

Radiation Technologies: Processes and Products

Introduction

The group is involved in R&D applications of gamma radiation, namely on radiation sterilisation of medical devices and pharmaceuticals, preparation and characterisation of graft copolymers and detection of irradiated food.

Radiation sterilisation is oriented to good manufacturing practices evaluation and studies of microbiological parameters of products need to be sterile in conformity with EN and ISO standards and Pr-standards.

A *consortium* contract -the BIoSTER Project- including official institutions and industries is in progress. Extensively reports of the work carried out were presented and the second and third “audits” by AdI / PRAXIS XXI experts were successful passed.

Scientific and technological assistance to certification and normalisation institutions and industry has been performed.

Preparation of **graft copolymers** by gamma radiation has continued. Thermal characterisation techniques, DSC and TGA, were optimised and are currently applied. The work developed has been presented to scientific meetings.

The collaboration with the University of Coimbra, Prof. M. Helena Gil, has continued. A PhD student is preparing the dissertation thesis under Prof. Gil orientation.

The inter-comparison study on **detection of irradiated food** developed under the European project “Establishment of Eastern Network of Laboratories for Identification of Irradiated Foodstuffs” came to the end. The data obtained are either presented in the EU Report of this contract either in press for publication. The IAEA Research Contract on “Irradiation for disinfestation of dried fruits” has been also concluded. The results are in press for publication in IAEA special issue. Co-operation in these matters with INETI, INIA, ISA and IST has continued and a student has obtained a PhD in Agro- Industries.

Research Team

	Radiation Sterilisation	Polymers	Food Irradiation
Researchers Staff	1 (1)	--	1 (1)
Research Students	2+ 3 ^(a)	1 ^(b)	1 ^(b)
University Students	--	1 ^(d)	3
MSc Student	--	--	1
Technicians Staff	1	1	--

() PhD or equivalent

^(a) PRAXIS grant holder

^(b) PRAXIS grant holder (PhD Student)

^(c) On leave from INIA (PhD Student)

^(d) ITN grant holder

Publications

Journals –	3	and 1 in press
Special Publ. –		1 in press
Conf. Commun.: -	5	
Theses:		
PhD	1	
Lic. –	2	

	10 ³ PTE
Expenditure:	23 616
Missions:	1 888
Other Expenses:	20 364
Hardware & Software:	1 358
Other Equipment:	6

		10 ³ PTE
Funding:		32 985
OE/ITN	OF	7 286 ⁽¹⁾
	PIDDAC	1 182
External Projects:	1997	7 828 ⁽²⁾
	1998	8 958
Others		7 732 ⁽³⁾

⁽¹⁾ Grants
⁽²⁾ Funding not used in 1997
⁽³⁾ UTR Services: 7 230

RADIATION STERILIZATION

Study Case on Medical Devices Manufacturing

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³*on leave of FCL, University of Lisbon*

Abstract

This study is developed under the contract of *consortium* BIOSTER (AdI/PRAXIS XXI med. 3.1). It involves three Industries of medical devices, BASTOS VIEGAS, FAPOMED and OFTALDER, which the main products are surgical gauze, surgical gowns and ophthalmic dressings. The bioburden estimate along the year was obtained for the three “products family” based on protocols validated during the precedent year. The correlation of the numbers of microorganisms along fourteen days of counting was studied, for each product in order to find out the minimum days of counting for the future control. The variation of the bioburden estimate on the three “products family” pointed to greater values intra-lots than inter-lots. The bioburden of each product (growth in TSA) was classified in XI groups with two main purposes: (i) to compare the numbers of each group with the growing in a specific medium for each, in order to skip these analysis in routine control (ii) to detect the main(s) contaminant(s). It was find out that *Micrococaceae* (Group I) were the most frequent contaminants of surgical gowns and surgical gauze. The genus *Bacillus* as well as pigmented cocci and gram-negative and gram-positive-rods (Groups I, VI and IX) are also common contaminants of the three products. The seasonal influence on the numbers and type of microorganism’s in/on the products were studied based on the temperature and humidity records along the year, so far no differences were detected in the overall contamination. Microbiological studies in the production line of each factory were performed. The principal factors studied were raw materials, environmental (water, air and surfaces) equipment and hands of personnel. Education of the factories’ workers for improving the hygienic conditions was performed. Analyses of the hygienic parameters for the hands were done and were found out high contamination in detergents and hand-dryers. Corrections in productions line were undertaken in order to obtain a better microbiological quality of the products. The results achieved so far point to the raw materials as the principal origin of contamination in the three “products family”.

