



STANDARD OPERATING PROCEDURE

Department:	SOP No.:
Title: Preparation, Approval, Distribution, Control, Revision and Destruction of Specifications, Standard Test Procedure and Analytical Raw Data Sheets	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for preparation, approval, distribution, control, revision and destruction of specifications, standard test procedures and Analytical raw data sheets.

2.0 SCOPE:

This procedure is applicable to QC department (documentation section) and serves as guidelines for its preparation, implementation and control of specifications, standard test procedures and analytical raw data sheets used during analysis.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control
Head – Quality Control

4.0 PROCEDURE:

4.1 Preparation of Specifications, Standard Test Procedures:

- 4.1.1 Specifications, Standard test procedure and Raw data sheets of Finish product, In process and raw materials shall be provided by Corporate Quality assurance.
- 4.1.2 Standard A4 size (Width: 8.27” and Height: 11.69”, Font size: 12 Arial) white paper shall be used.
- 4.1.3 The text of specifications and standard test procedures shall be in “Arial” font in a clear, unambiguous, easy to understand and easy to follow language.
- 4.1.4 The specifications or standard test procedures shall consist of the following sections:
 - 4.1.4.1 The header for specifications or standard test procedures shall include the following sections:
 - 4.1.4.2 Each document shall be printed with “*Restricted Circulation*” on the top right hand side corner, above the header.
 - 4.1.4.3 The header of each document shall contain the *Name of Company* and site address along with *Logo* on the top right hand corner



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- 4.1.4.17 The middle section of first page include the material/product information shall give all details related to the material/product which shall include but not limited to sampling procedures, market, CAS Registration No. (as applicable) sample quantity, retention sample quantity (as applicable), Sampling quantity for re-testing (as applicable), packaging (handling precautions), storage conditions, standard test procedure number, reference specification no., retest period (as applicable), approved vendor and other details as applicable.
- 4.1.4.18 Specification section shall include the Sr. No., Test and Specification.
- 4.1.4.19 Method Reference no. column incorporate for finished product specification (except In process) and Stability Specification.
- 4.1.4.20 The specification and test procedure shall be prepared according to the PDR/ARD document (if available); respective pharmacopoeia; Vendor document (if available) or as per In-house requirement.
- 4.1.4.21 The test procedures shall include details of the testing procedure, which shall contain but not limited to instrument/equipment, reagents and procedures, precautions, analytical techniques as applicable.
- 4.1.4.22 Each specification and standard test procedure shall include the revision card giving the details of Revision No.; Change Control No.; Effective Date, Details of revision and reason (s) for revision, which shall be retained with the master copy for reference and shall not be part of the distributed copies.
- 4.1.4.23 In case of new document, "Nil" shall be indicated in the Revision card.
- 4.1.4.24 The footer of the document shall include the following:
- 4.1.4.25 Signature of the persons responsible for preparing, checking, reviewing and approving the documents as defined in the "Responsibility".
- 4.1.4.26 The name and designation (with department) of the respective persons shall be preprinted in the document.
- 4.1.4.27 The names of signatories shall be based on the responsibility of the individuals with respective departments.
- 4.1.5 A draft specification/standard test procedure shall be prepared and given to the designated



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personnel for checking along with the reference PDR/ARD specification/STP as applicable.

4.1.6 After incorporating all the corrections, the final print shall be taken and distributed to the designated persons for their approval.

4.1.7 Each signatory shall sign in blue pen in full / initial and put the date of signature.

4.2 Preparation of Specifications and Standard Test Procedures for Packing material:

4.2.1 Common specification and standard test procedure of packing material shall be prepared for respected materials like carton, printed foil, leaflet, PVC, PVDC, corrugated box etc.

4.2.3 Packing material annexure prepared individually for the respective materials and attached with respective specifications as per annexure - XVI.

Common specified test parameters shall maintained in the specification and other variable test parameters shall be maintained in packing material annexure.

