



Submission Form 4-R89 E&L and Packaging Testing

002-FOR-9117759

IMPORTANT Instructions:

- 1) Please kindly fill in the form at the computer or in capital letters. Please kindly consider that quantities are intended per monograph.
- 2) Fields in light blue must be completed. The missing of information could lead to a delay of CoA issuing.
- 3) Please kindly print "Sender Information" "General Information" and "Other Monographs/Tests related page" and send them with samples.

For any type of issue please contact: DG_CIT005_StaifelPackTest@bpl.eurofins.eu.com

Please note that **deliveries** are allowed **between 8:00am and 5:00pm from Monday to Friday and from 8:00am to 11:00am on Saturday**.
IMPORVANT: Please note that customers delivering **samples weighing more than 100 Kg** must use a courier with a truck equipped with a hydraulic tail lift or a pallet truck to handle heavy packages.

SENDER INFORMATION

Company:			
Company Site:			
Sender Name/Surname:		Date:	
Sender Phone Number:			
Sender email Address:			

SECTION A: CLIENT'S INFORMATION (to be filled by Sender)

Issued documents	Contacts (please list as first the main contact)	e-mail Addresses	Phone Numbers
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Sample Registration Acknowledgement
 (notification of completed samples registration)

Certificate of Analysis

Invoice

SECTION B: GENERIC SAMPLE INFORMATION (to be filled by Sender)

Transport Temperature	Not relevant temperature at delivery		<input type="checkbox"/>			
	Controlled Room Temperature (15-25°C)		<input type="checkbox"/>			
	Freezer -20°C		<input type="checkbox"/>			
	Freezer -80°C		<input type="checkbox"/>			
Storage Temperature	Refrigeration (5±3°C)		<input type="checkbox"/>			
	Room temperature	<input type="checkbox"/>		Refrigeration (5±3) °C	<input type="checkbox"/>	
	Freezer (Specify T)	°C	<input type="checkbox"/>	Other:	<input type="checkbox"/>	
	Human	<input type="checkbox"/>	Veterinary	<input type="checkbox"/>	Other (Specify):	<input type="checkbox"/>
Typology	Finished product	<input type="checkbox"/>	Raw Material	<input type="checkbox"/>	Investigational medicinal product (IMP)	<input type="checkbox"/>
	API	<input type="checkbox"/>	Packaging	<input type="checkbox"/>	Other (Specify):	<input type="checkbox"/>
	H300 Fatal if swallowed	<input type="checkbox"/>	H310 Fatal if inhaled	<input type="checkbox"/>	H350 May cause cancer	<input type="checkbox"/>
	H310 Fatal in contact with skin	<input type="checkbox"/>	H340 May cause genetic defects	<input type="checkbox"/>	H360 May damage fertility or the unborn child	<input type="checkbox"/>
Return of samples at the end of the test	Not Needed	<input type="checkbox"/>	Needed	<input type="checkbox"/>	Share the vector account (freight collect)	<input type="checkbox"/>