The exposure of the products to sub-lethal times and/or doses of lethal agents (steam under pressure and γ or ϵ radiation) are in progress in order to find out the minimum time and/or dose to attain the SAL 10^{-6} . Resistance of contaminant microorganisms to the lethal agents is under study.

The progress work in 1998 was presented and scientific experts from AdI/PRAXIS XXI undertook an audit. The project passed successfully to this event.

October 1998, 2nd and 3rd report “Study Case on Medical Devices Manufacturing – Bioburden Studies in/on Product. Gamma Sterilisation with Steam under Pressure” submitted to AdI/PRAXIS XXI. 36 pages (Statistical Data Analysis by Sinese- 132 pages).

Estudo de Dose Absorvida em Produtos Médico-Cirúrgicos Irradiados

M. Luisa Botelho¹, Isabel F. Gonçalves¹, Ana C. Moura²

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² Student from Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa

Abstract

O conhecimento da dose absorvida, bem como a sua distribuição e uniformidade em produtos médico-cirúrgicos que são submetidos a radiação gama é fundamental para garantir a eficácia do processo de esterilização.

Apresenta-se um estudo comparativo de distribuição de dose absorvida determinada por dos métodos distintos: simulação e método experimental. Este estudo foi efectuado em produtos médico-cirúrgicos passíveis de esterilização por radiação gama (compressas e pensos oftálmicos).

Para o estudo por simulação utilizou-se o Programa de Monte-Carlo MCNP. No método experimental utilizaram-se dosímetros de PMMA (Amber Perspex).

O local de irradiação foi a Unidade de Tecnologias de Radiação, (UTR), no *campus* de Sacavém. Utilizou-se um local fixo de irradiação em que se determinou previamente o débito de dose por dosimetria de Fricke.

A uniformidade de dose encontrada foi 1,3 para os pensos oftálmicos e de 1,4 para as compressas.

Os resultados apresentam um bom acordo entre os dois métodos.

Communication to: "11^a Conferência Nacional de Física", Maia Portugal ,September 1998.

Work developed under project *BIOSTER L-1347 AdI/PRAXIS XXI*

Strategy for Financial Management of Consortium Project - BIOSTER

M. Luisa Botelho and Helena Marcos

Nuclear and Technological Institute, ITN, Physics, E. N. 10, 2685 Sacavém, Portugal

Abstract

It was developed a new financial management for the second year of consortium Project. BIOSTER. ITN as the leader centralised the management of the purchases done by Industries Consortium members by means of a common worksheet developed by the system operator.

The 2nd and 3rd Financial Report of BIOSTER Project L-1347 was submitted to AdI/PRAXIS XXI in October 1998.

Current Work

Microbiological Validation on Product LYOMER - Determination of Sterilisation Dose

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² JABA Farmacêutica, P.O. Box 165, Abrunheira

³ sponsored by Jaba

Abstract

Microbiological validation on product Lyomer is in development based on Method 2 of ISO 11137 - "Sterilisation of health care products - Requirements for validation and routine control-Radiation sterilisation".

An experimental design was developed by both JABA and ITN laboratories under the scientific advise of ITN staff.

Bioburden estimates, before and after irradiation to sub-lethal doses were performed by JABA laboratories and the determination of natural contaminant resistance to gamma radiation is in processing at ITN lab.

Short progress reports were given to JABA with the analysis of data obtained so far.

Audit

M. Luisa Botelho

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Abstract

Under invitation of IPQ (Instituto Português de Qualidade) a technical audit was performed to a company which deals with control of environmental conditions (controlled areas).

Expertise Services

M. Luisa Botelho

Nuclear and Technological Institute, ITN, Physics, E. N. 10, 2685 Sacavém, Portugal

Abstract

Participation as portuguese delegate at the meetings of ISO/TC 198 (Sterilisation health care products), ISO/TC 209 (Cleanrooms and Associated Controlled Environments), CEN/TC 204 (Sterilisation of medical devices). Written expert advice and votes of documents were done in these fields.

