possible to use ready for use basis for oral suspension available in commerce )

Quality control for suspensions:

Granulometry, sedimentation and re- suspendibility, viscosity, density ,accelerated aging, API tituli

Other example SULFADIAZINE ORAL SUSPENSION : use the API in cp , mortar and peste, then add water

To better solve API ( ex 40 ml ) , mix well and add base ready for use to the final volume .

Verify there are not aggreates before fill the bottle.

Captopril oral suspension : generally stable 14 days

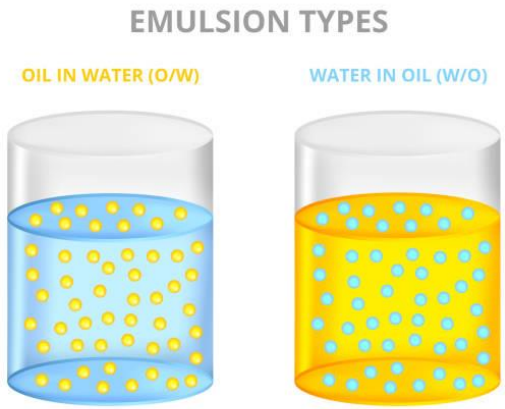



Fig. n 44 emulsions ( methods ENGLISH and Continental)

**Emulsions as pharmaceutical form** : a liquid , dispersed phase into other liquid , disperdent phase not mixable whit it

Use : oral and external : emulsion of olea of castor oil, bases for skin emulsion

Preparation : set the tensioactive and its concentration, dispersion of the phases, dissolution of idrosolubile component in water phase and the liposoluble in olea phase, dissolution of tensioactive in acqueso phase or oleous .

Are used mechanical mixer, ultasonic, omogeneators

Modifications: creaming, flocculation, coalescence and rupture

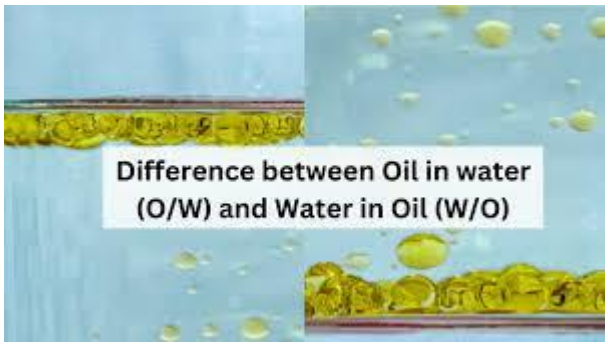



Fig n 45

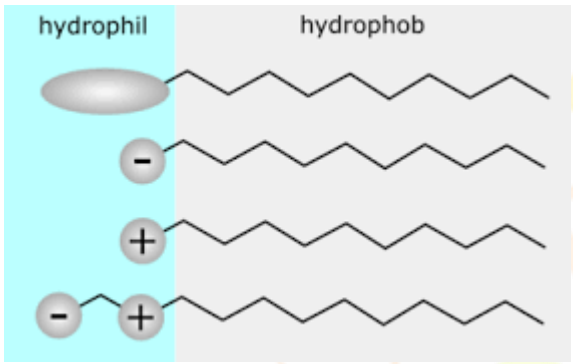



Fig. n 46 tensioactive

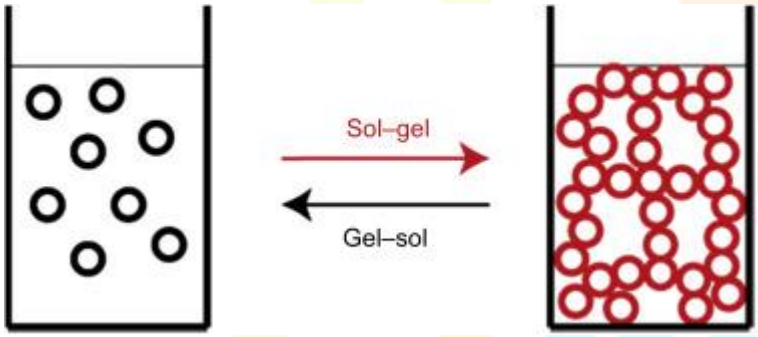



Fig n 47 gel

**GELS in galenic labs**:

colloidal dispersion,the disperse phase impeded in the movement hold the disperdent phase inside.