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Instructions:		
1) Select the right flag by ticking the corresponding monograph box		
2) Click on the right link flag by ticking the corresponding monograph box		
GENERAL INFORMATION		
PHARMACOPOEIA CHAPTER		
FLAG	Test List required (Mandatory Link to be filled by Sender)	
EP 3.1.3 Polyolefins	<input type="checkbox"/>	Link
EP 3.1.4 Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations	<input type="checkbox"/>	Link
EP 3.1.5 Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations	<input type="checkbox"/>	Link
EP 3.1.6 Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations	<input type="checkbox"/>	Link
EP 3.1.7 Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations	<input type="checkbox"/>	Link
EP 3.1.8 Silicone Oil used as a lubricant	<input type="checkbox"/>	Link
EP 3.1.9 Silicone elastomer for closures and tubing	<input type="checkbox"/>	Link
EP 3.1.10 Materials based on non-plasticised poly(vinyl chloride) for containers for non-injectable, aqueous solutions	<input type="checkbox"/>	Link
EP 3.1.11 Materials based on non-plasticised poly(vinyl chloride) for containers for solid dosage forms for oral administration	<input type="checkbox"/>	Link
EP 3.1.14 Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion	<input type="checkbox"/>	Link
EP 3.1.15 Polyethylene terephthalate for containers for preparations not for parenteral use	<input type="checkbox"/>	Link
EP 3.1.18 Styrene block copolymers	<input type="checkbox"/>	Link
EP 3.2.1 Glass Containers for Pharmaceutical Use	<input type="checkbox"/>	Link
EP 3.2.9 Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze-Dried Powders	<input type="checkbox"/>	Link
EP 3.2.2.1 Plastic Containers for Aqueous Solutions for Infusion	<input type="checkbox"/>	Link
EP 3.2 Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components	<input type="checkbox"/>	Link
EP 3.3 Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components	<input type="checkbox"/>	Link
USP 381 Elastomeric Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems	<input type="checkbox"/>	Link
USP 660 Glass Container	<input type="checkbox"/>	Link
USP 661 Polyethylene Container	<input type="checkbox"/>	Link
USP 661 Polypropylene Container	<input type="checkbox"/>	Link
USP 661 Polyethylene Terephthalate Bottles and Polyethylene Terephthalate G Container	<input type="checkbox"/>	Link
USP 661 Physicochemical Tests for Plastic Packaging System and their Materials of Construction	<input type="checkbox"/>	Link
USP 661.1	<input type="checkbox"/>	Link
USP 661.2	<input type="checkbox"/>	Link
USP 670 Silica gel Auxiliary Packaging Components	<input type="checkbox"/>	Link
JP 7.01 Glass containers for injections	<input type="checkbox"/>	Link
JP 7.02 Plastic containers for aqueous injections	<input type="checkbox"/>	Link
JP 7.03 Test for Rubber Closure for Aqueous Infusions	<input type="checkbox"/>	Link
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Instructions:
 All fields in light blue must be completed. The missing of information could lead to a delay of CoA Issuing
 * For each test the minimum number of items required has to be reported in the column "Minimum number of rubber closures"
 * Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

Quotation number:		Rubber Closure Test - EP 3.2.9 - Information form	
RUSH	<input type="checkbox"/>	Batch	
Sample Description (as it appears on the COA)	Total Elasticomeric Closure Surface (cm ²)	Type of rubber closure	Please specify the method of sterilisation:
		Type 1 non-sterilised <input type="checkbox"/>	
		Type 2 non-sterilised <input type="checkbox"/>	
		Type 2 sterilised <input type="checkbox"/>	
	_____cm ²		
Test name	Text code	Minimum number of rubber closures	Operative Instructions
Identification A (IR absorption)	GP15U <input type="checkbox"/>	10 samples	Please specify if the rubber is: Coated <input type="checkbox"/> Uncoated <input type="checkbox"/> If identification A is requested please provide Type Sample (elastomeric reference specimen). Type sample could be asked to the manufacturing of rubber closure. Tick the right box, concerning sample preparation: Sample to analyzed as it by ATR <input type="checkbox"/> Pyrolyzate sample analyzed by ATR <input type="checkbox"/>
Identification B (Total ash)	GP27R <input type="checkbox"/>	Provide a number of closures in order to reach at least 2 g of rubber	Please specify if the rubber is: Coated <input type="checkbox"/> Uncoated <input type="checkbox"/> If identification B is requested please provide: type sample (elastomeric reference specimen) or Total ash specification obtained in accordance with EP method 2.4.16 (TOTAL ASH)
Solution S	GP6F4 <input type="checkbox"/>	(120/Total Elastomeric Closure Surface) x 2	Solution S is a mandatory test in order to perform chemical tests. One solution S is enough for all chemical tests. See below an example of calculation: Total elastomeric Closure Surface: 10 cm ² . Number of closures = (120/10)x2 = 24 items.
Appearance of solution S	GP18V <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Acidity or alkalinity	GP14U <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Absorbance	GP1EG <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Reducing substances	GP1EH <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Ammonium	GP1E <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Extractable zinc (on elastomeric closure)	GP0B0 <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Extractable zinc (on solution S provided by the Client)	GP0B0 <input type="checkbox"/>	See operative instructions.	At least 30 ml of solution S is necessary
Extractable heavy metals (old version)	LV3R1 <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Residue on evaporation	GP1EE <input type="checkbox"/>	Chemical test: see solution S for the minimum number of items	For this test, solution S is a preliminary mandatory test to perform: GP6F4 must be flagged.
Volatile sulfides	GP1EP <input type="checkbox"/>	(20/Total Elasticomeric Closure Surface) x 2	See below an example of calculation: Total elastomeric Closure Surface: 10 cm ² . Number of closures = (20/10)x2 = 4 items.
Permeability	GP1EB <input type="checkbox"/>	Physico mechanical test: 20 additional elastomeric closures are necessary with the minimum number of items of solution S	Specific clamp, vial and cap seal need to be provided if the closure is not 13mm stopper or 20mm stopper
Fragmentation	GP1FG <input type="checkbox"/>	Physico mechanical test: 20 additional elastomeric closures are necessary with the minimum number of items of solution S	Specific clamp, vial and cap seal need to be provided if the closure is not 13mm stopper or 20mm stopper
Self-sealing test	GP1H <input type="checkbox"/>	Physico mechanical test: 20 additional elastomeric closures are necessary with the minimum number of items of solution S	Specific clamp, vial and cap seal need to be provided if the closure is not 13mm stopper or 20mm stopper



