



Australian Government
Department of Health
 Therapeutic Goods Administration

Laboratories Branch

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

Protocol Checklist

Product name: CSL Rh(D) IMMUNOGLOBULIN VF (human) 250IU injection vial	
AUST R: 76643	LIMS number 1608003191

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:	3690850044	Expiry date:	8/08/2018
CoA provided?	Yes	Complies with CPD Specifications?	Yes
Quantity to be released:	8078	CPD date:	31/10/2016
Drug Substance batch No: (if provided)	n/a	Expiry date:	NA
Diluent Batch No (vial):	n/a	Comments: NA	
Diluent Expiry Date:	NA		
Shipping data			
Shipping Data Submitted?	Choose an item.		Comments: Manufactured by CSL Behring in Australia. Shipping data not required
Shipment No:	n/a		
Shipping Data Acceptable:	Choose an item.		
Actual Temp range recorded:	Min:	NA °C	
	Max:	NA °C	
Product 'Testing and Post Market Summary' updated			Yes

	Name	Date in LIMS
Analyst	s22	28/11/2016
Test Manager	s22	01/12/2016

Record Details	R16 940079 Protocol Check - Rh(D) Immunoglobulin VF (human) 250IU - 1608003191 - B#3690850044.DOCX
Last Editor	s22 Edit Date 23/09/2022 1:39 PM
Print Date	23/09/2022 1:39 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:	Hard copy
Data Location (TRIM File/Container #)	2016/026155
Comments: E-file 2016/026155	

	Name	Date in LIMS
Analyst	Enter text.	Enter a date.
Test Manager	§22	01/12/2016