(Gel idrophila or idrofobic)

Gelificat used at 0,5-2% , the methods of preparation depends on the kind of gelificant used

Carbopol must to be slowly added in water under mixing, gelatin need hot water, metilcellulose need hot water and mixing.

Polimer used: gomma guar, pectine, alginate, carragenine, gomma xantano, gelatina , amido, carbopol, natrosol ( idrossietil cellulosa), HMPC

Are needed preservants to avoid microbial contaminations.

Es.of formulation LAT GEL for wounds is a topical anesthetic : of Lidocaine, Epinefrine, , Tetracaine that is used in conjunction with suturing patients in hospital emergency rooms, CALCIUM GEL ( used in hospital emergency ,antidote for fluoridic acid burns ).

Other example : xylocain viscose oral gel 2% for oncological patient ( after radiotherapy or other )

API at 2% , eccipient idrossetil cellulose in preserved water .

**Creams:**

multiphases, 2 phases lipofilic and acqueous

2 types : water in oil or idrofobe , occlusive , greasy and oil in water or idrofilic , washable with water

Ex cetomacrogol base cream : vaselin, paraffin, alchool cetosterilic,macrogol 1000 ,water

Fusion first of the 4 component then emulsioning of the water at the same temperature, mix well.

**Unguents** :

semisolids, that melt at body temperature

They can be idrophobe ( for dry skin or lesions , increase idratation, are emollient ,occlusive) this are more persistency then cream , or hydrophil (in ex PEG based , non occlusive)

Hydrofobe: vaselin, paraffin, vegetal oil, cere

Unguent that absorbe water : emollient , occlusive : lanolin, sorbitan ester

Ex macrogol base unguent FUXII ED peg 4000 40 gr + peg 400 60 gr, heat at fusion temp then mix since solidification

**PASTE**

Usually this contain at least 20% of solids. Generally are used oleose basis and it is required to heat up

**LASSAR PASTE :** use mortar and pestle, micronizate well the powders , sieve ,melt vaselin and incorporate in portion the mix of the powder , mix well since cooling dawn. Used in eczema

**SUPPOSITORY :** ex glicerole supp , 2,5 gr - glicerolo 85% 90% and ecc. 10%

**OVULA:** in ex lattic acid ovula, composition ac lattic, gelatin, glicerin , water

**RECTAL MICROCLISM :** diazepam , anticonvulsivant in emergency pediatry

Ex of formulation API needed plus clisma base ready for use.

**COLLIRIA :**

this preparates need sterility , so it ca be prepared **only** if the lab meet the normative rules prescriptions.

Are used specific software for the calculation, is needed a bilance with precision of centesime of mg

Needed white chamber or isolator according full NBP and GMP, whit ZONE A,B,C,D, in sovrapression, closing system that avoid simultaneous opening of the doors. Needed chesk system for Pressure .

( It must to be verified regularly ) , in a HEPA hood vertical flux .

Before the hood use and after : treat with ETOH 70 % the inside of the the working environment.

(Used also wood UV ligth ).

The pharmacist must use mask ffp3 , sterile sovra shirt, sterile gloves and all is required.

All operation are performed in sterile conditions, with final filtration with filter 0,2 micron.

Are used sterile final bottle opened under the hood.

Conservation of the final product 2-8 grades.

They need strictly sterility, specific tonicity ,PH, viscosity adeguate, preservation for microbial contamination

Es cyclosporine colliria 1%

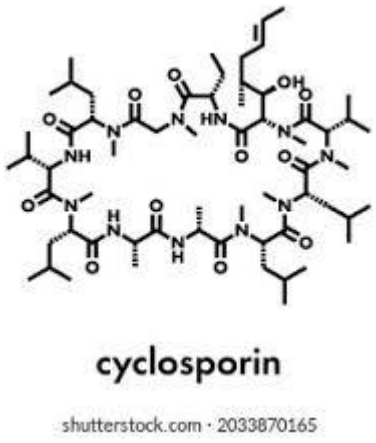



Fig. n 48

Diluition of the resitered drug , in artificial tears. Conservation 30 days at 2-8 grades

