



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Validation Of Calculator	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for validation of Digital Calculator.

2.0 SCOPE:

This SOP is applicable to all digital calculator use in Quality Control Department at Macleods Pharmaceuticals Limited, Nalagarh.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department
Head – Quality Control Department

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 Identification to Calculator

5.1.1 Calculators existing in department shall be identified by specific alpha numeric pattern as given

EQ/QCD/SC/01...02...03

5.1.2 Ensure that all the digit of a calculator is visible and printed matter on buttons are clearly legible.



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5.2 Procedure for calculator Validation

5.2.1 Check the accuracy of the calculator by carrying out the following set of calculation.

Set No.	Data					Mean	Sample Standard Deviation	Sample Variance
1	8	9	10	11	12	10	1.581138	2.50
2	0.8	0.9	1.0	1.1	1.2	1.0	$S \times 10^{-1}$	2.50×10^{-2}
3	0.08	0.09	0.10	0.11	0.12	0.10	$S \times 10^{-2}$	2.50×10^{-4}
4	0.008	0.009	0.010	0.011	0.012	0.010	$S \times 10^{-3}$	2.50×10^{-6}
5	78	79	80	81	82	80	S	2.50
6	708	709	710	711	712	710	S	2.50
7	7008	7009	7010	7011	7012	7010	S	2.50

5.2.2 Record the observation as per Annexure I and match with the above figures.

5.2.3 Carry out the similar calculation by another chemist and record the observation.

5.2.4 Record the observation made by both the chemist. The acceptance criteria for accepting the calculator for laboratory calculation are that “No difference up to 6th digit after decimal should be observed”.

6.0 ABBREVIATION (S):

QCD – Quality Control Department

SOP – Standard Operating Procedure

CAL – Calculator

S – Standard deviation

7.0 REFERENCE (S):

Geenfield and Diday, The statistician, 29: 33-35 (1980)



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8.0 ANNEXURE (S):

Annexure I - Validation Datasheet for Calculator

9.0 REVISION CARD:

S.No.	Revision no.	Revision date	Details of revision	Reason (s) for revision