Member of Technical Committee-CT/87 (Medical Devices Normalisation)

POLYMER MODIFICATION AND METHODS OF CHARACTERISATION

Preparation of Polymeric Biomaterials Using Gamma Radiation

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Abstract

The graft copolymerization technique induced by gamma radiation to prepare polymeric materials of high biocompatibility, as alternative route to the usual chemical synthesis, has shown very promising results.

Some of the most interesting applications of this technique are related with the possibility of graft copolymers utilization in *Biotechnology* (enzyme immobilization), and as a *Biomaterial* (implants, continuous drug delivery systems, biosensors).

The copolymerization of proper chains onto a polymeric base allows the modification of its chemical and physical properties, which can be used for the immobilization of catalysts, drugs and enzymes. Besides that, it is possible to increase the biocompatibility of some polymeric materials (*e.g.* polyethylene, polypropylene, etc) by re-vesting them with gels (*e.g.* poly(hydroxyethyl methacrylate), poly(vinyl pyrrolidone), etc).

Communication to: *V Jornadas Portuguesas de Protecção Contra Radiações*, Évora, Portugal (1998); and *Radioproteção*, (in press).

Thermal Stability of Polymeric Materials Prepared by Gamma Irradiation

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Abstract

The studies about the preparation of new polymeric materials by gamma irradiation, that have been carried out at the Polymer Characterisation Laboratory (LCP) of the ITN, allowed to obtain several samples of the copolymer polyethylene-g.co-hydroxyethyl methacrylate (PE-g.co-HEMA).

This material has shown good potentialities to be applied either in biotechnology (immobilisation of enzymes) either as biomaterial (implants, drug delivery systems, biosensors).

The gamma radiation doses absorbed by the reagent system PE/HEMA, results in changes in the molecular structure of the base polymer, PE, and in the final copolymer architecture. If some of these changes are in agreement with the purposes wanted (*e.g.* high grafting yield), another ones result in a mechanical resistance decrease of the base polymer, which is responsible for the new material stability.

With the aim of study the behaviour profile of the PE-g.co-HEMA with the gamma radiation, were analysed by Differential Scanning Calorimetry (DSC) and by Thermogravimetry (TGA), samples of this material obtained in different experimental conditions. These ones included:

- i) Different dose rates of irradiation;
- ii) Different initial monomer concentrations, and

iii) Different environments of irradiation (presence and absence of air).

The use of these calorimetric techniques has shown to be very useful in the evaluation of the thermal stability of this material. The available data allow to conclude that:

- The thermal stability of PE-g.co-HEMA decrease with the absorbed radiation dose.
- The grafting of branches of poly(HEMA) onto PE, leads to an open of the polymeric matrix, which drive, consequently, to a cristalinity reduction of the support.
- The change of T_f and ΔH_f shown by the different samples of copolymer depends of the irradiation environment. The decrease of thermal stability of PE-g.co-HEMA is higher when the polymeric system is irradiated in the presence of air. This fact is associated with the increase of degradability tendence of PE in those irradiation conditions.

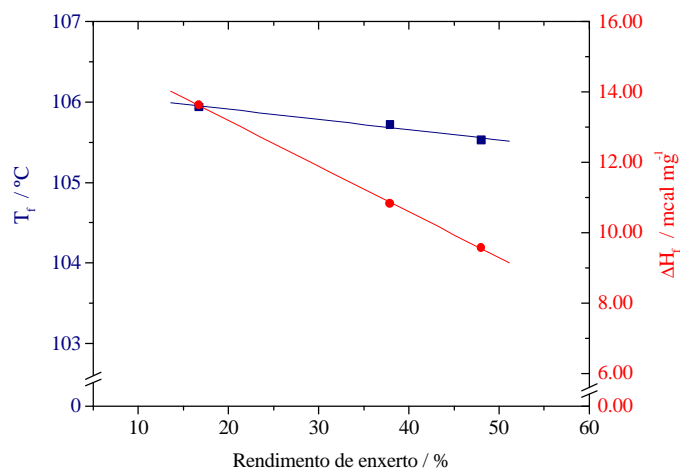


Fig. 1: Change of T_f (■) and of ΔH_f (●) with the grafting yield in PE-g.co-HEMA copolymers.

Experimental conditions: [HEMA] = 10% ; $X^\bullet = 0.5 \text{ kGyh}^{-1}$; Irradiation environment: Presence of air.