Amfotericine B colliria 2,5 ml / ml

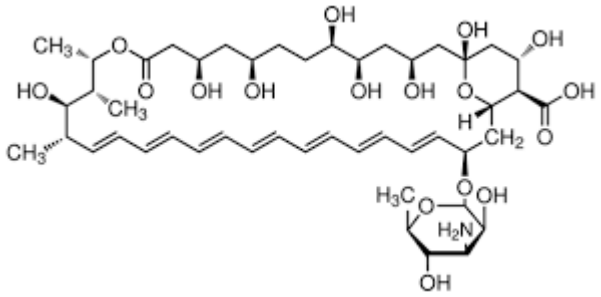


Fig. n 49

Reconstituition of the drugs Fungizon 50 mg with 2 ml Water PI , then remove in sterile way 1 ml

And diluite this solution with 9 ml PI water. ( see SIFO formulation)

To better understand the need of strictly sterile conditions to be followed for this kind of pharmaceutical form it is Interesting to read this article : Wolters Kluwer HEALTHMAY 29, 2015

Sterile Compounding Oversight Changes Since the 2012 Meningitis Outbreak

In 2012, contaminated injections made by a compounding pharmacy in Massachusetts sickened 751 people in 20 states and led to the death of 64.

“Since then, new laws and increased regulations have tightened oversight of compounding pharmacies to provide greater protection of patients and limit the possibility of another outbreak.”

Other device and instrument used in galenic labs:

Fig n 50 fusion point

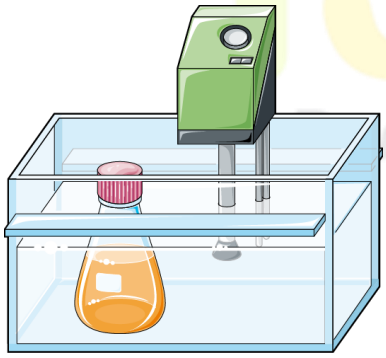


Fig. n 51 baign marie

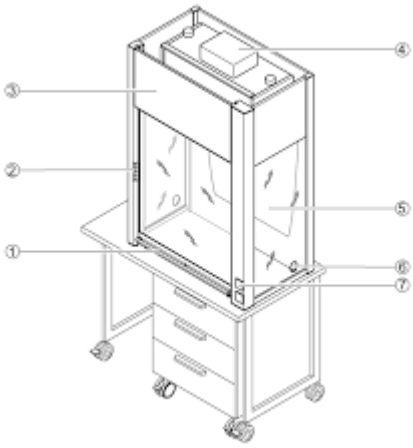


Fig. n 52 classic chemical hood

## CHAPTHER 5 Practical project

In this part are analyzed the italian normative rules ( NBP ( NORME DI BUONA PREPARAZIONE) ) and the semplified as DM Salute 18.nov.2003 norme di buona preparazione" applied by law as mandatory in the galenic lab setting inside the pharmacy ( public, private – hospital , comunity ).

(NBP ( NORME DI BUONA PREPARAZIONE) or GMP good manifacturing practice)

The GMP philosophy are based essentially on :

documentation of all the process , registrations, every phases of the process, activity , since the single operations.

- team must receive an adeguate practical training , formalized , WRITTEN REPORT

-responsability must to be clearly identified and documented, under the responsability of the director

-Quality of thte API and eccipients must to be certified

- cleaning and sanitization procedure ( lab, instruments, glassware)

-Regular check of the instruments, documentation

- process validation, procedure of

- NC non conformity :management of this

So In italy by law the pharmacist that work in a galenic lab. according DM 22/06/05 must to follow or the FULL NBP ( NORME DI BUONA PREPARAZIONE) of ITALIAN FU ( more complex) or DM Salute 18.nov.2003 ( if not sterile magistral preparations or officinal reduced scale )

The pharmacy that prepare non sterile magistral formula NSMF or officinal reduced scale can follow or full NBP ( NORME DI BUONA PREPARAZIONE) or semplified NBP ( NORME DI BUONA PREPARAZIONE).