4.2.5 Packing material annexure shall be updated as and when required.

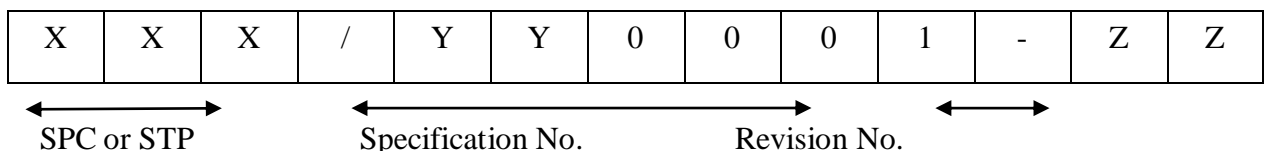
4.2.6 If any new artwork received or material item code revised then packing material annexure shall be incorporated and version no. shall be revised.

4.2.7 While making the entry of new materials in annexure first update the all tests as per requirement and incorporate their specification limits. If new version of any existing code material received, previous version to be removed during updating.

4.2.8 Filled packing material annexure shall be reviewed and approved by QC and QA respectively prior to release of the material.

4.2.9 Prepare packing material specification and standard test procedure as per point no. 4.1.4 to 4.1.7. The specification and standard test procedure numbering as per given below.

4.2.10 For Packing material **Specification No.** or **Standard Test Procedure No.** in which first 10 digits are specification or STP number and last 2 digits are revision number, represented as :



4.2.11 The first three digits (XXX) represent SPC or STP referring to specification or standard test



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procedures respectively.

4.2.12 The fourth digit is a slash “/”

4.2.13 The fifth to tenth digit (PM0001) represents the specification / STP no. of the packing material (Where YY represents Packing material (PM))

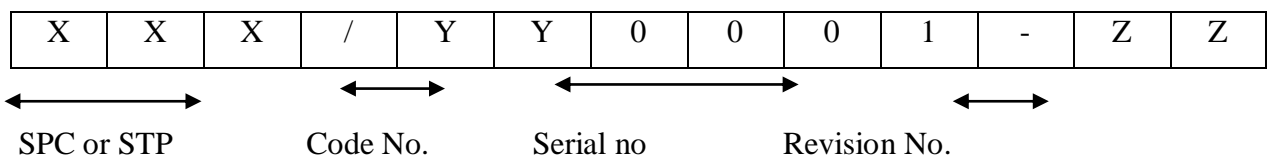
4.2.14 The eleventh digit is a dash “-”

4.2.15 The twelfth and thirteenth digit (ZZ) represents the revision no. which shall start with “00” for the first version followed by sequential numbers for each subsequent revision.

4.3 Preparation of Specifications and Standard Test Procedures for Water:

4.3.1 Prepare water specification and standard test procedure as per point no. 4.1.4 to 4.1.7. The specification and standard test procedure numbering as per given below.

4.3.2 For Raw water / Purified water **Specification No.** or **Standard Test Procedure No.** in which first 10 digits are specification number or Standard test procedure number and last 2 digits are revision number, represented as :



4.3.3 The first three digits (XXX) represent SPC or STP referring to specification or standard test procedures respectively.

4.3.4 The fourth digit is a slash “/”

4.3.5 The fifth to tenth digit (YY0001) represents the respective Specification / STP no. of the water type. (Where YY represents types of water i.e. Raw water, Chlorinated water, Soft water, RO water and EDI water (RW)/Purified water (PW)).

4.3.6 The eleventh digit is a dash “-”

4.3.7 The twelfth and thirteenth digit (ZZ) represents the revision no. which shall start with “00” for the first version followed by sequential numbers for each subsequent revision.

4.4 Preparation of Specifications and Standard Test Procedures for Stability:

4.4.1 Prepare Stability specification and standard test procedure as per point no. 4.1.4 to 4.1.7. The specification and standard test procedure numbering as per given below.



