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| PRODUCT NAME : Glucose Intravenous Infusion B.P (50g/L) MFG. DATE : APR-09  BATCH NO. : 030010 EXPIRY DATE : APR-12  TEST STARTED ON : 27/07/09 BATCH SIZE : 2000L  TEMP & HUMIDITY : 30 ± 2°C, 65 ± 5% RH COMPLETED ON : 16/05/12 | | | | | | | | | | |
| RESULTS OF ANALYSIS | | | | | | | | | | |
| TEST | LIMITS | INITIAL RESULT | AFTER 03 MONTHS | AFTER 06 MONTHS | AFTER 09  MONTHS | AFTER 12 MONTHS | AFTER 18 MONTHS | AFTER 24  MONTHS | AFTER 30  MONTHS | AFTER 36  MONTHS |
| Description | A clear, colourless solution. Maybe not more than faintly yellow in colour. | Complies | Complies | Complies | Complies | Complies | Complies | Complies | Complies | Complies |
| Identification | 1. To meet the test.  2. To meet the test. | Complies | Complies | Complies | Complies | Complies | Complies | Complies | Complies | Complies |
| Extractable volume | NLT nominal volume (250mL). | 508mL | 508mL | 507mL | 507mL | 508mL | 508mL | 516mL | 515mL | 515mL |
| pH | 3.5 - 6.5 | 05.81 | 04.23 | 04.48 | 04.53 | 04.00 | 04.06 | 04.50 | 03.81 |  |
| Particulate Matter | 12 per mL(Max)  2 per mL (Max | 0.53  0.10  Complies | N/A | N/A | N/A | 0.70  0.10  Complies | N/A | 0.43  0.07  Complies | N/A | 1.53  0.67  Complies |
| Bacterial endotoxins | Less than 0.25IU /mL | <0.25IU /mL | N/A | N/A | N/A | <0.25IU/mL | N/A | <0.25IU/mL | N/A | <0.25IU/mL |
| Heavy Metal | NMT 0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% | <0.0025% |
| 5- hydroxymethylfurfural and related substances | Absorbance of not more than 0.25 | 0.015 | 0.015 | 0.060 | 0.043 | 0.089 | 0.010 | 0.007 | 0.109 | 0.017 |
| Assay | 95.0% -105.0% | 100.65% | 96.67% | 96.57% | 97.43% | 98.19% | 97.80% | 98.76% | 98.00% | 98.38% |
| Sterility | No growth on incubation for 14 days | complies | N/A | N/A | N/A | Complies | N/A | Complies | N/A | Complies |
| Observation & Conclusion | To meet specification | complies | complies | complies | complies | complies | complies | Complies | Complies | Complies |