Instead if prepared the sterile products , toxic preparates , poison molecule , anticancer drugs and radiodrugs, it must to be used biological hood : it is mandatory to follow full NBP ( NORME DI BUONA PREPARAZIONE).

For non sterile products NSP it is possible in italy to deviate from full NBP ( NORME DI BUONA PREPARAZIONE) and to follow the semplified rules if it is possible to keep under control all the process , prooving it. ( quality efficacy , safety depends on organization and consistent control) .

First NBP ( NORME DI BUONA PREPARAZIONE) was introduced in (FU IX ed.)1989.

In the chapter 795 of USP, pharmaceutical compounding of non sterile products NSP , related the difficulty of the preparations, its stability , storage conditions, dosage form FF, complexity in calculations,sistemic, topic use, risk level for pharmacist, damage risk for patients are classified 3 general situations :simple compounding , moderate and complex compounding .

It is request to produce the master formulation records and also the compounding record.

Like NBP ( NORME DI BUONA PREPARAZIONE) the USP rules are based on the quality of the final products and on the documentation of all the process.

Some preparations at high microbiological quality need to be prepared in zone with HEPA FILTER HF according the regulatory rules in force .

A translation of Semplified NBP ( NORME DI BUONA PREPARAZIONE) an its phylosophy (DM Salute 18.nov.2003 ) and their meaning are reported

Results :

translation of the meaning of the NBP ( NORME DI BUONA PREPARAZIONE) procedure semplified DM 18/nov /2003

Application field :( non sterile magistral NSM and officinal forms reduced lots) for hospital and comunity pharmacy

medical prescription for magistral formula MF and Pharmacopeia for Officinal reduced scale production

Preliminar evaluation about opportunity -possibility to prepare the galenic requested or needed

( avaiability of API and eccipients)

definitions: magistral formula, officinal, reduced batch RB

lab hygienic written procedure, frequency of this ( provided by director of the pharmacy or lab. Responsible).

lab area: it must to be adequate to the kind of the galenic products produced, ceiling and walls wahable

it can be in a separate room or not separate inside the pharmacy.

Instruments: mandatory list according PHARMACOPEA uff. ITALIAN table n. six , the measure insntrument 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 contaniners PC).

Raw material RM : chemical denomination, date of arrive into the pharmacy lab , batch number , expiration date or date of retitulation, certificate of analisys CA signed by producer ( according pharmacopeia quality requirement), conservation condition or use, date of first use . ( it is necessary a register of raw materials , eccipients and API, with a progressive numeration).

The empty container of the raw material must to be keeped for SIX month after final use.

Fulfillments ( preventive and after setup ) to the preparations .

Prescription verify, according the normative requirement , sign of phisician, iperdosages verify ( according table n. 8 pharmacopeia italy), Incompatibility verify , the possibility to prepare into the lab.

After setup: to be writed on the prescription the progressive number of the preparation, date of the praparation, expiration date, the eccipients used, precautions and cautions, then label must to be attached.

Sign of the pharmacist in the label , on the prescription or in the working sheet

Labeling – batch numb. and expiration date, composition qualitative quantitative , API

Eccipients , date limits for use, precautions, storage condition

Price ( for comunity pharmacy)

Douments storage - ( time ) , emplty bottle .

The written prescritption must to be keeped into the pharmacy for 6 month and the same working sheet.

(working sheet).

The prescription of narcotics must to be keeped in pharmacy for the time required by normative rules NR.

Quality control CQ : right following of the procedure, organolectic characteristics, control of the pakaging, sealing of the container , right label compilation, mass uniformity accordinf the FU acceptation limits

A copy of the label must to be attached to the working sheet WS for the documentation

Documentation : of the working space, instruments, raw materials RM

Expiration time ET of the drugs prepared : accordin FU requirement : 30 days that can be prolonged to 6 month acording chemico -phisical microbiological stability documentated by official informations.

Mandatory equipment and tools in pharmacy a ( TABLE N 6 pharmacopea italian in force)

1. balance sensitivity to the mg , scale = 0,001 g, loading capacity at least 500 g or in alternative way 2 different balances , 1 with a sensitivity at the mg (d=0,001g) with a loading capacity at least 50 g and the other with sensitivity at level SL of 0,50 g (d=0,50 g) with carry load at least of 2 kg.