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Instructions:
 1) Fields in light blue must be completed. The missing of information could lead to a delay of CoA issuing.
 Additional information:
 • For each test the minimum number of containers required has to be reported in the column "Minimum number of Containers"
 • Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

Glass Container Test - EP 3.2.1 - Information form

Quotation number:							
RUSH		<input type="checkbox"/>					
Sample Description (as it appears on the COA)	Batch	Nominal Volume (mL, filling volume range, type of vial 2R, GR etc)	Type of glass	Test name	Test code	Minimum number of containers (sum up the amount for each test)	Operative instructions
Type 1 <input type="checkbox"/>				Determination of filling volume	GP1AR <input type="checkbox"/>	6 containers (from 1 mL to 100 mL) 3 containers (above 100 mL)	Filling Volume is a preliminary mandatory test to be performed: Test A, Test C and Arsenic.
				Test A (surface test)	GP1AI <input type="checkbox"/>	40 containers (from 1 mL to 4 mL) 24 containers (from 5 mL to 9 mL) 15 containers (from 10 mL to 20 mL) 8 containers (above 20 mL to 50 mL) 5 containers (above 50 mL to 100 mL) 4 containers (above 100 mL)	For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GP1AR must be flagged.
				Test B (glass grains test)	GP1AI <input type="checkbox"/>	240 containers (1 mL) 150 containers (from 2 mL to 3 mL) 80 containers (from 4 mL to 5 mL) 50 containers (from 6 mL to 10 mL) 25 containers (above 10 mL to 20 mL) 15 containers (above 20 mL to 30 mL) 10 containers (above 30 mL to 50 mL) 5 containers (above 50 mL)	As an alternative please provide a number of containers in order to reach at least 300 g of glass
				Test B (etching test)	GP1AK <input type="checkbox"/>	40 containers (from 1 mL to 4 mL) 24 containers (from 5 mL to 9 mL) 15 containers (from 10 mL to 20 mL) 8 containers (above 20 mL to 50 mL) 5 containers (above 50 mL to 100 mL) 4 containers (above 100 mL)	For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GP1AR must be flagged. In addition for this test, we need the result of test A.
Type 2 <input type="checkbox"/>				Arsenic	GP09I <input type="checkbox"/>	45 containers (1 mL) 22 containers (from 2 mL to 3 mL) 10 containers (from 4 mL to 5 mL) 7 containers (from 6 mL to 8 mL) 5 containers (above 8 mL to 10 mL) 4 containers (above 10 mL to 15 mL) 3 containers (above 15 mL to 20 mL) 2 containers (above 20 mL to 40 mL) 1 containers (above 40 mL)	For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GP1AR must be flagged.
				Spectral transmission for coloured glass containers	GP1AL <input type="checkbox"/>	3 containers (all volumes)	Specify the use of glass container: Parenteral <input type="checkbox"/> Non Parenteral <input type="checkbox"/>
Type 3 <input type="checkbox"/>							

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 Additional Information:
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 • Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

