

**CERTIFICATE OF ANALYSIS**

|                        |   |
|------------------------|---|
| <b>PRODUCT:</b>        | SIMULATED INTESTINAL FLUID (without enzyme)<br>DISSOLUTION MEDIA CONCENTRATE  |
| <b>PRODUCT No.:</b>    | DMC031-25   |
| <b>LOT NO:</b>         | DMC31115B1  |
| <b>DATE OF TEST:</b>   | 12 <sup>th</sup> February 2015  |
| <b>EXPIRY DATE:</b>    | 28 <sup>th</sup> January 2017   |
| <b>MEAN pH VALUE:</b>  | 6.52@25°C   |
| <b>SPECIFICATION:</b>  | pH 6.50 - 6.60 @25°C after dilution   |
| <b>DENSITY (g/ml):</b> | 1.1299 @25°C  |
| <b>COMPOSITION:</b>    | Potassium dihydrogenorthophosphate<br>Sodium Hydroxide  |
| <b>pH MEASUREMENT:</b> | Tested in accordance with in-house method TPPHB.<br>Measured with a combination glass electrode after multiple<br>point calibration with reference materials.   |
| <b>TRACEABILITY:</b>   | Standard buffer solutions are certified traceable to the<br>following U.S. National Institute of Standards and<br>Technology, SRM 185i Potassium Hydrogen Phthalate,<br>SRM 186-I-g Potassium Dihydrogen Phosphate and SRM<br>186-II-g Disodium Hydrogen Phosphate. |

This certificate relates solely to the lot number given above. The uncertainty of measurement has been calculated not to exceed  $\pm 0.02$  pH units at 95% confidence level.

This product complies with the USP requirements for dissolution media when diluted with purified water as instructed.

**Approved By:** QC Supervisor  
**Date:** 12<sup>th</sup> February 2015

*Margaret Davnan*