TITLE: ANALYST QUALIFICATION

1.0 PURPOSE:

To lay down a procedure for analyst qualification of quality control analysts, to ensure the consistency and reliability in the analytical results.

2.0 SCOPE:

This SOP is applicable to all the analysts working in the Quality Control department at Discovery.

3.0 RESPONSIBILITY:

3.1 Analyst-QC is responsible to follow this SOP.

3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

4.0 DEFINITIONS:

NIL

5.0 PROCEDURE :

5.1 The Analyst qualification is intended to ensure the analyst's ability in understanding the SOPs, STPs and knowledge about using the instruments and performing the analysis, evaluation of the analytical results and reporting.

5.2 The ability of the analyst shall be evaluated in terms of the accuracy and precision to perform the tests and reporting the same.

5.3 The analyst qualification shall be done for all the quality control personnel below Assistant manager level.

5.4 The Analyst qualification shall be done in the following two cases;

5.4.1 For new analyst, after initial training, before allotting him/her the regular work.

5.4.2 For existing analyst whenever his/her work place is changed from one area to another area.

5.5 Whenever new employee below Assistant Manager Cadre joins in Quality control department, induction and orientation training shall be given to him.

5.6 After training, employee shall allocate either for wet analysis or instrumentation based on the qualification and experience of the employee depending on the requirements.

5.7 Training on all equipment's of his section shall be given to the employee based on his experience.

5.8 After completion of training on each equipment / analysis, the employee shall be evaluated

5.9 Head- QC or his designee shall give sample from approved batch to the analyst for 'analyst qualification along with analyst qualification raw data.

Note: Disclose the necessary information required for analysis before start up.

5.10 The initial analytical results shall not be disclosed to the analyst.

5.11 A code shall be assigned for the sample which shall be given to the analyst for 'analyst qualification'.

e.g.: Sample coding: AQ16001

Where,

AQ : Analyst Qualification

16 : Current year for 2016 (16 for 2016, 17 for 2017 so on)

001 : Serial number

5.12 Head-QC or his designee shall enter the information about sample in the 'Analyst qualification log' (QC024-FM060).

5.13 Number of tests shall be selected based on the job carried out by the particular analyst as per annexure-I.

5.14 The QC analyst shall prepare the sample in duplicate and shall test according to the approved standard test procedure of respective sample.

5.15 The analyst shall complete the testing within seven working days from the date of sample given by the Head-QC or his designee.

5.16 During the analyst qualification analysis, the Head-QC or his designee shall observe the work done by the analyst.

5.17 The analyst shall enter the analysis data in the 'Analyst qualification-raw data' (QC024-FM089) along with chromatograms, strip charts and shall handover to Head- QC or his designee for checking.

5.18 Head-QC or designee shall enter the analyst qualification results along with the original results in the 'Analyst qualification report' (QC024-FM059).

5.19 The ability of the analyst to perform tests shall be considered satisfactory, if and only if the results reported by the analyst are within the tolerance limits as per mentioned in section 5.25.

5.20 For water content / loss on drying tests, if the specification limit is ≤ 0.1 %, then the difference of the individual values should be within ±0.03% of the mean value.

5.21 For tests by IR & UV Spectroscopy, the results should meet the specification limit.

5.22 If the results are within the acceptance criteria the analyst will be deemed as qualified and capable of performing the regular analysis.

5.23 If the results obtained by the analyst do not meet the acceptance criteria, the analyst shall be explained her/his deficiency/mistake and trained accordingly. In this case analyst shall be re-qualified before deploying on job. HOD of QC / designee shall review the previous analysis data of that analyst.

5.24 During routine operation if any major analyst related error occurs then the analyst shall be re-trained for respective test and re-qualified.

5.25 Acceptance criteria for tests during analyst qualification:

S. No	Test name	Tolerance Limits (On the original value)
1	For Assay (by HPLC or titrimetric)(% w/w)	± 0.5

S. No	Test name	Tolerance Limits

		(On the original value)
2	For Related substances by HPLC (% w/w or % area)	
2.1	Individual impurity(% w/w or % area) (if specification limit is ≤ 0.05)	±0.01
2.2	Individual impurity(% w/w or % area) (if specification limit is > 0.05 to ≤ 0.10)	±0.02
2.3	Individual impurity(% w/w or % area) (if specification limit is > 0.10 to <0.50)	±0.03
2.4	Individual impurity(% w/w or % area) (if specification limit is ≥0.50)	±0.10
2.5	Total impurities(% w/w or % area) (If specification limit is >0.10% to <0.50%)	±0.03
2.6	Total impurities(% w/w or % area) (If specification limit is ≥ 0.50% to ≤1.0%)	±0.10
2.7	Total impurities(% w/w or % area) (If specification limit is ≥ 1.0%)	±0.20
3.0	Residual solvents by GC	
3.1	If specification limit is less than 100 ppm	± 20 %
3.2	If specification limit is between 100 & 500 ppm	± 15 %
3.3	Residual solvents by GC (More than 500 ppm)	± 10 %
4.0	For Purity by GC/HPLC(% area)	± 0.5
5.0	Water content	
5.1	For water content (Specification > 1.0% w/w)	± 0.1
5.2	Water content (Specification >0.5 to ≤ 1.0)(% w/w)	± 0.05
5.3	Water content (Specification ≤ 0.5)(% w/w)	± 0.03
6.0	Loss on drying	
6.1	Loss on drying (Specification > 1.0% w/w)	± 0.1
6.2	Loss on drying (Specification >0.5 to ≤ 1.0)(% w/w)	± 0.05
6.3	Loss on drying (Specification ≤ 0.5)(% w/w)	± 0.03
7.0	UV / IR	Should be meet to specification limit.

Example for checking the tolerance:

Actual assay value of the approved batch : 99.5 %

Assay value obtained by the analyst during qualification : 99.8 %

Tolerance limit for the Assay : ± 0.5

5.26 **ANALYST RE-QUALIFICATION:**

5.26.1 The Re-qualification of the analyst shall be performed as per the frequency once in 3 years ±15 days.

5.26.2 Requalification shall be decided by Head –QC based on the analyst results and skills.

5.26.3 Requalification is required if the analyst is shifted to new work area.

5.26.4 If the analyst is on long leave requalification shall be performed for the allotted work area.

6.0 FORMATS / ANNEXURE(S):

6.1 Analyst qualification- raw data : QC024-FM089

6.2 Analyst qualification log : QC024-FM060

6.3 Analyst qualification report : QC024-FM059

6.4 Matrix of analyst qualification parameters : Annexure-1

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.06.2007	New SOP is introduced across all the API manufacturing facilities of Discovery.	--
01	01.01.2011	The following point incorporate with SOP, re analyst qualification shall be performing once in year	--
02	01.06.2014	1. Procedure change with clear and clarity. 2. Analyst qualification inventory record introduced	--
03	01.01.2015	1. Revised as per more clarity	--
04	01.01.2017	1. SOP format changed make to in line with SOP-QA-001-04 2. Acceptance criteria are modified. 3. Re-qualification frequency modified. 4. Altogether procedure has been rephrased for better clarity.	QC-CRF-025/16

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