Rubber Closure Test - USP 381 - Information form

Quotation number:	RUSH <input type="checkbox"/>		Batch	Total Elastomeric Closure Surface (cm ²)	Type of rubber closure	Please specify the method of sterilisation:	Test name	Test code	Minimum number of rubber closures	Operative instructions
				_____ cm ²	Type 1 non-sterilised <input type="checkbox"/>		Solution 5	GP19Q <input type="checkbox"/>	(120/Total Elastomeric Closure Surface) x 2	Solution 5 is a mandatory test in order to perform chemical tests. One Solution 5 is enough for all chemical tests. See below an example of calculation. Total elastomeric Closure Surface: 10 cm ² . Number of closures = (120/10)X 2 = 24 Items.
					Type 1 sterilised <input type="checkbox"/>		Determination of turbidity Procedure A	GP1C3 <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 1 sterilised <input type="checkbox"/>		Determination of color	GP1AQ <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 1 sterilised <input type="checkbox"/>		Acidity or alkalinity	GP19S <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 1 sterilised <input type="checkbox"/>		Absorbance	GP19T <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 2 non-sterilised <input type="checkbox"/>		Reducing substances	GP19U <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 2 non-sterilised <input type="checkbox"/>		Ammonium	GP19X <input type="checkbox"/>	Chemical test: see solution 5 for the minimum number of Items	For this test, Solution 5 is a preliminary mandatory test to perform: GP19Q must be flagged.
					Type 2 non-sterilised <input type="checkbox"/>		Volatile sulfides	GP19Y <input type="checkbox"/>	(20/Total Elastomeric Closure Surface) x 2	See below an example of calculation. Total elastomeric Closure Surface: 10 cm ² . Number of closures = (20/10)X 2 = 4 Items.
					Type 2 sterilised <input type="checkbox"/>		Fragmentation	GP1AI <input type="checkbox"/>	Physico mechanical test: 20 additional elastomeric closures are necessary	Specific crimping, vial and cap seal need to be provided if the closure is not: 13mm stopper or 20mm stopper
					Type 2 sterilised <input type="checkbox"/>		Fragmentation	GP1AI <input type="checkbox"/>	Physico mechanical test: 20 additional elastomeric closures are necessary	Specific crimping, vial and cap seal need to be provided if the closure is not: 13mm stopper or 20mm stopper

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Instructions:

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Additional Information:

- For each test the minimum number of containers required has to be reported in the column "Minimum number of Containers"
- Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

Glass Container Test- USP 660 - Information form

Quotation number:		RUSH		Batch		Nominal Volume (mL)		Type of glass		Test name		Test code		Minimum number of containers		Operative instructions	
Sample Description (as it appears on the COA)		Type 1 <input type="checkbox"/>		Type 2 <input type="checkbox"/>		Type 3 <input type="checkbox"/>		Test A (surface test)		Test B (glass grains test)		Test C (etching test)		Arsenic		Spectral transmission for coloured glass containers	
Determination of filling volume		GPI10 <input type="checkbox"/>		GPI09 <input type="checkbox"/>		GPI11 <input type="checkbox"/>		GPI12 <input type="checkbox"/>		GPI13 <input type="checkbox"/>		GPI14 <input type="checkbox"/>		40 containers (from 1 mL to 4 mL) 24 containers (from 5 mL to 9 mL) 15 containers (from 10 mL to 20 mL) 8 containers (above 20 mL to 50 mL) 5 containers (above 50 mL to 100 mL) 4 containers (above 100 mL)		Filling Volume is a preliminary mandatory test to be performed: Test A, Test C and Arsenic.	
40 containers (from 1 mL to 4 mL) 24 containers (from 5 mL to 9 mL) 15 containers (from 10 mL to 20 mL) 8 containers (above 20 mL to 50 mL) 5 containers (above 50 mL to 100 mL) 4 containers (above 100 mL)		240 containers (1 mL) 150 containers (from 2 mL to 3 mL) 80 containers (from 4 mL to 5 mL) 50 containers (from 6 mL to 10 mL) 25 containers (above 10 mL to 20 mL) 15 containers (above 20 mL to 30 mL) 10 containers (above 30 mL to 50 mL) 5 containers (above 50 mL)		As an alternative please provide a number of containers in order to reach at least 300 g of glass		For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GPI10 must be flagged. In addition for this test, we need the result of test A.		For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GPI10 must be flagged.		For this test, Determination of filling Volume is a preliminary mandatory test to be performed: GPI10 must be flagged.		Specify the use of glass container: Parenteral <input type="checkbox"/> Non Parenteral <input type="checkbox"/>					



