

Status	Effective	Effective Date	26-Apr-2016	Version	12.0	Doc Name	FORM-7045
Title	Certificate of Conformance						
Doc Alias	FORM-000001392 GCF02670					Site Code / Department	grc / Quality Assurance GC



Pfizer Ireland Pharmaceuticals
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GRANGE CASTLE CERTIFICATE OF CONFORMANCE (CoC)		
Section I – Material Description		
<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Amendment	Replaces CoC Issued: _____
Batch Number	AA1763	
Material Part Number	H000003719	
Description	SERO TYPE 23F MBC	
Section II – Material Disposition		
<input type="checkbox"/> Approved for Further Processing <input checked="" type="checkbox"/> Released for Distribution <ul style="list-style-type: none"> <input type="checkbox"/> Released with NO Distribution Restrictions carried forward <input checked="" type="checkbox"/> Released with No EU Distribution Restrictions carried forward <input checked="" type="checkbox"/> Released with No US Distribution Restrictions carried forward <input checked="" type="checkbox"/> Released with distribution restrictions for non-EU Markets (See Attachment 1) 		
Authorized By: <u>Sarah Flynn</u> (Qualified Person)		Date: <u>09 Jan 19</u>
<p>This signature represents that all procedures were followed and documented as per cGMP's. The above material has been manufactured and tested in accordance with the requirements of approved licenses and Technical Quality Agreements, subject to any distribution restrictions listed in Attachment 1 (as applicable), and is in compliance with the principles and guidelines of current Good Manufacturing Practices (cGMP) for medicinal products.</p> <p>This also certifies that any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/ or formulation of the batch of product specified above fulfill the prescriptions defined in EMEA/410/01(rev 3.0) and have therefore been demonstrated to be in accordance with the current CPMP "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products".</p>		
Reference SOP-13441 "Site Procedure for Disposition at Pfizer Grange Castle"		

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**Certificate of Conformance – Attachment 1
Distribution Restrictions**Batch No: AA1763Product: Serotype 23F Monovalent Bulk ConjugatePart Number: H000003719Date of Manufacture: 10Nov18Date of Expiry: 30Oct20

DRN #	PCF #	Site
568461	N/A	Andover
N/A	2016-009018	Grange Castle
N/A	2018-005532	Grange Castle

No Significant Investigation(s)Completed by:Sarah Flynn
Qualified PersonDate:

09 Jan 19