*The following information shall be labelled on the carton, inner label and the blisters or strips of the investigational drug product for a clinical trial:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Unit carton* | *Inner* | *Blister or* |
| *Parameters* | *or subject* |
| *Labels* | *Strips* |
|  | *kit* |
|  |  |  |
| Clinical trial protocol number | √ | √ | √ |
|  |  |  |  |
| Visit | √\*\* | √\*\* | √\*\* |
|  |  |  |  |
| No. of the subjects or initial of the subject | √ | √\* | √ |
|  |  |  |  |
| Investigational drug product name or code | √ | √ | NA |
|  |  |  |  |
| Dosage form | √\*\* | √\*\* | √\*\* |
|  |  |  |  |
| Name of active substance | √\*\* | √\*\* | √\*\* |
|  |  |  |  |
| Strength of active substance | √\*\* | √\*\* | √\*\* |
|  |  |  |  |
| Instructions for use | √ | √\* | √ |
|  |  |  |  |
| Batch number | √\*\* | √\*\* | √\*\* |
|  |  |  |  |
| Manufacturing date or retest date | √ | √ | √ |
|  |  |  |  |
| Expiry date | √ | √ | √ |
|  |  |  |  |
| For clinical trial use only | √ | √\* | √ |
|  |  |  |  |
| Name and address of manufacturer, final | √\*\*\* | √\*\*\* | √\*\*\* |
| release, product owner (corporate address) |
| or sponsor |  |  |  |
| Route of administration | √ | √ | NA |
|  |  |  |  |
| Storage condition | √ | √\* | NA |
|  |  |  |  |
| Pack sizes (unit or volume) | √ | √\* | NA |
|  |  |  |  |

NA Not Applicable

* Exempted for small label such as ampoule and vial.
* Where applicable
* With letter of authorisation

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner carton