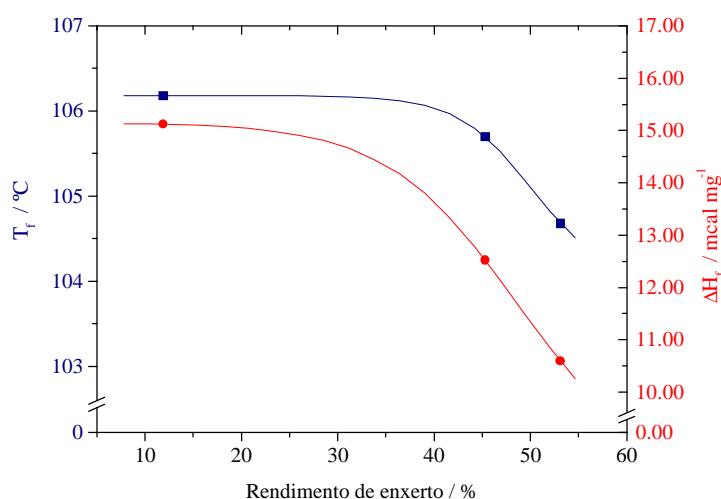


Fig. 2: Change of T_f (■) and of ΔH_f (●) with the grafting yield in PE-g.co-HEMA copolymers.

Experimental conditions: [HEMA] = 10% ; $X^\bullet = 0.5 \text{ kGyh}^{-1}$; Irradiation environment: Absence of air.

Communication to: *11ª Conferência Nacional de Física*, Maia, Portugal (1998).

Graft Copolymerization Induced by Gamma Radiation. A Technique for the Preparation of Biomaterials

L.M. Ferreira¹, M.E. Andrade¹ and M.H. Gil²

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² Dept. Chemical Engineering, Faculty of Science and Technology, University of Coimbra, Portugal

Abstract

Devido às suas potencialidades de aplicação em diversas áreas (Medicina, Farmácia, Biotecnologia, etc.), os *copolímeros de enxerto* têm sido objecto de numerosos estudos.

O polietileno (PE), é um dos polímeros mais utilizados como cadeia suporte para o enxerto de diferentes monómeros, por efeito da radiação gama. As suas propriedades mecânicas e baixa toxicidade, tornam-no num dos materiais mais promissores para ser aplicado em *biotecnologia* (imobilização enzimática) quer como *biomaterial* (implantes, sistemas de libertação contínua de fármacos, biossensores).

Sendo a sua biocompatibilidade e reactividade fracas, há que modificar a sua superfície. O enxerto de cadeias de poli(metacrilato de hidroxietilo), poli(HEMA), no PE é uma das formas de tentar atingir estes objectivos.

A preparação do copolímero *polietileno-g.co-metacrilato de hidroxietilo* (PE-g.co-HEMA) por radiação gama (proveniente de uma fonte de ⁶⁰Co), com as propriedades adequadas a cada aplicação implica a optimização dos parâmetros de enxerto. Nesta optimização estão envolvidos o *método de irradiação*, a *concentração do monómero* (HEMA), a *temperatura e atmosfera de irradiação*.

O protocolo de irradiação desenvolvido, tem permitido estudar a *Cinética de Enxerto do HEMA sobre o PE*, em diferentes condições experimentais de irradiação pelo *Método Mútuo*.

Estas envolvem:

Débitos de Dose de irradiação diferentes (0,3 e 0,5 kGy.h⁻¹);

Diferente concentração inicial de monómero (5, 10 e 15% (v/v em MeOH)) e,

Diferentes ambientes de irradiação (na presença e na ausência de ar).

O perfil das curvas cinéticas relativas a amostras irradiadas na presença de ar, independentemente do débito de dose e da concentração inicial de monómero, evidenciam um período inicial de indução. Este facto obriga ao fornecimento de doses de radiação relativamente elevadas para obtenção de um copolímero com um bom rendimento de enxerto (superior a 80%).

Elevadas doses de radiação originam um aumento da reticulação do polímero base (PE), dificultando o acesso dos monómeros aos centros activos mais interiores do PE. A reacção de copolimerização de enxerto começa assim a ser controlada por fenómenos de difusão, enquanto a homopolimerização do HEMA aumenta indesejavelmente.

O período de indução pode resultar da presença do inibidor no meio reaccional, que retarda a activação dos monómeros, ou pela presença de oxigénio no sistema³. A presença de oxigénio e de radicais monoméricos pode originar competição entre si no acesso aos centros activos criados no PE.

