



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Laboratories Branch**

| Operations         | Biochemistry – Forms   |
|--------------------|------------------------|
| <b>Procedure</b>   | Forms – Protocol Check |
| <b>Written</b>     | s22                    |
| <b>Authorised</b>  | s22                    |
| <b>Date issued</b> | 10 August 2015         |
| <b>Revision #</b>  | 9                      |

## Protocol Checklist

|                                                                                           |                        |
|-------------------------------------------------------------------------------------------|------------------------|
| Product name: RHOPHYLAC 1500IU human anti-D immunoglobulin solution for injection syringe |                        |
| AUST R: 153815                                                                            | LIMS number 1608003190 |

**Documents assessed:**

|                                                        |                                              |                                                     |
|--------------------------------------------------------|----------------------------------------------|-----------------------------------------------------|
| CoA (Drug Product) <input checked="" type="checkbox"/> | Shipping <input checked="" type="checkbox"/> | Additional Data <input checked="" type="checkbox"/> |
|--------------------------------------------------------|----------------------------------------------|-----------------------------------------------------|

| Final Drug Product                                |             |                                                                                                                                                   |                                                 |
|---------------------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Drug Product Batch No:                            | 4367600001  | Expiry date:                                                                                                                                      | 30/06/2018                                      |
| CoA provided?                                     | Yes         | Complies with CPD Specifications?                                                                                                                 | Yes                                             |
| Quantity to be released:                          | NA - Survey | CPD date:                                                                                                                                         | 1/10/2016                                       |
| Drug Substance batch No: (if provided)            | NA          | Expiry date:                                                                                                                                      | NA                                              |
| Diluent Batch No (vial):                          | NA          | Comments:<br>Manufactured before current CPD – checked against CPD Nov 2013 as well ie HAV-RNA, B19-DNA, Anti-A & B Haemagglutinins and Anti B19. |                                                 |
| Diluent Expiry Date:                              | NA          |                                                                                                                                                   |                                                 |
| Shipping data                                     |             |                                                                                                                                                   |                                                 |
| Shipping Data Submitted?                          | Yes         |                                                                                                                                                   | Comments:<br>Temperature above 8°C for 2 hours. |
| Shipment No:                                      | 110103081   |                                                                                                                                                   |                                                 |
| Shipping Data Acceptable:                         | No          |                                                                                                                                                   |                                                 |
| Actual Temp range recorded:                       | Min:        | 2.5 °C                                                                                                                                            |                                                 |
|                                                   | Max:        | 13.9 °C                                                                                                                                           |                                                 |
| Product 'Testing and Post Market Summary' updated |             |                                                                                                                                                   | Yes                                             |

|              | Name | Date in LIMS |
|--------------|------|--------------|
| Analyst      | s22  | 06/12/2016   |
| Test Manager | s22  | 24/01/2017   |

|                |                                                                                                     |           |                    |
|----------------|-----------------------------------------------------------------------------------------------------|-----------|--------------------|
| Record Details | R16 940585 Protocol Check - Rhophylac AntiD Immunoglobulin 1500IU - 1608003190 - B# 4367600001.DOCX |           |                    |
| Last Editor    | s22                                                                                                 | Edit Date | 23/09/2022 2:03 PM |
| Print Date     | 23/09/2022 2:03 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"/>   |                 |
| Testing raw data for Drug Substance <input type="checkbox"/> | Choose an item. |
| Deviation report <input type="checkbox"/>                    | Choose an item. |

### Other (please specify below)

|                            |                 |
|----------------------------|-----------------|
| Manufacturer's Declaration | attached        |
| Enter text.                | Choose an item. |
| Enter text.                | Choose an item. |

|                                       |                |
|---------------------------------------|----------------|
| Data format:                          | Choose an Item |
| Data Location (TRIM File/Container #) | 2016/026155    |
| <b>Comments:</b><br>NA                |                |

|              | Name | Date in LIMS |
|--------------|------|--------------|
| Analyst      | s22  |              |
| Test Manager | s22  | 24/01/2017   |

|                |                                                                                     |           |                    |
|----------------|-------------------------------------------------------------------------------------|-----------|--------------------|
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| Print Date     | 23/09/2022 2:03 PM                                                                  |           | Page 2 of 2        |