2. Bain marie BM or other equipement that can assure ,in heating , temperature since to 100 °C.

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

4. Point of fusion equipement . ( to test raw material)

5. chemical glassware, graduated, sufficient for the normal execution of the preparation.

6. percolator – at empty Concentrator (1).

7. an encapsulator (2)

8. a Tablet press (3).

9. a powder Aspiration system AS (4).

10. moulds or plastic valve for ovules - suppositories (5).

11.tools and devices necessary to guaranteee sterility of the preparation (6)

Beyond the reported lab instruments , the pharmacy must have all other instruments,equipements ,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 FU indications.

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

Note:

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

(2) - mandatory for the pharmacy that prepare the capsules CPS

(3) – mandatory for the pharmacy that prepare the tablets .

(4) – mandatory for pharmacy that prepare tablets, capsules ,CPS, teas sachets .

(5) – mandatory for pharmacy that prepare the suppositories or ova .

(6) - for pharmacy that prepare the sterile products.

**CHAPTHER 6 DISCUSSION**

As reported in this work are clear the advantages to produce some kinds of drugs in a galenic lab.

Even the industrial epoca , with the pharmaceutical industry PI increase , the industrial production of drugs Was rapidly developed and so was reduced or stopped the production in the pharmacy galenic labs

this process was due to The complexity of the process to produce with an high quality the finished drugs in the amonut requested by the hospital and by the patient need .

But the same some condition need to mantein this procedure : for magistral formula MF prescription (single patient based) and for the production of officinals reduced scale , disinfectants, reagents or other kind of product into the hospital or asked in private pharmacy.

It must also to be remembered that during the LAST C-19 PANDEMIA one of the main producers of antispetic gel hands and alcoolic solution was the hospital pharmacy in their lab as well as in the private pharmacy.

The industry in fact ,in this situation , was not able to provide ready to use a great amount of this product needed in few time for the public safety. (3)

The galenic hospital lab in the public hospital guarantee this production and the safety of the patient and healtchare professional HP.

But novelty in filed of galenic lab are crucial even if an ancient origin discipline :

Today The technological innovation (TI) make possible to better cover the need for today drugs shortcomings.

In this BOOK it is submitted a new technology usefull in galenic labs : the 3D PRINTING SYSTEM As an innovation for quality and global efficiency of the process.

About the normative rules in galenic laboratory :

Comparing full NBP ( NORME DI BUONA PREPARAZIONE) to the reduced DM 18 .11, 2003 it is possible to verify that NBP ( NORME DI BUONA PREPARAZIONE) require separate or separable locals , chek by other pharmacist vs the one that prapare the drug in lab., and required as mandatory the written procedures WP accreditated .

For the cited Decreto instead it is not mandatory complex quality check on final products, no mandatory written procedure are needed ( even if suggested): this last are more easy to be followed also for lab that not prepare the sterile products.

It is clear that innovation in field of galnic imply a great management system to cover the cost of instrument.

The same a managerial method make possible to rule the pharmacist involved related

The formative programs, continous updating of the knowledge , API and eccipient ordering activity

Monitoring of the costs .

**About SAFETY :**

It is clear that all galenic lab activities must to be performed observing the chemical risk safety rules as well as safety law for the pharmacist lab worker, using individual DPI and collective PROTECTIONS DISPOSITIVE CPD and other needed .

Are To be Followed all procedure related.

Before start the preparation it is necessary read techincal and safety sheet of materials used.

Use anti split kit if accident.

Formative course are fundamental .(it must to be documented), CHEMICAL RISK course .

See italy law 81/2008 abour safety for workers.

**Here are reported Some Simply rules in lab :**

prepare one magistral formula or an officinal formula one at time .

use DPI needed

use collective protection system as needed

before start the preparation study the components and procedure , literature or technical texts, normative rules, professional website and org.