No entanto os dados obtidos em amostras irradiadas na ausência de ar, sugerem que o período de indução resulta do efeito conjunto da presença de inibidor e oxigénio no sistema. Ao existir competição dos radicais monoméricos com o oxigénio, os primeiros mais difíceis de gerar, devido à presença de inibidor, constituem a segunda opção de estabilização dos centros activos no PE. Isto até ao consumo total ou parcial dos radicais oxigénio presentes na solução.

Desta forma, na fase inicial da reacção de copolimerização de enxerto, conduzida na presença de oxigénio, o processo dominante de estabilização dos centros activos no PE parece ser a peroxidação.

Oral Communication to: *XII Encontro Luso-Galego de Química*, Matosinhos, Portugal (1998).

Use of Calorimetric Techniques for Characterization of Polymeric Materials Prepared by Gamma Irradiation

M. H. Casimiro¹, L.M. Ferreira¹, M.E. Andrade¹ and M.H. Gil²

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² Dept. Chemical Engineering, Faculty of Science and Technology, University of Coimbra, Portugal

Abstract

A técnica de copolimerização de enxerto induzida por radiação gama tem vindo a ser otimizada para a preparação de materiais poliméricos com elevada biocompatibilidade, como alternativa à síntese química tradicional.

Os bons resultados obtidos por esta técnica na preparação de PE-g.co-HEMA (copolímero de base polietileno enxertado superficialmente com cadeias de metacrilato de 2-hidroxiétilo), é um dos exemplos mais recentes.

As doses de radiação gama absorvidas pelo sistema reagente PE/HEMA, conduzem a alterações na estrutura molecular do polímero base, PE. A arquitectura e propriedades finais do copolímero estão dependentes destas alterações. Algumas satisfazem os objectivos pretendidos (*e.g.*, elevado rendimento de enxerto), outras conduzem a uma diminuição da resistência mecânica do polímero base, responsável pela estabilidade do novo material.

Estas alterações dependem de diversos factores. O ambiente em que decorre a irradiação, o débito de dose e a concentração de monómero no meio reaccional são factores de grande importância.

Para avaliar a estabilidade térmica de suportes PE-g.co-HEMA com diferentes rendimentos de enxerto, em função dos factores anteriormente referidos, foram analisadas por Calorimetria de Varredura Diferencial (DSC), e por Termogravimetria (TGA), amostras deste material obtidas em diferentes condições experimentais.

A informação proporcionada por estas técnicas permitiu tirar algumas conclusões importantes para a continuação do estudo deste sistema:

A estabilidade térmica do copolímero PE-g.co-HEMA diminui com a dose de radiação absorvida.

O enxerto de cadeias de metacrilato de 2-hidroxiétilo em polietileno provoca uma abertura da matriz polimérica, o que conduz a uma redução da cristalinidade do suporte.

A diminuição de cristalinidade do PE é acompanhada por um aumento da degradabilidade do copolímero.

A redução da estabilidade térmica do PE-g.co-HEMA é mais acentuada quando o sistema polimérico é irradiado na presença de oxigénio, o que estará relacionado com o aumento da tendência de degradação do PE nessas condições.

Uma maior concentração de HEMA em torno do polímero base resulta num escudo protector, atrasando a sua degradação por efeito de radiação.

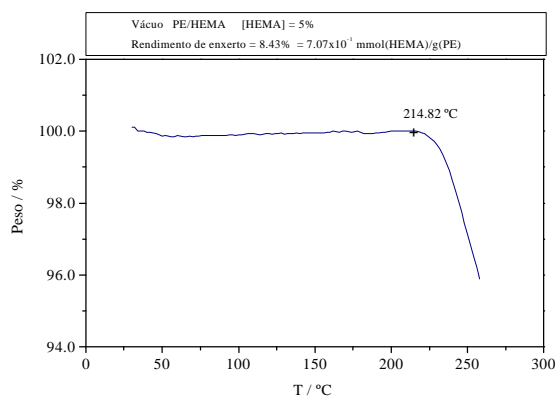


Fig. 1.1: Termograma de TGA de PE-g.co-HEMA com 8.43% de enxerto.

