



Australian Government
Department of Health
 Therapeutic Goods Administration

Laboratories Branch

Operations		Biochemistry – Forms	
Procedure	Forms – Protocol Check		
Written	s22	.	s22
Authorised	s22		
Date issued	10 August 2015		
Revision #	9		

Protocol Checklist

Product name: CSL NORMAL IMMUNOGLOBULIN VF (human) 800mg/5mL injection vial	
AUST R: 61216	LIMS number 1610003685

Documents assessed:

CoA (Drug Product) <input checked="" type="checkbox"/>	Shipping <input type="checkbox"/>	Additional Data <input type="checkbox"/>
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Final Drug Product			
Drug Product Batch No:	3620050074	Expiry date:	20/05/2017
CoA provided?	Yes	Complies with CPD Specifications?	Yes
Quantity to be released:	NA - Survey	CPD date:	1/02/2016
Drug Substance batch No: (if provided)	NA	Expiry date:	Enter a date.
Diluent Batch No (vial):	NA	Comments: Enter text.	
Diluent Expiry Date:	Enter a date.		
Shipping data			
Shipping Data Submitted?	No	Comments: Enter text.	
Shipment No:	Enter text.		
Shipping Data Acceptable:	Choose an item.		
Actual Temp range recorded:	Min:		
	Max:	Enter temp.	°C
Product 'Testing and Post Market Summary' updated			Yes

	Name	Date in LIMS
Analyst	s22	13/12/2016
Test Manager	s22	23/03/2017

Record Details	R16 966614 Protocol Check - CSL normal IgG 800mg - 1610003685 - B# 3620050074.DOCX		
Last Editor	s22	Edit Date	23/09/2022 1:21 PM
Print Date	s22	23/09/2022 1:21 PM	Page 1 of 2

Protocol Checklist (cont.)

Additional Data (if provided)	
CoA for Drug Substance (bulk/API) <input type="checkbox"/>	Choose an item.
Testing raw data for Drug Product <input type="checkbox"/>	Choose an item.
Testing raw data for Drug Substance <input type="checkbox"/>	Choose an item.
Deviation report <input type="checkbox"/>	Choose an item.

Other (please specify below)

Enter text.	Choose an item.
Enter text.	Choose an item.
Enter text.	Choose an item.

Data format:	Choose an Item
Data Location (TRIM File/Container #)	Enter text.
Comments: Click here to enter text.	

	Name	Date in LIMS
Analyst	Enter text.	Enter a date.
Test Manager	Enter text.	Enter a date.