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PRODUCT REGISTRATION FORM


Part-I

1.	Client's Name	:	
2.	Client Registration Number allotted by ARPF Facility In-Charge	:	
3.	Registered Office Address	:	
	Phone No./ Fax No.	:	
	Mobile no.	:	
	E-mail	:	
4.	FDA Loan Licence No., if applicable	:	
5.	Description of Product	:	
6.	Mode of Irradiation	:	
7.	Purpose of Irradiation	:	
8.	Required Minimum Dose (kGy)	:	
9.	Maximum Acceptable Dose (kGy)	:	
10.	Material used for Manufacturing of Product	:	
11.	Dimension of product box	:	
12.	Weight of product box (empty)	:	
13.	Weight of product box (filled with product)	:	
14.	Orientation of items inside the product box	:	
15.	Bulk density	:	
16.	Any extra precaution to be taken for processing	:	
17.	Number of boxes sent for pre irradiation dose mapping (minimum six Nos.)	:	

Deceleration

We M/s..... understand that the product dose mapping is a destructive process and after mapping product become unusable. Our company will not claim for any loss/ return of material/ product.

	Signature	
	Name	
	Designation	
	Seal of Company	


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For Use by ARPF Officials (PART-II)

Date & time of receipt of Product lot (Consignment)		:	
S. No.	Inspection Parameters	Observation	Accepted / Rejected
1.	Product/ Box Cleanliness	Clean/ Dirty	
2.	Physical Condition of the Boxes (any damage)		
3.	Sealing of Product Boxes/ Cartons		
4.	Dimension of the product boxes		
5.	Average weight of the product boxes		
6.	Orientation of items inside the product boxes		
7.	Product item distribution in boxes		
8.	Labeling on the product boxes		
9.	Number of boxes received		
10.	Remarks, If Any:		
		Dated Signature of QC Officer:	
	 (Name of QC Officer)	
Product Dose Mapping (PDM) Number allotted by ARPF & Date			
		Dated Signature of Facility in-charge/ Radiation processing in-charge:	

Note:

1. Client will send minimum six number of dully packed boxes for pre-irradiation dose mapping.
2. ARPF will conduct Product Dose Mapping (PDM) and optimize the process parameters, packaging dimension, weight and product orientation to deliver the dose within the specified limits and generate the process specifications. PDM is one time activity

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performed for each product to generate the process specifications. These process specifications shall be used for further bulk irradiation.

3. A unique product dose mapping (PDM) number shall be issued for the product and the will be communicated to the client with process specification (box dimension, weight of box, product orientation inside box, labeling on box etc).
4. Out of six boxes, one box will be handed over to the client for performing the sterility test and confirming the process of sterilization. Report of sterility test will be submitted to the ARPF. In case additional number of boxes are required for performing sterility test, additional number of boxes can be sent with consignment.
5. For regular irradiation, the client shall fill the order registration form (Doc. No. - ARPF/OFR/04) in duplicate & send with your products. The second copy of order registration form will be handed over to you after allotting an order registration no. with tentative date of delivery of radiation processed product.
6. An irradiation certificate is issued in form (Doc. No. ARPF/OFR/10) for each lot of the product irradiated at the facility.
7. All the forms like inquiry form, client registration form, registration of client product for irradiation form, and order registration form are available at ARPF office.