Submission Form 4-R89 E&L and Packaging Testing

1-P-SC-FOR-9117759

Instructions:
 1) Fields in light blue must be completed. The missing of information could lead to a delay of CoA Issuing
Additional information:
 • For each test the minimum number of items required has to be reported in the column "Minimum number of plastic containers"
 • Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.2.2.1 Plastic containers for aqueous solutions for infusion - Information form

Quotation number:							
RUSH		<input type="checkbox"/>					
Sample Description (Monograph name if applicable) (as it appears on the CoA)	Lot / Batch #	Nominal Volume (ml)	Test Code (as defined in Quotation e.g. GRXXX, LVVYV, ZXXX)	Requested tests (as defined in quotation)	Minimum number of plastic containers	Operative instructions	
					Considering the nominal capacity please kindly send us at least the number of containers in order to reach 100ml + 1 additional container. For example for a nominal capacity of 5 ml the number of items required is 20 plastic containers of 5 ml (= 100 ml) plus 1, so in total 21 containers.	Choose the right material of the container: Polyethylene <input type="checkbox"/> Polypropylene <input type="checkbox"/> Other material <input type="checkbox"/>	
						Please Provide Nominal Capacity: <input type="text"/> ml	



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 - Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.1.3 Polyolefins - Information form

Quotation number:					Minimum amount needed of plastic containers	Operative instructions
RUSH	<input type="checkbox"/>					
Sample Description (Monograph name if applicable) (as it appears on the COA)	Lot / Batch #	Test Code (as defined in Quotation e.g. GPXXX, LVYY/ZXXX)	Requested tests (as defined in quotation)	Minimum amount needed of plastic containers	Operative instructions	
				Amount needed 250 g	<p>If identification A is requested please provide Type sample (plastic reference specimen). Type sample could be asked to the manufacturing of the plastic material. Please note that in accordance with the updating of our internal procedures, the comparison with Type Sample is mandatory and we cannot proceed by comparison with a spectrum provided by the Client. Without Type Sample we cannot release a CoA with EP 3.1.3 compliance but we can proceed with the analysis as "Only for information".</p> <p>Identification B complies with the supplementary tests corresponding to the additives present in the composition</p> <p>For test code GP1A9,GP1AA,GP1AB and GP1AC "S1 test" is mandatory, For test code GP1AE,GP1AF,GP1AG and GP1AH "S3 test" is mandatory.</p>	
					<p>Identification C: To be performed only on opacified material with titanium dioxide</p>	



Submission Form 4-R89 E&L and Packaging Testing

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- Instructions:**
- 1) Fields in light blue must be completed. The missing of information could lead to a delay of CoA issuing
- Additional information:**
- For each test the minimum number of items required has to be reported in the column "Minimum number of plastic containers"
 - Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.1.4 Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations - Information form

Quotation number:						
RUSH		<input type="checkbox"/>				
Sample Description (Monograph name if applicable) <i>(as it appears on the CoA)</i>	Lot / Batch #	Test Code (as defined in Quotation e.g. GPXXX, LYYYYZZXX)	Requested tests (as defined in quotation)	Minimum amount needed of plastic containers	Operative instructions	
				Amount needed 250 g	<p>If identification A is requested please provide type sample (plastic reference specimen). Type sample could be asked to the manufacturing of the plastic material. Please note that in accordance with the updating of our internal procedures, the comparison with Type Sample is mandatory and we cannot proceed by comparison with a spectrum provided by the Client. Without Type Sample we cannot release a CoA with EP 3.1.4 compliance but we can proceed with the analysis as "Only for information".</p>	
					<p>For test code GP1F7, GP1F8, GP1F9 and GP1FA "S1 test" is mandatory. For test code GP1FC "S2 test" is mandatory. For test code GP1FD "S3 test" is mandatory.</p>	

