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PROTOCOL FOR THE USE OF STANDARDIZED PHOTOSENSITIVE INJECTABLE DRUGS IN THE PUBLIC HOSPITAL NETWORK OF THE STATE OF TOCANTINS

Lorena Altino Ferreira*[1], Matheus Sá Paiva[1], Yara Silveira[2], Vanderson Ramos Mafra[3], Renata Ferreira Diogo[4], José Antônio Pereira[5], Thalita Melo França Costa[6], Natallia Moreira Lopes Leão[7], Moziane Alves Guimarães[8], Matheus Viana Maciel[9], Hédipo José Ribeiro e Silva[10], Lucas Cardoso Santos[9], Vera Lúcia Cavalcante Rodrigues[11] and Marllos Peres de Melo[12]

[1]Pharmacist Regional University of Gurupi - Gurupi, TO. Brazil; [2]Pharmaceuticals. Professor. Regional University of Gurupi - Gurupi, TO. Brazil; [3]Pharmacist. Master Professor. Regional University of Gurupi - Gurupi, TO. Brazil; [4]Pharmaceuticals Centro Universitário Tocantinense Presidente Antônio Carlos (UNITPAC) - Araguaína, TO. Brazil; [5]Chemical. Doctoral candidate in Chemistry at the Federal University of Mato Grosso do Sul. Brazil; [6]Pharmaceuticals. Specialist in clinical pharmacology with an emphasis on prescription. Professor. Regional University of Gurupi - Gurupi, TO. Brazil; [7]Pharmaceuticals. Master Professor. Regional University of Gurupi - Gurupi, TO. Brazil; [8]Pharmaceuticals Centro Universitário Tocantinense Presidente Antônio Carlos (UNITPAC) - TO. Brazil; [9]Regional University of Gurupi - Gurupi, TO. Brazil; [10]Graduated in Mechatronics Engineering - UnB, Graduated in Electrical Engineering - UFG, Master in Biomedical Engineering - UnB (University of Brasília), Graduating Medicine, Regional University of Gurupi - Gurupi, TO, Brazil; [11]Chemistry. Master Professor. Regional University of Gurupi - Gurupi, TO. Brazil; [12]Professor. Regional University of Gurupi - Gurupi, TO. Brazil

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ABSTRACT

When preparing drugs, several scientific principles must be applied to guarantee the expected therapeutic result. In this storage, preparation, and preservation conditions ervation must be observed and, among them, photosensitivity. Photosensitive drugs are a group of drugs that must be kept protected from light both in the hospital pharmacy and in the patient care units. Exposure of drugs to light can cause photodecomposition, and cause them to undergo a degradation process. To prepare a protocol with the standardized photosensitive injectable drugs in the Public Hospital Network of the State of Tocantins. This is documental, descriptive research, carried out using analysis and identification of photosensitive injectable drugs, developed by consulting information from sources such as specific books like Trissel, clinical pharmacy books, drug dilution manuals, and pharmaceutical laboratories package inserts. After reviewing the standardized injectable drugs, we identified 40 with photosensitive active ingredients and 6 injectable drugs requiring a photosensitive line for administration. The material prepared provides information for the correct storage of photosensitive injectable drugs, contributing to the care provided to the patient by the health team.

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INTRODUCTION

In a hospital, the practice involving medications can be defined as a complex system with several interconnected processes, interdependent and involving professionals from different areas of knowledge, to provide quality, effective, and safe health care to patients [1]. Several scientific principles must be applied to guarantee the expected therapeutic result when preparing drugs. In this process, storage, preparation, and preservation conditions must be observed and, among them, photosensitivity [1]. Photosensitive drugs are a group of drugs that should be kept protected from light both in the hospital pharmacy and inpatient care units. Some are already protected by the industry in amber bottles, but if this is not the case, they should be kept in the manufacturer's original packaging, or wrapped in aluminum foil, or other opaque paper. They mustn't be exposed to light until the time of administration to the patient [2]. Exposing drugs to light can cause photo-decomposition, and cause them to degrade. The quality of the drug may be compromised when stored improperly. Light can be prevented by the use of

photoprotective coatings and packaging. In this case, the development of the ideal packaging is of paramount importance to maintain the effectiveness of the product [3]. To ensure the quality of the medication in the hospital, they must be received and stored appropriately so as not to compromise their stability, aiming for the interests of the patient and the hospital institution [4]. Stability is defined as the period over which the pharmaceutical product, or even the raw material considered in isolation, maintains within specified limits and during the entire storage and use period, the same conditions and characteristics that it had at the time of its manufacture [5]. Several factors affect the stability of a pharmaceutical product and may decrease its pharmacological activity, be potentially toxic, or lead to changes in organoleptic characteristics. To avoid or delay these kinds of reactions, a series of measures can be taken, among them controlling the action of light [6].