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Note: Only an approved document shall be considered for distribution and control.

4.6.3 All photocopies shall be stamped as “CONTROLLED COPY / DEPT. CODE NO.” in red ink at the center bottom portion on all the pages and shall be signed by QC person controlling the STP and specifications.

4.6.4 **NOTE:** For specimens of the stamps used for the control and distribution of the documents and department code no. refer SOP.

4.6.5 The personnel responsible for the distribution of the revised documents shall ensure reconciliation of previous distributed copies and destroy the distributed controlled copies of STP/specification received from respective departments and enter the details in the respective format.

4.6.6 The “MASTER COPY” of the old version maintained in the QC department shall be stamped as “OBSOLETE” in red ink and stored.

4.6.7 The original document shall be retained by the QC department in safe custody under limited access.

4.6.8 The distribution of the documents shall be controlled by the issuing personnel of the QC department.

4.6.9 The details of distribution shall be entered in their respective distribution format.

4.7 Destruction procedure for Specifications and Standard Test Procedures:

4.7.1 The retrieved copies of specifications and standard test procedures shall be destroyed by any one of the following methods.

- Complete shredding
- Incineration

4.7.2 The issuing person in the QC department shall be responsible for recording this activity in the respective format.

4.8 Preparation of Analytical raw data sheets:

4.8.1 The analytical raw data sheets shall be prepared for Packing materials, miscellaneous items, Stability study, Water analysis, etc. according to the respective specifications and standard testing procedures in individual formats given in annexure.



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- 4.8.2 In case, if additional tests are required to be performed during analysis of Packing material, Stability then an “Additional raw data sheet” as per annexure-XIII shall be issued.
- 4.8.3 For thin layer chromatography test, record the observation diagrammatically on annexure-XV. The observation made by analyst should authenticate with TLC plate by the reviewer.
- 4.8.4 The analytical raw data sheet for reagent preparation record as per annexure - XIV.
- 4.8.5 The header of data sheet for Packing material shall include the following sections:
- 4.8.5.1 Each data sheet shall contain the ‘Page No.’ on the top right hand side corner, above the header.
- 4.8.5.2 The header section of each data sheet shall contain the *Name of Company* and site address along with *Logo* on the top right hand corner.
- 4.8.5.3 The next section shall contain the heading of the document followed by “Name of Material”, “Manual A.R. No.” and “Item code.” etc as per annexure-III
- 4.8.6 The middle section shall include the following:
- 4.8.6.1 The data sheet shall include the Specification No., STP No., manufacturer, supplier, quantity received, quantity sampled, GRN No./Date and date of completion of the respective document (for first page only).
- 4.8.6.2 In data sheets leaving blank space to record all the tests with brief details of procedure as mentioned in the STP and should have provision to record the equipment (s) ID, Weight print etc. used for the test to be filled manually during analysis.
- 4.8.6.3 Each test shall have ‘Analysed by/date’ and ‘Checked by/date’ column except for tests performed at outside laboratory where only the ‘Checked by/date’ column shall be mentioned.
- 4.8.6.4 In case of packing material data sheet shall be prepared individually formatting depending upon the material specification and standard test procedure.
- 4.8.6.5 At the end of the middle section includes the “Remarks, Reviewed by/Date and Approved by/Date shall be mentioned.
- 4.8.7 The footer section of the each data sheet shall include the following:
- 4.8.7.1 Signatories of the persons responsible for preparing, checking, reviewing and approving the documents.



