On Going Stability Protokol		
No. PSTA 01	**Nafsu Makan Capsules**	**Revision No.: 0**
Date Issued 14 Sep 2016	Department **Quality Control**	**Effective Date** *1 Oktober 2016*
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1. Purpose

To monitor Nafsu Makan Capsule throughout shelf life and ensures that the product meets the specifications of storage conditions as stated in the label.

2. Stability Test Design

The product is packed in PVC blister

- Alumunium foil with 18 microns thickness, heat sealed PVC (8 g/^{m2})
- Forming PVC foil of 250 microns thickness

5 blisters are packed in carton folding box and stored as oultined in the 2.2. Test Schedule and Storage Condition.

2.1. Product Information

Product Name	: Nafsu Makan Capsule
Plan batch no.	:
MFD/ED	:

2.2. Test Schedule and Storage Condition:

Storage condition **30 °C ± 2 °C / 70 % RH ± 5 %**	Stability Intervals (month)							
	Initial	3	6	9	12	18	24	N
Plan sampling date								
Sampling date								
Analysis date								

3. Testing and Test Criteria

QC Dept. is responsible for storing and testing the sample in accordance with the storage condition and the valid test method.

The samples are taken out of the storage prior to the planned testing date, and kept at .....^{0} C until the time for analysis.

The analytical work should be concluded not later than 4 weeks after the samples have been out of storage.
The testing procedure is: No. XXXX.and the results shall comply to Specifification No. XXXXX

Parameters to be tested are as follows:

No.	Test Parameters	Specification	No of samples
1	Appearance	xx	200 capsules
2	Average weight	xx	
3	Water content	xx	
4	Disintegration time	xx	
5	Content/marker	xx	200 capsules
6	Total Aerobic Microbial Count	xx	200 capsules
7	Total combimed mould and yeast	xx	
8	Specified pathogenic microorganism	xx	

4. Report Content :

- Responsibility
- Summary
- Objective
- Test Material
- Packaging
- Storage condition and testing materials (Schedule)
- Testing Procedures
- Reference Standard/markers
- Results
- Discussion/Conclusion
- Test result in tabular form