Verify pharmaceutical form and dosage

Verify compatibility between API and eccipient , related way of subministration

Attention to acronimus and abbreviations

Verify that the magistral formula are signed by physician authorized

Verify errors in the prescription or data incomplete

Verify age or weight or body surface if needed

ask to other pharmacist information also if possible.

look at the safety and technical sheet of ingredients

verify instruments

verify dropper = 20 gtt water for millilter

repeat the calculation two times

not error in volume measure level or in weighting

attention to the limits accepted by pharmacopea ( ex + - 10%)

not interruption

keep calm

write data of first use for eccipients and API

verify instrument of measure and other instruments used, chemical hood and other

register the lavoration steps

perform quality control

not give drink to the strong acid

pay attention to electric instruments

right hygiene procedure ( hands) and sanification of enviroment

pay attention to drugs with narrow therapeutic index ( where the pharmacological effect are near to the toxic ones)

pay attentions at maximum doses for adults and children ( tab 8 FU XII ED and accordin pediatric manuals like BNF for childrens)

in mixing powder use the geometric method

in mixing PAI and eccipient use alimentar colour to veryfy the complete mixing expecially for very active drugs

in oral dispersione ans syrup of very active drugs : crucial to add label with the phrases: needed to mix before the use .

Similia similibus solvuntur

Pay attention to the microbial contamination risk, preservative use

Pay attention to the poison raw material, caustic or corrosive or strong acid.

Pay attention to the dosage of narcotics

Pay attentions to the flamable substantie and free flame

Rlated stability verify FU , literature , or stability proof

**API** : this can be used as pharmacetutical powder or from registered drugs ( tablets, cps and other ) , fitoterapic extract

**Related the Raw materials:**

EU reg. REACH registration evaluation , authorizationand restriction of chemicals and CLP classification labeling of chemicals.

Register the raw material arrived , label with the first use, keep empy jars for six month

Verify certificate of analisys , or measure fusion point .

**Drug containers:** according normative rules, compatible with API and eccipients , verify closing system, use safety caps for children

Of interest the new **list classification of Technological operation** in galenic lab of pharmacy ( italy ) :

according new italian tariffario Decreto min. salute 22 sept 2017 and Decreto 13 dec 2017: weighed, heating, filtration, volumetric measure, grinding, dissolution, mixing, ripartition, sterilization,trituration, pulverization, sieving, analytical test, PH measure, gelification, concentration, extraction, filling cps, and other.

**And about Concentration and other measure or chemico physical factors:**

% p/p gr/100 gr % p/ v gr/100 ml % v/v ml/100 ml

Molarity = n. moli/ liter micromol millimol

Normality gr equivalent milliequivalent

Equivalent weight = atomic weight/ valence

Ratio strenght part/part ex 1:20

Unity : in example for sodium eparine ex 250 UI/5 ML

ppm part for milion

Density = m/ vol = gr/ml to search volume V= gr/density

Weight = vol x density

Water density 1 gr/1ml

Solubility: concentration of a solute in saturated solution at a determinate temperature.

Solubility, velocity of ( increased by shaking, increase in temperature and molecular size, PH)

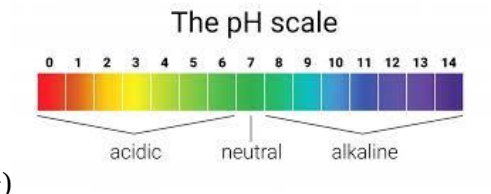
The temperature increase molecular mobility

| HLB Numbers | Applications |
|---|---|
| 4-6 | Water-in-Oil Emulsifier |
| 7-15 | Wetting Agent |
| 8-18 | Oil-in-Water Emulsifier |
| 10-15 | Detergent |
| 10-18 | Solubilizer |

HLB balance- hydrophilicity -lipophilicity

polarity

Cristalline status : amorphus or cristalline




PH= -Log ( conc. H+)


Fig. n. 53 litmus paper

Buffer solutions, acid solutions, basic solutions ( to set PH range )

Temperature( ATTENTION TO TERMOLABILE API), attention to API to be conserved 2-8 grades

Boiling point ( water) , fusion temperature ( suppository eccipients )

Storage temperature TA, < 25 grades , 2-8 grades

Humidity content, dry

Cristallization water

Size of powder, porosity, apparent volume

State of materia: solid, liquid, gases

Granulometry ( powders)

