

F. Packaging Material		
In case the questionnaire covers more than one product, please use a separate form F for each product.		
Material Brand Name	Material Type	Product Code
1. Packaging Information		
1.1	Please provide a description of the material:	
1.2	Please provide an infra-red spectrum of the packaging material described above	Ref:

Supplier Quality Questionnaire

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1.3	<p>Please confirm by signature that the packaging material described above fulfills all of the following criteria:</p> <p>a) No BSE/TSE risk-related ingredients / materials have been used in the manufacture</p> <p>b) It is suitable for use in contact with foodstuffs and</p> <ul style="list-style-type: none">▪ it is in full compliance with Council Directive 1935/2004 <i>relating to materials and articles intended to come into contact with foodstuffs</i>, including its current amendments▪ it is in full compliance with Commission Directive 2002/72/EC <i>relating to plastic materials and articles intended to come into contact with foodstuffs</i>, including its current amendments▪ it is in full compliance with the relevant regulations of the BAG▪ it is in full compliance with the following relevant FDA regulations (please indicate applicable CFR references):▪ it is in full compliance with Council Directive 1935/2004 <i>relating to materials and articles intended to come into contact with foodstuffs</i>, including its current amendments <p>c) There are measures in place to avoid contamination of the product (particulate & microbial)</p> <p>d) It is in full compliance with the requirements of the following monographs of the current edition of the European Pharmacopoeia indicated in chapter 3.1. <i>Materials used for the manufacture of containers</i></p> <ul style="list-style-type: none">▪ Monograph number 30202: 3.2.2. Plastic containers and closures for pharmaceutical use▪ Monograph number 30103: 3.1.3. Polyolefines▪ Monograph number 30111: 3.1.11. Materials based on non-plasticized poly (vinyl chloride) for containers for dry dosage forms for oral administration▪ Monograph number 30113: 3.1.13. Plastic additives
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Date, Location

Print Name

Signature

Position