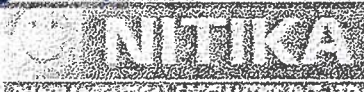


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NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD., NAGPUR

CERTIFICATE OF ANALYSIS

PRODUCT NAME: STANPURE [®] CALCIUM CARBONATE USP/NF	GRADE : CUSTOMISED
Received Date : 09/08/2015	Page : 1 of 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 acid 1 N, in hydrochloric acid 3 N, and in nitric acid 2 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	<i>[Signature]</i>
Checked By:	Mr. Vyankat Singh	QC Manager	<i>[Signature]</i>
Approved By:	Mr. Kiran Keshwar	QA Head	<i>[Signature]</i>
Formal No. NP/QAD/COAN/FU/02		Ref. SOP No. QAD/052	

NITIKA

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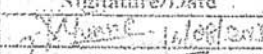
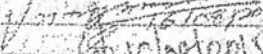
Re. Eval. Date : JUL.:2020

	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 Munne	QA Chemist	 16/08/2015
Checked By:	Mr. Vyankat Singh	QC Manager	 16/08/2015
Approved By:	Mr. Kiran Kelwatkar	QA Head	 16/08/2015
Formal No. NP/QAD/COAN/FI/02		Ref. SOP No. QAD-002	