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- 4.8.7.2 The name, designation and department name of the respective persons shall be preprinted in the format.
- 4.8.7.3 The names of signatories shall change based on the responsibility of the individual.
- 4.8.8 The header of data sheet for miscellaneous shall include the following sections:
- 4.8.8.1 Each data sheet shall contain the 'Page No.' on the top right hand side corner, above the header.
- 4.8.8.2 The header of each data sheet shall contain the *Name of Company* and site address along with *Logo* on the top right hand corner.
- 4.8.8.3 The next section shall contain the heading of the document followed by "Name of material", "Batch No./Lot No. and "A.R. No." etc as per annexure-XII
- 4.8.9 The middle section shall include the following as per point no. 4.8.6.1 to 4.8.6.3
- 4.8.10 The footer of the document shall include the following as per point no. 4.8.7.1 to 4.8.7.3
- 4.8.11 The header of data sheet for Raw water/Chlorinated Water /Soft Water/ RO water / EDI water / Purified water shall include the following sections:
- 4.8.11.1 The header of each data sheet shall contain the *Name of Company* and site address along with *Logo* on the top right hand corner.
- 4.8.11.2 The next section shall contain the heading of the document followed by "Type of water", "Sampling point", "A.R. No." "Date of analysis start" and "Date of completion " as per Annexure-VI
- 4.8.12 The footer of the document shall include the following as per point no. 4.8.7.1 to 4.8.7.3
- 4.8.13 Each data sheet shall contain the 'Page No.' on the bottom right hand side corner, below the footer.
- 4.8.14 The header of data sheet for Stability testing shall include the following sections:
- 4.8.14.1 Each data sheet shall contain the 'Page No.' on the top right hand side corner, above the header.
- 4.8.14.2 The header of each data sheet shall contain the *Name of Company* and site address along with *Logo* on the top right hand corner.
- 4.8.14.3 The next section shall contain the heading of the document followed by "Name of product", "Batch No.", "A.R. No." "Stability station" and "Storage condition" etc. as per Annexure-IX
- 4.8.15 The middle section shall include the following as per point no. 4.8.6.1 to 4.8.6.3



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4.8.16 The footer of the document shall include the following as per point no. 4.8.7.1 to 4.8.7.3

4.8.17 A draft Analytical raw data sheet shall be prepared and given to the designated personnel for checking.

4.8.18 After incorporating all the corrections, the final print shall be taken and distributed to the designated persons for their approval.

4.8.19 Each signatory shall sign in blue pen in initial / full and put the date of signature.

4.9 Revision procedure for Analytical raw data sheets:

4.9.1 The analytical raw data sheets shall be revised whenever there is a revision in the respective specification or standard testing procedure.

4.9.2 After review, there is no change in specification and standard test procedure, also review the datasheet, If no change in datasheet, same datasheet shall be used.

4.9.3 QA personnel shall take the old analytical raw data sheet from QC and put "OBSOLETE" stamp in red ink and store in QA custody. The revised copy shall then be handed over to the QC department.

4.10 Distribution and control procedure for Analytical raw data sheets:

4.10.1 After all the signatories are over, the original analytical raw data sheet shall be stamped as "MASTER COPY" in red ink on the top right hand side corner of all the pages.

4.10.2 The original analytical raw data sheet shall be retained by the QC department in safe custody in a designated place.

4.10.3 As per the requirement, the Xerox copy of the master analytical raw data sheet shall be issued to the analyst by the responsible person with "ISSUED BY (QC)/DATE" stamp on the bottom right hand side corner in blue ink.

5.0 ANNEXURE (S):

Annexure-I : Template for Packing material specification

Annexure-II : Template for Packing material standard test procedure

Annexure-III : Template for Analytical raw data sheet (Packing material)

Annexure-IV : Template for Water specification



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- Annexure-V : Template for Water standard test procedure
- Annexure-VI : Template for Analytical raw data sheet (water)
- Annexure-VII : Template for Stability specification.
- Annexure-VIII : Template for Stability standard test procedures.
- Annexure-IX : Template for Analytical raw data sheet (stability Product)
- Annexure-X : Template for Material specification (miscellaneous)
- Annexure-XI : Template for Standard test procedures (miscellaneous)
- Annexure-XII : Template for Analytical raw data sheet (miscellaneous)
- Annexure-XIII : Template for Analytical raw data sheet (additional)
- Annexure-XIV : Template for Analytical raw data sheet (reagent / indicator)
- Annexure-XV : Template for Thin Layer Chromatography Plate Observation Sheet
- Annexure-XVI : Template for Packing Material Annexure