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- Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.1.18 Styrene block copolymers - Information form

Quotation number:							
RUSH		<input type="checkbox"/>					
Sample Description (Monograph name if applicable) (as it appears on the COA)	Lot / Batch #	Test Code (as defined in Quotation e.g. GPXXX, LYYYY/ZXXX)	Requested tests (as defined in quotation)	Minimum amount needed of plastic containers	Operative instructions		
				Amount needed 250 g	If Identification A is requested, please provide type sample (plastic reference specimen). Type sample could be asked to the manufacturing of the plastic material. Please note that in accordance with the updating of our internal procedures, the comparison with Type Sample is mandatory and we cannot proceed by comparison with a spectrum provided by the Client. Without Type Sample we cannot release a CoA with EP 3.1.18 compliance, but we can proceed with the analysis as "Only for information. For the Identification A, the following tests are required: Solution S2, Butylhydroxytoluene R5 and Plastic additive 08 R5		
					For test code Identification C, we need to perform Phenolic antioxidants test A, Phenolic antioxidants test B and Stearates test. In addition Phenolic antioxidants, Solution S2, Butylhydroxytoluene R5 and Plastic additive 08 R5 tests are mandatory.		
					Sulfated ash: provide % of titanium dioxide		



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- Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.1.6 Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations - Information form

Quotation number:						
RUSH		<input type="checkbox"/>				
Sample Description (Monograph name if applicable) <i>(as it appears on the CoA)</i>	Lot / Batch #	Test Code (as defined in Quotation e.g. GPXXX, LYYYYZZXX)	Requested tests (as defined in quotation)	Minimum number of plastic containers	Operative instructions	
				Amount needed 250 g	<p>If identification A is requested please provide Type sample (plastic reference specimen). Type sample could be asked to the manufacturing of the plastic material. Please note that in accordance with the updating of our internal procedures, the comparison with Type Sample is mandatory and we cannot proceed by comparison with a spectrum provided by the Client. Without Type Sample we cannot release a CoA with EP 3.1.6 compliance but we can proceed with the analysis as "Only for information".</p> <p>Identification B complies with the supplementary tests corresponding to the additives present in the composition</p> <p>For test code GP1BX, GP1BY, GP1BZ and GP1CO "S1 test" is mandatory. For test code GP1C2,GP1C5,GP1C6,GP1C7,GP1C9 and GP1CA "S3 test" is mandatory.</p> <p>Identification C: To be performed only on opacified material with titanium dioxide</p>	



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 - Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

EP 3.1.7 Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations - Information form

Quotation number:					Minimum amount needed of plastic containers	Operative instructions
RUSH <input type="checkbox"/>						
Sample Description (Monograph name if applicable) <i>(as it appears on the CoA)</i>	Lot / Batch #	Test Code <i>(as defined in Quotation e.g. GPXXX, LVYYY, ZXXX)</i>	Requested tests <i>(as defined in quotation)</i>			
					Amount needed 250 g	<p>If identification is requested please provide type sample (plastic reference specimen). Type sample could be asked to the manufacturing of the plastic material. Please note that in accordance with the updating of our internal procedures, the comparison with Type Sample is mandatory and we cannot proceed by comparison with a spectrum provided by the Client. Without Type Sample we cannot release a CoA with EP 3.1.7 compliance but we can proceed with the analysis as "Only for information".</p>



Submission Form 4-R89 E&L and Packaging Testing

002-FOR-9117759

Instructions:

1) Fields in light blue must be completed. The missing of information could lead to a delay of CoA issuing

Additional information:

- For each test the minimum number of items required has to be reported in the column "Minimum number of plastic containers"
- Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

USP 661 - Information form

Quotation number:					
RUSH		<input type="checkbox"/>			
Sample Description (Monograph name if applicable) (as it appears on the COA)	Lot / Batch #	Test Code (as defined in Quotation e.g. GPXXX, LVVYJZXXX)	Requested tests (as defined in quotation)	Minimum amount needed of plastic containers	Operative instructions
				Amount needed: 2400 cm ² In the case of PET and PET G containers provide the amount in order to reach at least 200 mL after the filling at nominal capacity with solvent	Provide inner and outer surface of the sample: inner surface = <input type="text"/> cm ² outer surface = <input type="text"/> cm ²
					Choose the right material: LDPE <input type="checkbox"/> HDPE <input type="checkbox"/> Polypropylene <input type="checkbox"/> PET <input type="checkbox"/> PET-G <input type="checkbox"/> other material <input type="checkbox"/>