Therefore, factors related to the packaging of the product, the packaging of the material, the quantity to be transported and the means of transport used are important to ensure the integrity of the drug. There must be specific training for personnel who handle highly active, radioactive, subject to special control, sensitizing, thermolabile, or photosensitive drugs [7]. The hospital pharmacist is directly responsible for ensuring that quality requirements are met throughout the preparation process, taking into account the risks associated with the medication, the preparation area, and the patient, to maintain efficacy and improve medication safety [8]. Problems reported with drug therapy can be avoided with preventive intervention, among them is the education of the nursing staff involved in drug administration as an important factor in preventing medication errors [9]. Therefore, this study aims to elaborate a protocol with the standardized photosensitive injectable drugs in the Public Hospital Network of the State of Tocantins, to improve the quality of services and patient safety.

METHODOLOGY

This is documental, descriptive research, carried out through the identification and analysis of the standard injectable photosensitive medications in the Public Hospital Network of the State of Tocantins (Portaria/SES/GASEC Nº 425, from August 19, 2020) [10]. The work was developed through analysis in scientific websites and specialized literature, focusing on the theme of photosensitive drugs, carried out in specific books such as Trissel, clinical pharmacy books, drug dilution manuals, in addition to pharmaceutical laboratories' package inserts and/or sources provided by the manufacturer. In the drug standardization of the hospital network in the state of Tocantins, there are 665 items, of which we analyzed only the injectable presentations, therefore, the standardized injectable photosensitive drugs were included in the study and the other pharmaceutical forms, those injectable drugs that are not photosensitive, as well as oncological drugs, were excluded. The results were analyzed and presented in table form, using the Word for Windows® program tool, to meet the research objectives. There was no need to submit to the Research Ethics Committee, CNS resolution (466/2012) because this is research whose information was obtained in materials already published and available in the literature.

INRESULTS AND DISCUSSION

After reviewing the standardized injectable drugs in the Public Hospital Network of the State of Tocantins, 40 drugs with photosensitive active ingredients were identified, according to table I containing conservation and storage guidelines. There were also analyzed and inserted in a table, 06 injectable drugs that need a photosensitive line for their administration, thus ensuring their efficacy and safety. They were presented by active ingredient, reconstitution and dilution, stability after reconstitution and dilution, and infusion time (Table II). Results from Sanchez-Quiles et al, [2] describe that a photosensitive drug is a group of medications that, due to their characteristics, need to be kept protected from light and should be stored in appropriate containers. The incidence of sunlight accelerates the process of loss of stability of some drugs,17they must be protected from the direct action of sunlight, moisture, and heat to preserve their chemical, physical and microbiological integrity, ensuring their quality and safety [18,19]. Telles and Cassiani's research 20cites that photosensitive drugs must be packaged in special containers and that the instructions for handling these drugs must be strictly followed. Another study also shows that the packaging of a drug is an important factor in maintaining its stability. Thus, the choice of excipients, packaging, and its composition should also be carefully conducted to ensure the chemical and physical stability of the pharmaceutical product [21,22].

For this reason, in hospital pharmacies, drugs with photosensitive active ingredients must be protected from light, once out of their original packaging. For this, parenteral preparations must be protected in opaque bags, 2 both during the storage of the commercial presentation (ampoule, vial, etc.) and after dilution in vials or bags of liquid for administration, provided that the material of the latter does not protect from light. 23In these cases, requiring specific equipment [24]. In the research by Rubén et al, [25] of the 734 drugs reviewed, 225 (30.7%) contained photosensitive active ingredients, in 165 (22.5%) no data were found, so they were treated in the same way as drugs with photosensitive active ingredients. Regarding parenterally administered drugs requiring reconstitution (80) and / or dilution (172): 73 (91.3%) and 108 (62.8%), respectively, require light protection measures.

Another study pointed out a significant percentage of photosensitive drugs, or drugs for which no photosensitivity data are available (229; 58.6%), are marketed with inadequate primary packaging that allows the drug to be exposed to light. 2 Thus, Usarralde-Pérez states that outside the proper preservation conditions, these photosensitive drugs may suffer a decrease in potency and safety due to the toxicity of possible degradation products [8]. Mirco and Rocha [26], in their work, describe that the shelf life is the period in which the product can be used, according to stability studies, therefore, it is the maximum period that the manufacturer guarantees for use with product effectiveness and safety to the final consumer. As long as the storage recommendations contained in the package inserts are respected and followed correctly. With this, storage has the function of ensuring that the physicochemical and pharmacological properties of the drugs are preserved, because when stored inadequately, the drugs can suffer alterations in their properties, which makes them, in the limit, unfit for consumption [27]. Costa [28] explains in his studies that in recent decades it has been verified that health institutions, especially those of higher complexity, have begun to worry more intensively about the quality and also the safety of services provided to patients. Among the alternatives implemented in healthcare facilities to verify and ensure the achievement of this quality, clinical interventions can be mentioned, among which the pharmaceutical interventions that aim to detect and prevent medication errors stand out.