Velocity of dissolution

Flocculation -deflocculation suspension , sedimentation status

Tonicity, isotonicity ( 0,9% nacl P/V) , ipo ( ex 0,45% nacl ), ipertonicity ( ex 3% nacl) , osmotic property

Plasma osmolality = 280 mOsm/kg

Viscosity

Surface tension

Additive presence: tensioactive, complexant

Vapour pressor

Sobstitution factor : for suppository : 1 gr of API shift f gr of eccipient

Where f= density eccipient/drug density

**About UDM** measure units: SI international system

Gr, centigr , milligram, kilogram

Ml , liter , centiliter

Grades

**kind of Water in galenic lab:**

Depurated

PPI water , sterility, pyrogen remove

Parenteral : pyrogen, endotoxins ( LAL test )

1 ml water = 20 gtt

**Alchoolic grade : % v/v**

**alchool diluition**

## Dilution, Concentration and Alligation

- **Alligation**
- **Alligation alternate**
- A method by which we may calculate the number of parts of two or more components of a given strength when they are mixed to prepare a mixture of desired strength. A final proportion permits us to translate relative parts to any specific denomination.
- **Example:** in what proportion should alcohol 95% and 55% strengths be mixed to make 70% alcohol?
- Available strength desired strength number of parts
- **95%** **15 parts (95%)**
- minus gives
- **70%**
- from gives
- **55%** **25 parts ( 55%)**

*Dr. Osama A. A. Ahmed* 8

Fig. n 54

**Liquid diluition :**

dil 1:10 = 1 part + 9 part diluent

other example :

500 ml at 15% solution to be diluited to 1500 ml , how will be % final of the diluited solution?

Volume initial x % initial = vol final x % finale

500 ml x 15% = 1500 ml x X X= 5%

Symple syrup FU

Saccarose 66,5% p/p water 33,5%

An example of medicated syrup :Niaprazin syrup :

API, K sorbate, tartaric acid , water PI, Saccarose , aroma

(Or using ready for use basis)

Heat PI water then solve Ksorbate and tartaric acid ,coll dawn, add API an aroma and mix well.

So add the simple syrup to final volume .

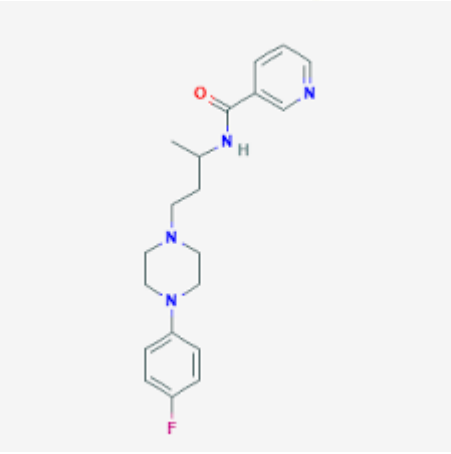



Fig. n 55 niaprazin

**The Calculation:** crucial step in laboratory

ratio strenght , proportion, conversion of measure unit, %

Significant digit, rounding

Prefix: milli gr , centi, deci , gr ,deca gr, hetto gr, kg and milliter ,centilt, decilt, liter

**Other to be take in consideration :**

Simbols , acronimus , abbreviation

Pediatric dosage : weight based, body surface , age based

Narcotics free basis and salts : transformation calculations

Prescriptions: physicians, specialist, veterinary, in label , off label, orphan drugs

Repeable prescription , not repeteable, limitative prescription, narcotics , poison substantie , officinal formula

Reduced scale production, limits

**Type of products:** narcotics , poison substantie based, doping , corrosive, caustic, acid, flamable products

It must to be followed the specific normative rules


Fig. n 56

**About "POISON** " in lab galenic : substantie that are listed in Tab n. 3 F.U.I. XII IT, and also substantie classified as "letal" = labeled H300, 310 e 330.

**General Labeling Attention phrases :**

keep not accessible to children , mix before use, poison, under narcotics rules, keep in refrigerator , veterinary use, doping et other

**Galenic exception rule :** in Italy state council sententia n. 4257/2015 make possible to unpak registerd drugs to prepare magistral formula ( for different dosages and for therapeutic need )

**Kinds of Eccipients:**

diluents,adsorbent,disgregants, polimer for release, wet eccipients, sweeteners, lubrificants, glidants , binders, tensioactives, humectants, viscosifying, antimicrobials ,chelants, antioxidant et other.

