

EVALUATION OF THE PREPARATION OF STERILE INTRAVENOUS MIXTURES IN THE PHARMACY SERVICE OF THE GENERAL UNIVERSITY HOSPITAL OF ELCHE, ACCORDING TO THE RISK MATRIX

Belén Martínez Fernández*, Blanca Lumbreras Lacarra, Ana Cristina Murcia López

BACKGROUND

The preparation of intravenous mixtures is an important part in all hospital pharmacy services, since parenteral drugs present a greater risk for the patient and an increased risk of microbiological contamination during handling. For this reason, the *Guide for good practices for the preparation of medicines in hospital pharmacy services* has been prepared, which proposes a risk matrix for the evaluation of sterile preparations in order to determine the level of quality in the preparation process. The objective of this study is to evaluate all the preparations of intravenous mixtures made in the pharmacy service of the General University Hospital of Elche, applying the proposed risk matrix.

Each level of risk establishes the most appropriate **preparation and conservation requirements**.

3 possible levels of risk:
high, medium or low.

The decision criteria for risk assessment are grouped into **6 categories**.

Each category is assigned an alphabetical factor of risk ranking **from A to D**.

A combination of 6 letters is obtained.

RESULTS

A total of 87 different preparations are analyzed:

- High risk > No preparation
- Medium risk > 74 preparations (85%)
- Low risk > 13 preparations (15%)

TABLE 5. Results (part 1).

DRUG		RECONSTITUTION		MIXTURE		REVIEW	COMBINATION OF LETTERS	RISK LEVEL	PREPARATION REQUIREMENTS	CONSERVATION REQUIREMENTS
ACTIVE SUBSTANCE	DESCRIPTION	VOLUME/ VIAL	STABILITY	VEHICLE	STABILITY					
ABATACEPT	Orencia® Solución (500-750-1000mg / 100ml)	10ml API	24h to 2-8°C	SSF 0,9%	24h to 2-8°C	OK	CBAAAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
AGALSIDASA ALFA	Replagal® Solución (mg / 100ml)	NP	NP	SSF 0,9%	24h to 2-8°C	OK	CBAAAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
AGALSIDASA BETA	Fabrazyme® Solución (mg / 250ml)	1,1 / 7,2ml API	No data	SSF 0,9%	24h to 2-8°C	OK	CBAAAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ALBÚMINA	Solución de albúmina al 5%	NP	NP	SSF 0,9%	5 days to RT	OK	CBBAAB	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ALEMTUZUMAB	Lemtrada® Solución (12mg / 100ml)	NP	NP	SSF 0,9%	8h to 2-8°C > PL	OK	BBAABA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ALFA-1-ANTITRIPSINA	Prolastina® Solución	40ml API	3h to RT	NP	NP	OK	CBAABA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
AMPICILINA	Ampicilina Solución (10mg/ml)	4ml API	No data	SSF 0,9%	24h to RT or 3 days to 2-8°C > PL	OK	BBAABA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ANFOTERICINA B LIPOSOMAL	Ambisome® Solución inhalada (4mg/ml)	12ml API	24h to RT or 7 days to 2-8°C > PL	NP	NP	OK	CBBAAB	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ANFOTERICINA B LIPOSOMAL	Ambisome® Solución neonatos (1mg/ml)	12ml API	24h to RT or 7 days to 2-8°C > PL	SG 5%	72h to RT or 7 days to 2-8°C	OK	CBBAAB	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ANFOTERICINA B LIPOSOMAL	Ambisome® Solución (mg / 100ml)	12ml API	24h to RT or 7 days to 2-8°C > PL	SG 5%	72h to RT or 7 days to 2-8°C	OK	CBBAAB	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
ANIDULFUNGINA	Ecalta® Solución (50-100-200mg)	30ml API	2 days to RT or 5 days to 2-8°C	SSF 0,9%	6 days to 2-8°C	OK	ABAAAA	LOW	*Nursing units	*1h to RT / 1h to 2-8°C / Do not freeze
AZATIOPRINA	Imurel® Solución (2mg/ml)	10ml API	5 days to 2-8°C	SSF 0,9%	48h to RT or 14 days to 2-8°C > PL	OK	CBCAAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
AZATIOPRINA	Imurel® Solución (mg / 100ml)	10ml API	5 days to 2-8°C	SSF 0,9%	8 days to RT or 16 days to 2-8°C > PL	OK	CBCAAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
AZTREONAM	Azactam® Solución (500mg / 100ml)	4ml API	No data	SSF 0,9%	7 days to 2-8°C	OK	ABAAAA	LOW	*Nursing units	*1h to RT / 1h to 2-8°C / Do not freeze
BACILLUS CALMETTE GUERIN	BCG Live USP® Solución (120mg / 50ml)	1ml SSF 0,9%	No data	SSF 0,9%	2h to 2-8°C > PL	OK	CACABA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
BELIMUMAB	Benlysta® Solución (mg / 250ml)	1,5 / 4,8ml API	8h to RT or 2-8°C	SSF 0,9%	8h to RT or 2-8°C	OK	CBAABA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
CASPOFUNGINA	Candicidas® Solución (35-50-70mg)	NP / 10,5ml API	NP / No data	SSF 0,9%	24h to RT or 48h to 2-8°C	OK	ABAAAA	LOW	*Nursing units	*1h to RT / 1h to 2-8°C / Do not freeze
CEFOTAXIMA	Cefotaxima Solución desensibilización	10ml API	No data	SSF 0,9%	24h to RT	OK	BBABAA	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C
CEFTAZIDIMA/ AVIBACTAM	Zavicefta® Solución (mg / 100ml)	NP / 10ml API	Immediate use	SSF 0,9%	12h to RT or 24h to 2-8°C	OK	ABAAAA	LOW	*Nursing units	*1h to RT / 1h to 2-8°C / Do not freeze
CEFTOLOZANO/ TAZOBACTAM	Zerbaxa® Solución (mg / 100ml)	NP / 10ml API	NP / 4 days to 2-8°C > PL	SSF 0,9%	24h to 2-8°C > PL	OK	BBAAAA	LOW	*Nursing units	*1h to RT / 1h to 2-8°C / Do not freeze
CICLOSPORINA	Sandimmun® Solución	NP	NP	SSF 0,9%	14 days to RT	OK	CBBAAB	MEDIUM	Pharmacy service (clean room)	30h to RT / 9 days to 2-8°C / 45 days ≤ -20°C

LEGEND:

RED	Dangerous drug group 2	It is assumed that drugs considered to be dangerous (group 2 or 3) should always be prepared in a vertical laminar flow hood with the necessary precautions and measures for handling and administration.
ORANGE	Dangerous drug group 3	
GREEN	Low risk preparation	* According to the objective of the study, it is established that the preparation requirements of these are in the nursing unit without a controlled environment.

API = Water for injection / SSF = Physiological serum / SG = Glucose serum / NP = Not precise / PL = Protected from light / RT = Room temperature

CONCLUSIONS

Low risk preparations are the most interesting, as they are the only ones that could be prepared in the nursing units of the hospitalization floors. Therefore, it would be justified to have some preparations done by the pharmacy service and others could be done by the nurses with the necessary recommendations.

Thanks to the application of the risk matrix, we can ensure more adequate preparation conditions; providing a better organization and use of resources to all parties involved.