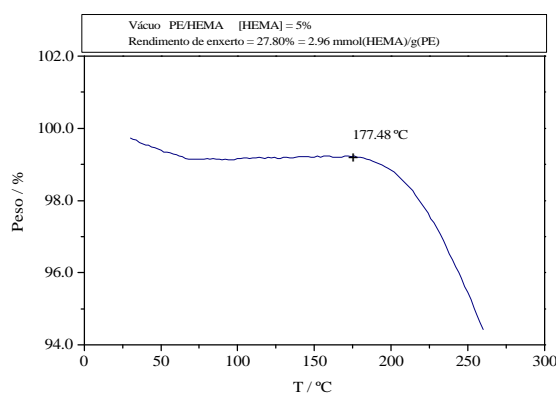


Fig. 1.2: Termograma de TGA de PE-g.co-HEMA com 27.80% de enxerto.

Current Work

Kinetic Studies of the Grafting Copolymerisation Reaction of HEMA onto PE, by Gamma Radiation

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The studies related with the kinetic of the graft reaction of HEMA onto PE, by gamma radiation have continued.

We have been trying to apply different *kinetic models* to experimental data, in order to determine the *Kinetic Constants* and *Initial Rates* of the graft copolymerisation reaction in the twelve different experimental conditions.

Concerning the knowledge of the reactive system evolution the actual data show that a high monomer concentration involving the base polymer, works as a protective shield against gamma radiation. This effect is responsible for the low degradation level of the base polymer caused by the radiation, improving the final copolymer properties.

Thermal Properties Characterisation of Polyethylene Based Polymeric Supports

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The aim of this experimental program is the study of the thermal properties of PE-g.co-HEMA copolymeric supports, prepared according with the protocol developed at the LCP.

The copolymeric samples, had different grafting yield and were obtained at different experimental conditions.

Work development:

1. Definition of an experimental reference methodology for DSC and TGA copolymeric samples preparation.
2. Assay of different "Heating Methods", so that could be possible to define the best analyses methodology for the thermal properties study of PE-g.co-HEMA copolymer.
3. Samples characterisation:
 - Enthalpy of fusion
 - Crystallinity
 - Glass transition temperature
 - Degradation temperature
 - Degradative fragmentation by temperature effect

The obtained data allow to make two conference communications with the follow titles:

- Thermal Stability of Polymeric Materials Prepared by Gamm Irradiation

- The Use of Calorimetric Techniques for the Characterisation of Polymeric Materials Prepared by Gamma Irradiation

Evaluation of Gamma Radiation Effects on Pulveriser Valves of LYOMER/RHINO SPRAY Product, After a Sterilisation Dose Between 21 kGy and 29 kGy

L.M. Ferreira and M.H. Casimiro

Physics, Nuclear and Technological Institute, ITN, P.O. Box 21, 2685 SACA VÉM Codex, Portugal

JABA Farmacêutica S.A. demanded this study to LCP, and the aim was:

- Identification of constituent material of pulveriser valves from *Lyomer / Rhino Spray* (JABA) product.
- Qualitative evaluation of material conditions before and after sterilisation by gamma radiation.

FOOD IRRADIATION

Detection of Prior Irradiation in Dried Fruits by Electron Spin Resonance (ESR)

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² *Instituto Tecnológico e Nuclear (ITN), Estrada Nacional 10, P-2685 Sacavém, Portugal*

³ *Instituto Superior Técnico (IST), Av. Rovisco Pais, P-1096 Lisboa Codex, Portugal*

Abstract

In the frame of a COPERNICUS European programme, dried almonds, raisins, dates and pistachio were irradiated using either gamma radiation or electron beam, at an average absorbed dose of 5 kGy.

To detect the previous irradiation different parts of the dried fruits were analysed by ESR spectroscopy as follows: almonds: skin; raisins: dried pulp; dates: dried pulp and stone; pistachio: nutshell.

Analyses were carried out 2-3 months and 6 months after irradiation. A series of signals, tentatively described as “cellulose-like”, “sugar-like” and “complex” were observed, and some slight differences between spectra from samples irradiated with gamma rays and electrons were evident.

All control samples have presented a single line spectrum. Nevertheless, the characteristics of ESR spectra of irradiated samples differed.

The characteristic “cellulose” radical, that has been considered as a triplet (Raffi, 1996) though only a pair of lines occurring to the left and right side of the major signal are obvious, looks like a doublet and was recorded for almond (skin) and pistachio (shell).

