

Validation Protocol Deviation Report Form

(Ref. SOP VAL-175)

| | | | |
|---|------------------------------|----------------------------------|-----------------------------------|
| Project Number | | Protocol Deviation Report Number | |
| Does this Deviation directly affect product status? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | If yes, raise a quality deviation |
| Deviation ID | | | |

A. Identification of the Section of the Protocol Affected

| |
|--|
| |
|--|

B. Description of the Protocol Deviation

| |
|--|
| |
|--|

C. Discussion of the Deviation Occurrence

| |
|--|
| |
|--|

D. Reason (Root Cause) for the Deviation Occurrence and Impact on the Validation Study

| |
|--|
| |
|--|

E. Resolution of the Deviation

| |
|--|
| |
|--|

F. Attachments

| |
|--|
| |
|--|

Note: This form may be reproduced in both "hardcopy" and in an electronic format. The authorisation of this form is located on a separate page to permit reproduction of this form electronically.

| | | | | |
|-------------------------------|------|--|------|--|
| Deviation Report Prepared By: | Sign | | Date | |
| Reviewed and Approved By: | Sign | | Date | |
| Quality Assurance Approval: | Sign | | Date | |