The pharmacist is an indispensable professional in the health team assigned to the care of patients who are using medication and must act in an integrated manner with the other professionals (doctors, physiotherapists, nurses, biomedical, nutritionists) with the sole purpose of promoting health and ensuring effective treatment for the patient [29,30]. In light of this, it is the pharmacist's responsibility to ensure that the medication provided to the patient meets acceptable stability criteria. For this, the pharmacist must be aware of these when handling and storing medications. [31] Likewise, Cavallini and Bisson [32] in their work demonstrate that hospital pharmacists have an important role in the development and introduction of processes that can prevent medication errors. By participating in all the processes that involve the medication in the hospital, preventing expenses, and improving the orientations about the medications used in the hospital unit.

Table 1. List of photosensitized injectable medicines, according to storage and conservation guidelines

ACTIVE INGREDIENT	PRESENTATION	REMARKS	REF.
AMINOCAPROIC ACID	200MG/ML-20 ML BOTTLE	Protect from light during storage	11
ASCORBIC ACID (VIT. C)	100MG/ML-5 ML AMPOULE	Protect from light during storage	12
AMINOFILIN	24MG/ML-10 ML AMPOULE	Protect from light during storage	13
AMPHOTERICIN B	50MG LIPOSOMAL CYLINDER BOTTLE	Protect from light during storage and after reconstitution	11
AMIODARONE	50MG/ML-3 ML AMPOULE	Protect from light during storage	11
ATROPINE	0.25MG/ML-1ML AMPOULE	Protect from light during storage	11
CEPHAZOLINE	1G VIAL	Protect from light during storage	11
CEFEPIME	1G AND 2G VIAL	Protect from light during storage	11,14
CEFUROXIME	750MG VIAL-AMP	Protect from light during storage	11
CEFTAZIDIME	1G VIAL	Protect from light during storage	11
CEFTRIAXONE	1G VIAL	Protect from light during storage	11
CIPROFLOXACIN	2MG/ML-100ML POUCH	Protect from light during storage. Remove the bag from packaging only at the time of use	11
CHLORPROMAZINE	5MG/ML - 5 ML AMPOULE	Protect from light during storage	14
DANTROLENE	20MG PO LIFILO + DILUENT VIAL	Protect from light during storage	13
DEXAMETHASONE	2MG - 1ML AND 4MG/ML- 2,5ML AMPOULE	Protect from light during storage	11
DIAZEPAM	5MG/ML-2 ML AMPOULE	Protect from light during storage	11,14
DIPYRONE	500MG/ML-2 ML AMPOULE	Protect from light during storage	14
DOBUTAMINE	12,5MG/ML - 20 ML AMPOULE	Protect from light during storage	14,15
DROPERIDOL	2,5MG/ML - 1 ML AMPOULE	Protect from light during storage	11,14,15
EPHEDRINE	50MG/ML-1 ML AMPOULE	Protect from light during storage	11
HUMAN ERYTHROPOIETIN (ALPHA-EPOETIN)	4.000UI IN A FILLED SYRINGE/CYLINDER BOTTLE	Protect from light during storage	13
ETHANOLAMINE OLEATE	5% (50MG/ML) - 2ML AMPOULE	Protect from light during storage	14,15
PHENYTOIN	50MG/ML-5 ML AMPOULE	Protect from light during storage	13,14
PHENOBARBITAL	100MG/ML INTRAVENOUS 2 ML AMPOULE	Protect from light during storage	11
FENTANYL	0.05MG/ML 10ML AND 2ML AMPOULE	Protect from light during storage	11
FITOMENADIONA (VIT. K)	10MG/ML - 1ML IM/SUBC AMPOULE	Protect from light during storage (Rapidly degraded)	13
HALOPERIDOL	5MG - 1 ML AMPOULE	Protect from light during storage	14
HYDROCORTISONE	100MG AND 500MG CYLINDER BOTTLE	Protect from light during storage and after reconstitution	11,16
LEVOFLOXACIN	5MG/ML 100 ML POUCH	Protect from light during storage	11,14
LIDOCAINE	2% (20MG/ML) - 5ML AMPOULE	Protect from light during storage	13,14
LINEZOLID	2MG/ML- 300 ML POUCH	Protect from light during storage. The bag should be in the foil packaging and box until the moment of use	11
METHYLPREDNISOLONE	500MG + DILUENT FRANCO-AMPOLA	Protect from light during storage	13
METOCLOPRAMIDE	5 MG/ML 2 ML AMPOULE	Protect from light during storage	11,14
METOPROLOL	1MG/ML-5 ML VIAL/AMP	Protect from light during storage	14,16
METRONIDAZOLE	5MG/ML 100 ML POUCH	Protect from light during storage. Once opened, it should be used immediately	11
MICAFUNGINA	50MG VIAL-AMP	Protect from light during storage, after reconstitution, and dilution. Protect from light only the pouch	14
MIDAZOLAM	1MG/ML-5ML,5MG/ML-10ML,5MG/ML-3ML AMPOULE	Protect from light during storage	11
MORPHINE	0,2MG/ML; 10MG/ML -1ML AND 1MG/ML 2 ML AMPOULE	Protect from light during storage	11
NALOXONE	0.4MG/ML-1 ML AMPOULE	Protect from light during storage	13,14
NITROGLYCERIN	5MG/ML 10ML AMPOULE	Protect from light during storage	13,16
OCTREOTIDE	0.1MG/ML-1 ML AMPOULE	Protect from light during storage	14,16
OMEPRAZOLE	40MG VIAL-AMP	Protect from light during storage	13,14
ONDANSETRON	2MG/ML- 4 ML AMPOULE	Protect from light during storage	14
PARECOXIBE	40MG VIAL-AMP	Protect from light during storage and after reconstitution	14,15
PETITION	50MG/ML - 2 ML AMPOULE	Protect from light during storage	13,14
PROMETHAZINE	25MG/ML - 2 ML AMPOULE	Protect from light during storage	11,14
RANITIDINE	25MG/ML - 2 ML	Protect from light during storage	11,14
SULFAMETHOXAZOLE + TRIMETHOPRIM	80MG/ML + 16MG/ML - 5 ML AMPOULE	Protect from light during storage	14
VERAPAMIL	2,5MG/ML - 2 ML AMPOULE	Protect from light during storage	14
B COMPLEX VITAMINS	2 ML AMPLE	Protect from light during storage	13
PYRIDOXINE (VIT B6) + THIAMINE (VIT B1) + DEXPANTHENOL (VIT B5) + RIBOFLAVIN (VIT B2) + NICOTINAMIDE (VIT B3))			

