

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION Filinvest Corporate City Alabang, City of Muntinlupa



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| Wanner of Notification | | | <u> </u> | * <u> </u> | | , |
| Purpose of Inspection | | | | | · · · · · · · · · · · · · · · · · · · | <u> </u> |
| Reference / Inspection Standard | | | | · · · · · · · · · · · · · · · · · · · | - | |
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| | For Critical findings (for local and foreign establishments) |
| | Result of the inspection revealed that the company was not able demonstrate compliance to GMP, for this reason we are filing a report of violation and other regulatory remedies as appropriate. |
| | ☐ A copy of the report will be endorsed to the Product Recall Committee of the respective Centers for evaluation. |
| | For Foreign GMP Inspection |
| | ☐ Disapproval of application ☐ Disapproval of product line |
| | For Corrective Action/Preventive Action (CAPA) |
| | Address the deficiencies and submit CAPA Plan thru FDA Central Receiving Unit including submission of objective evidence of compliance within the specified timeline reckoned on the following day of receipt of summary of observations/findings: |
| | ☐ Thirty (30) calendar days for critical deficiencies |
| <u> </u> | ☐ Forty-five (45) calendar days for major deficiencies & other deficiencies |
| | inspected By |
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| Date | Food-Drug Regulation Officer Food-Drug Regulation Officer Time: |
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| - | Establishment's Representative Establishment's Representative |
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| | For Critical findings (for local and foreign establishments) | | | | |
| | Result of the inspection revealed that the company was not able demonstrate compliance to GMP, for this reason we are filing a report of violation and other regulatory remedies as appropriate. | | | | |
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| Compliance made by the company | | | |
| ☐ Submitted CAPA ☐ Accepted Recommendation (to Licensing): | □ Not 2 | Accepted | |
| Print name and signature of Reviewed by: | f FDROs | | Date |
| Print name & signature of Team Le | ader/Supervisor | | Date |

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| Print name & signature of Team Lead | der/Supervisor | | | Date | |

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