They must to be inert vs API, Organism and vs pakaging.

**Sterilization methods:**

filtration, heat ( humid and dry), radiations( UV, ionizant ), chemical methods.

Indicators of sterilization( chemical, biological)

**Tecnical Balance characteristic** : max payload , sensibility ( the smaller value that can be measured ), precision( reporducibility ) , accuracy ( mrasured value vs real)

**Innovation in galenic field : trends**

Oral suspension : introduced in the market of already for use basis products ( or for syrup): various producers into the market ( also for gatrosensible principle active )

Excipient basis ( powders) redy for use, for humans and also for veterinary

Ready for use Bases for spatulated tablets

Shifting ,when possible, pediatric prescription of capsules into oral suspension

Ready Basis for cp

Topical veiculy ready for use , transdermal

Introduction into the market of Estract already titolated of cannabis CBD THC (no more needed HPLC titulation of the final preparation whit complex analytical intruments ). The extract is diluited with vegetal oils. The amount of extract is weighted ( gr ) then bring at final volume with a cilinder.

Vaporizators

Micronizzators, mixer

V type powders mixers

Introduction of spatolated cp methodology

Dose unit systems

Robots: for sterile galenics

3D printing Systems for capsules and cp

Advanced software for lab. Management( order, calculi , labels, raw material management, working sheet)

Procedure for Shorteness of registered drugs , orphan drugs

Software for global management of the galenic lab

Sterile products : colliria and ophtalmic vitreal injections ( only uder strictly rules), introduced normative rules for pharmacy

Academy on line

## CHAPTHER 7 CONCLUSION

As conclusion of this Book it is possible to say that observing the Italian Reduced NBP ( NORME DI BUONA PREPARAZIONE) rules in an advanced countries like Italy can be applietd also in the non advanced countries with great benefit for healthcare of the various kinds of patients.

This rules report general behavior and procedure to be followed by the pharmacist to be sure that the durgs produced are safe and useful for the patiens or for healthcare org.

Not all labs in the world have the same intruments or level of complex lab ( due by economic avaiability) but in every lab It is crucial to know the responsability as well as procedure adopeted ( quality control of raw material RM ,active substantie API , qualification of the pharmacist , traceability of the lots , API, eccipients and other.)

For this reason it is opinion of the authors that this rules must to be translated in their general meaning from the italian to the english languages as reported in this work.

The authors submit to the reseachers and pharmacists a new innovative tool : the 3D PRINTING systems for galenic lab. use : a system that make possible to increase global efficiency of the preparation of capsules CPS or other pharmaceutical form during a period of drug shortages as today situation.

A managerial government of the innovation in galenic field added to the clinical competencies

( clinical pharmacy and pharmaceutica care ) Make possible to provide in healthcare system a great contribution also in this years.

DISCLAIMER: this work has no any terapeutic intent , only to submit to the international researcher and reader some interesting concept.

CONFLICT OF INTEREST: no

ETICAL IMPLICATION : considered all rules

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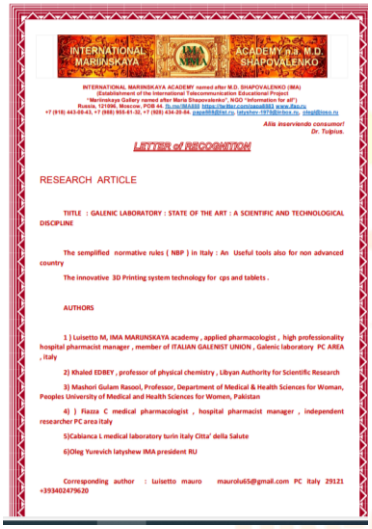

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KEYWORDS

Galenic laboratory , magistral formula, clinical pharmacy , pharmaceutical care , personalized pharmacy, drug shortage ,NBP, semplified rules, official pharmacopeia, control process, quality management system, Rare disease, 3d PRINTING systems