Table 2. List of injectable medicines requiring photosensitive equipment

Active ingredient	Presentation	RECONSTITUTION/ STABILITY	DILUTION/STABILIT Y	INFUSION TIME	REMARKS	REF.
Amphotericin b	50mg Cylinder bottle	10ml AD or proper diluent 24h AT or 7 days Under Ref. and protected from light	490ml SG 5%. 24h AT, protected from light (Do not dilute in SF)	2h - 6h	Store vials intact under refrigeration and protected from light. Use photoresist equipoise.	
Dopamine	5mg/ml - 10 ml ampoule	-	Standard: 5 amp (250mg in 200ml SF; SG 5%. 24h TA	Continuous	Protect from light during storage. Use a dark cover for the serum bottle. Use photoresist equipment. Color-changing solutions should not be used.	
Epinephrine (adrenaline)	1mg/ml - 1 ml ampoule	-	Standard: 1mg in 250ml SF; SG 5%; SGF 24h TA or Under Ref.	Continuous	Protect from light during storage. Must be protected during continuous infusion. Use photoresist equipment sent.	
Furosemide	10mg/ml - 2 ml ampoule	-	Standard: 100ml (2-10mg/ml) SF; SG 5%; RL; SGF 24h TA	Do not exceed a speed of 4mg/min	Protect from light during storage. Must be protected during continuous infusion. Use photoresist equipment.	
Sodium nitroprusside	50mg Vial/ampoule	Flask/Ampoule 2ml of the proper diluent or SG 5%. (discard leftovers)	Standard: 1 amp (50mg) in 250ml SG 5%. Water restriction (1mg/ml) 24h RT or under Ref. protected from light	Continuous (serum thiocyanate control with use > 72h)	Protect from light during storage and after reconstitution. Use photoresist equipoise. Wrap the infusion vials with a protective envelope.	
Norepinefrine	2mg/ml - 4 ml ampoule	-	Standard: 2 amp (16mg) in 250ml SG 5%; SGF 24h TA (Avoid SF use)	Continuous	Protect from light during storage and after dilution. Use photoresist equipment.	11

AD (Distilled Water), Ref (Reference), RL (Ringer Lactate), SF (Physiological Serum), SG (Glucose Serum), SGF (Glucophysiological Serum), Under Ref (Under Refrigeration), RT (Room Temperature).

CONCLUSION

The material prepared by this study provides information for the correct storage of photosensitive injectable drugs, minimizing problems and doubts, and contributing to the care provided to the patient by the health team. Given the lack of published studies related to photosensitive drugs and the specificity of each product/manufacturer, this research is important, as it aims to guide all professionals involved in the medication process. Ensuring the proper use, storage conditions, preparation, and administration of these drugs and consequently patient safety.

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