The characteristics of recorded ESR signals are tentatively described as “cellulose-like”, “sugar-like” and “complex”. “Complex signals” could either be only due to non-isotopic “sugar-like” spectra or to a mixture of these and a “cellulose-like” signal.

Radiation Physics and Chemistry, in press.

Establishment of Technological Parameters for Disinfestation of Dried Fruits

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² *Escola Superior Agrária de Santarém,*

Abstract

A study to determine the irradiation parameters for disinfestation of dried fruits: figs, pine nuts, raisins and walnuts have been carried out in the UTR cobalt-60 facility. The dose distribution in the UTR boxes was measured. Low doses for disinfestation (150 Gy - 300 Gy) were studied, for the commercial practice simulation/validation higher doses were used (15k Gy - 20 kGy). The absorbed dose uniformity ratio ($U = D_{max} / D_{min}$) determined was 1.16 up to 1.33

for the dried fruits studied. Different dosimetric systems were tested. Low dose range dosimeters: reference standard Fricke dosimeter, routine dosimeters: Harwell YR Gammachrome and China PMMA-YL dosimeter. High dose range dosimeters: routine dosimeters: Harwell Amber Perspex and Clear Perspex purchased at the local market. Label STERIN indicators of 125 Gy and of 300 Gy were assayed to establish a simple and direct process for verification, by customs inspectors, of a prior irradiation treatment. These indicators change their visual message if the threshold dose has been delivered. The performance of STERIN-125 and STERIN-300 suggested that these label indicators could properly be used for doses of 125 Gy and 300 Gy respectively, or higher than these ones.

IAEA Special publication, in press.

Current Work

Identification of Irradiated Foodstuffs

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¹Nuclear and Technological Institute, ITN, Physics, E. N., 2685 953 Sacavém, Portugal ²National Institute of Agricultural Research, INIA, Quinta do Marquês, 2780 Oeiras, Portugal

³Technical Superior Institute, IST, Av. Rovisco Pais, 1096 Lisboa Codex, Portugal

Abstract

The EU contract CIPA-CT-94-0134 “Establishment of Eastern Network of Laboratories for Identification of Irradiated Foodstuffs” has been concluded during 1998.

The ingredients and foodstuffs studied were a) spices: white and black pepper sweet and hard paprika; and b) dried fruits: almonds, dates raisins and pistachio. Samples of these products were gamma or electron irradiated and later assayed to detect prior irradiation by using the techniques EPR, Thermoluminescence and Viscosimetry.

The data obtained by all laboratories involved in this contract were consistent to the fact they could identify the prior irradiated samples. Thermoluminescence and Viscosimetry techniques, and EPR as well for paprika, proved to be useful tools for detection of irradiated items along the shelf life of the products. The work has contributed for the verification of standards EN 1787 (EPR technique) and EN 1788 (Thermoluminescence technique) and has collected a significant number of data for standardisation of the Viscosimetry technique.

The conclusions of this contract are described in the final report presented to the EC/Brussels

EU contract CIPA-CT-94-0134 “Establishment of Eastern Network of Laboratories for Identification of Irradiated Foodstuffs”.

Dosimetry for Radiation Sterilisation of Medical Devices

M.E.Andrade

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Abstract

The principal objective of this contract is to improve the accuracy of radiation dose delivered in industrial irradiation plants. This will be done through inter-comparison between industrial facilities and two calibration laboratories: Risø National Laboratory, DK (Risø) and National Physical Laboratory, GB (NPL) and through the development of protocols describing standard procedures for the calibration of industrial dosimetry systems.

Based on data obtained on the "first inter-comparison" a document entitled "Guidelines for Dosimetry Calibration" was prepared and submitted to discussion between the partners of the project. A "second inter-comparison" has already been performed for evaluation of the effectiveness of the procedures and protocols proposed. The data of this inter-comparison are being studied.

These protocols will support the uniform regulation of the sterile device industry throughout the European Union, and promote free trade in radiation sterilised devices.

EU contract SMT4-CT-96-2077 "*Dosimetry for Radiation Sterilisation of Medical Devices*"

New Bioactive Forms of Ophthalmologic and Dermathologic Products

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Abstract

The aim of this contract is to develop new forms of medicinal bioactive drugs sterilised by gamma radiation. Ointments for ophthalmology were submitted to absorbed doses of 15 kGy, 20 kGy and 25 kGy. The objective of this work was to determine the absorbed dose that confers to the ointments studied a high microbiological quality maintaining the stability and the efficiency of the active principles. A rheological study to measure alterations on the apparent viscosity of those ointments was carried out and data is being analysed.

