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NITIKA

# NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD., NAGPUR

## CERTIFICATE OF ANALYSIS

| PRODUCT NAME: STANPURE® CALCIUM CARBONATE USP/NF | GRADE : CUSTOMISED |
|---|---|
| Received Date : 09/08/2015 | Page : 1of 2 |
| Release Date : 16/08/2015 | Ref.Specification No.:QAD/FP/SPEC/AEL/CACB9/03 |
| Drug License No. : ND/15 | Analysis Report No. : NP/FP/ CACB/1298 /15 |
| Batch No. : CACB9E101 | Qty.Drawn for Analysis : 60 g |
| Mfg. Date : AUG.:2015 | Re.Eval.Date : JUL.:2020 |

| SN | TESTS | SPECIFICATIONS | RESULTS |
|---|---|---|---|
| 1. * | Description | White to slightly grayish colour crystalline fine powder, odourless, insipid. Exempt of any strange particles. | White fine powder |
| 2. | Solubility | Practically insoluble in water. Its solubility in water is increased by the presence of any ammonium salt or of carbon dioxide. The presence of any alkali hydroxide reduces its solubility. Insoluble in alcohol. Dissolves with effervescence in acetic acid1 N, in hydrochloric acid 3 N, and in nitric acid2 N. | Complies |
| 3. | Identification | Positive for calcium carbonate. | Complies |
| 4. * | Loss on drying at 200° for 4 hours. | Not more than 2.0 % of its weight. | 0.89 % |
| 5. | Acid-insoluble substances | The weight of the residue does not exceed 10 mg (0.2 %) | <0.2 % |
| 6. | Limit of fluoride | Max 0.005 % | <0.05 % |
| 7. | Arsenic | Max 3 ppm | < 3ppm |
| 8. | Barium | As Per USP | Complies |
| 9. | Lead | Max 3 ppm | < 3ppm |
| 10. | Iron | Max 0.1 % | < 0.1 % |
| 11. | Mercury | Max 0.5 µg per g. | < 0.5 µg/g |
| 12. | Limit of magnesium and alkali salts | The weight of the residue does not exceed 5 mg (1.0 %) | < 1.0% |
| 13. | Heavy metals | Max 0.002 % | < 0.002 % |
| 14. * | Assay | 98.0 % - 100.5 % of $CaCO_3$ (Dried at 200° for 4 hours). | 98.94 % |
| 15. | Residual Solvents | Meets the requirement <467> | Complies |
| 16. | Bulk Density | 0.45 – 0.75 g/ml | 0.46g/ml |
| 17. | Tapped Density (1000 TAPS) | 0.6 – 1.1 g/ml | 0.69g/ml |
| 18. * | Microbial Limits | | |
| | Total Microbial Plate Count | NMT 1000 cfu/g | 50 cfu/g |
| | Yeast and Mould | NMT 100 cfu/g | 10 cfu/g |
| | E. coli | Absent | Absent |

| | Name | Designation | Signature/Date |
|---|---|---|---|
| Prepared By: | Mr. Dinesh Munne | QA Chemist | |
| Checked By: | Mr. Vyankat Singh | QC Manager | |
| Approved By: | Mr. Kiran Kelwatkar | QA Head | |

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| | | | |
|---|---|---|---|
| | Salmonella | Absent | Absent |
| | Pseudomonas aeruginosa | Absent | Absent |
| | Staphylococcus aureus | Absent | Absent |
| 19. | Sieve Test | | |
| | 1) Retained Over Screen 60 mesh | NMT 1 % | 0.1 % |
| | 2) Retained Over Screen 80 mesh | NMT 5 % | 1.48 % |
| | 3) Retained Over Screen 100 mesh | NMT 10 % | 2.87 % |
| | 4) Retained Over Screen 200 mesh | NMT 25 % | 14.99 % |
| | 5) Accumulated Under Screen 200 mesh | NLT 50 % | 80.5 % |

**Remarks:-** In the opinion of the undersigned, the above sample is upto the standard quality as per specifications for above tests only.

**Note:** Asterisk mark (*) test shall be Retest Analysis, NMT:-Not More Than, NLT:-Not Less Than, Max: -Maximum

**Storage & Packing Condition:** Store in well closed Container.

| | Name | Designation | Signature/Date |
|---|---|---|---|
| Prepared By: | Mr. Dinesh Mumne | QA Chemist | |
| Checked By: | Mr. Vyankat Singh | QC Manager | |
| Approved By: | Mr. Kiran Kelwatkar | QA Head | |