Revision: 5

Local Reference : Mod. SOP/COM/001.R

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Submission Form 4-R89 E&L and Packaging Testing

002-FOR-9117759

- Instructions:**
- 1) Fields in light blue must be completed. The missing of information could lead to a delay of COA issuing
- Additional information:**
- For each test the minimum number of items required has to be reported in the column "Minimum number of rubber closures"
 - Fill out the following form for each sample to be analysed. If more than one sample has to be tested, please duplicate the sheet

USP 661.1 - Information form

Quotation number:								
RUSH		<input type="checkbox"/>						
Sample Description (Monograph name if applicable) (as it appears on the COA)	Lot / Batch #	Inner and outer surface (cm ²)	Test Code (as defined in Quotation e.g. GPXXX, LYYYY,IZXXX)	Requested tests (as defined in quotation)	Minimum amount needed of plastic containers	Operative instructions		
					Amount needed 100 g	Choose the right material:		
						Cyclic Olefin Polymer <input type="checkbox"/>		
						Cyclic Olefin Copolymer <input type="checkbox"/>		
						Polyamide 6 <input type="checkbox"/>		
						Polycarbonate <input type="checkbox"/>		
						LDPE <input type="checkbox"/>		
						HDPE <input type="checkbox"/>		
						PET <input type="checkbox"/>		
						PET-G <input type="checkbox"/>		
						Poly(ethylene-vinyl-acetate) <input type="checkbox"/>		
					Polypropylene <input type="checkbox"/>			
					Polyvinyl Chloride <input type="checkbox"/>			
					Polyvinyl Chloride Plasticized <input type="checkbox"/>			

Revision: 5
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Local Reference : Mod. SOP/COM/001.R
Approved document in EQMS



Submission Form 4-R99 E&L and Packaging Testing

002-FOR-311729

Instructions:
 1) Fields in light blue must be completed. The missing of information could lead to a delay of CoA Issuing.
 • For each test the minimum number of items required has to be reported in the column "Minimum number of plastic containers".
 • Fill out the following form for each sample to be analyzed. If more than one sample has to be tested, please duplicate the sheet.

USP 561.2 - Information form

Quotation number:	USP 561.2 - Information form							
RUSH	Sample Description (Monograph name if applicable) (at it appears on the CoA)	Lot / Batch #	Test Code (see table GPOXX, LVVXX, DXXK)	Requested tests Other Plastic Material (as defined in quotation)	Requested tests PET-G (as defined in quotation)	Requested tests PET (as defined in quotation)	Minimum number of plastic containers	Operative Instructions
<input type="checkbox"/>				GP01X <input type="checkbox"/> GP01Y <input type="checkbox"/> GP01Z <input type="checkbox"/> GP01Q <input type="checkbox"/> GP01R <input type="checkbox"/> GP01S <input type="checkbox"/> GP01T <input type="checkbox"/> GP01U <input type="checkbox"/> GP01V <input type="checkbox"/> GP01W <input type="checkbox"/> GP01X <input type="checkbox"/> GP01Y <input type="checkbox"/> GP01Z <input type="checkbox"/> GP01Q <input type="checkbox"/> GP01R <input type="checkbox"/> GP01S <input type="checkbox"/> GP01T <input type="checkbox"/> GP01U <input type="checkbox"/> GP01V <input type="checkbox"/> GP01W <input type="checkbox"/> GP01X <input type="checkbox"/> GP01Y <input type="checkbox"/> GP01Z <input type="checkbox"/> GP01Q <input type="checkbox"/> GP01R <input type="checkbox"/> GP01S <input type="checkbox"/> GP01T <input type="checkbox"/> GP01U <input type="checkbox"/> GP01V <input type="checkbox"/> GP01W <input type="checkbox"/> GP01X <input type="checkbox"/> GP01Y 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