PEDIP II, Contract BAT CC 6000 "New Bioactive Forms of Ophthalmologic and Dermathologic Products"

RADIATION TECHNOLOGY UNIT

Calculation of Dose Distribution at the Radiation Technology Unit by Simulation Methods

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Abstract

Descreve-se um estudo de simulação da instalação de irradiação gama do Instituto Tecnológico e Nuclear. O irradiador é formado por 30 tubos de aço inoxidável, 16 dos quais contêm 156 fontes de ⁶⁰Co, duplamente encapsuladas em aço inoxidável. O produto a ser irradiado é acondicionado em 28 carros transportadores, no interior da câmara de irradiação.

Na situação actual a actividade total da instalação é de $3,3 \times 10^{15}$ Bq ($8,9 \times 10^7$ kCi).

Os objectivos da simulação são: (a) optimização da distribuição de dose no interior da célula de irradiação no sentido de obtenção de doses mais elevadas e com maior homogeneidade; (b) cálculo de doses no interior de amostras e (c) cálculo de doses em pontos críticos para efeitos de protecção.

Neste trabalho de simulação foi utilizado o programa Monte Carlo MCNP [1], correndo num Pentium PC e numa estação de trabalho DEC.

Cálculos preliminares em 9 lugares diferentes mostram a contribuição para a dose final de fótons directamente provenientes da fonte e de fótons que sofreram várias reflexões em diferentes locais, tais como: estrutura metálica do irradiador, material da amostra, carros transportadores (metálicos), paredes, tecto e chão. O espectro da radiação depende do ponto considerado. Em pontos exteriores à câmara de irradiação, os espectros não contêm os picos correspondentes ao ⁶⁰Co; os fótons sofrem multi-reflexões antes de atingirem o local e, por isso, o espectro vem degradado. Resultados experimentais confirmam os valores calculados.

Foram também calculadas as distribuições de doses nos pontos centrais dos transportadores, em duas situações distintas. No primeiro caso os contentores estão cheios com um material de densidade 0,1 (semelhante à densidade média de dispositivos médicos); no segundo caso os contentores estão vazios. Na fiada mais junto à fonte, a razão entre as taxas de dose com material e sem material tem um valor médio de 0,96; na fiada externa esta razão é de 0,86. A diferença de valores deve-se à absorção da radiação no material. As taxas de doses variam entre 4,1 kGy/h na fiada central, no local mais perto da fonte e 0,11 kGy/h nas posições mais afastadas.

Para estudar a homogeneidade de distribuição de doses no mesmo transportador, calcularam-se as doses em vários pontos, em torno do ponto central.

Fizeram-se medições das taxas de dose utilizando dosímetros cérico-ceroso e amber-perspex.

Compararam-se e discutem-se os resultados obtidos.

[1] J.F. Briesmeister (ed.) MCNP – A general Monte Carlo n-particle transport code, version 4B, Los Alamos National Laboratory, Report LA-12625-M (1997).

Communication to: *11^a Conferência Nacional de Física*, Maia, Portugal (1998).

Current Work

Experimental Design for Irradiation of “LYOMER” at the UTR for Studies of Microbiological Validation

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Abstract

The main purpose of this work was the irradiation of Lyomer product for the microbiological validation under ISO 11137 “Sterilization of health care products - Requirements for validation and routine control – Radiation sterilization” Method 2.

An experimental design was developed including ceric-cerous dosimeters (similar composition of JABA product) and ambers perspex dosimeters (routine dosimeters) in order to study the geometry irradiation and to confirm the dose rate, previously calculated by MCNP simulations (see “*Dose Determinations by Monte Carlo - A Useful Tool in Gamma Radiation Process*”). The experimental results were in agreement with the MCNP simulations and irradiations are in progress.

Co-ordination and Technological Supervision of UTR, Technological Assistance and Irradiation Services to Institutions and Companies

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Irradiation services to institutions and companies such as: radiation sterilisation of medical devices and pharmaceuticals; radiation decontamination of raw materials, herbs, corks, etc., were supplied.