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

- SOP : Standard Operating Procedure
- STP : Standard Test Procedure
- SPC : Specification
- FG : Finished Goods
- TLC : Thin Layer Chromatography
- PDR : Process Development and Research
- ARD : Analytical Research and Development
- QA : Quality Assurance
- QC : Quality Control
- A.R.No. : Analytical Reference No.



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MA Holder : Marketing Authority Holder

CAS : Chemical Abstracts Service.

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----



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ANNEXURE I

TEMPLATE FOR PACKING MATERIAL SPECIFICATION

Header part for all pages:

RESTRICTED CIRCULATION

PACKING MATERIAL SPECIFICATION			
Specification No.		<Title of Material>	
Supersedes			
Status			
Effective Date			
Review Date			
Page No.		Material Code	

MATERIAL INFORMATION

Sampling procedure	
Sample Quantity	
Standard testing procedure No.	
Packaging	
Storage condition (if any)	
Approved vendor	
Reference Specification No.	
Retest period	

Footer part of all pages:

Prepared By	Checked By	Reviewed By	Approved By



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MATERIAL SPECIFICATION

S.No.	Tests	Specification

Tests for retesting in separate page:

TESTS FOR RETESTING

S.No.	Tests

Revision Card in separate page:

REVISION CARD

Revision No.	Change Control No.	Effective Date	Details of Revision	Reason(s) for Revision



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ANNEXURE II

TEMPLATE FOR PACKING MATERIAL STANDARD TEST PROCEDURE

Header part for all pages:

RESTRICTED CIRCULATION

PACKING MATERIAL STANDARD TEST PROCEDURE		
STP No.		<Title of Material>
Supersedes		
Status		
Effective Date		
Review Date		
Page No.		

Footer part for all pages:

Prepared By	Checked By	Reviewed By	Approved By

Revision Card in separate page:

REVISION CARD

Revision No.	Change Control No.	Effective Date	Details of Revision	Reason(s) for Revision



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ANNEXURE III
TEMPLATE FOR ANALYTICAL RAW DATA SHEET (PACKING MATERIAL)

Header part of all pages:

Page X of Y

ANALYTICAL RAW DATA SHEET (PACKING MATERIAL)			
Name of Material			
Item code		Manual A.R. No.	

Only First Page:

SPC No.		STP No.	
Manufacturer		Quantity Received	
Supplier		Quantity Sampled	
G.R.N. No. / Date		Date of Completion	

Footer Part for all pages:

Prepared By	Checked By	Reviewed By	Approved By



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ANNEXURE IV
TEMPLATE FOR WATER SPECIFICATION

Header part for all pages:

RESTRICTED CIRCULATION

WATER SPECIFICATION	
Specification No.	<Types of Water>
Supersedes	
Status	
Effective Date	
Review Date	
Page No.	

S.No.	Tests	Specification

Footer part for all pages:

Prepared By	Checked By	Reviewed By	Approved By

Revision Card:

REVISION CARD

Revision No.	Change Control No.	Effective Date	Details of revision	Reason (s) for revision



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ANNEXURE V
TEMPLATE FOR WATER STANDARD TEST PROCEDURE

WATER STANDARD TEST PROCEDURE	
STP No.	<Types of Water>
Supersedes	
Status	
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ANNEXURE VI
TEMPLATE FOR ANALYTICAL RAW DATA SHEET (WATER)

ANALYTICAL RAW DATA SHEET (WATER)			
RAW WATER/CHLORINATED WATER/SOFT WATER/RO WATER/EDI WATER/ PURIFIED WATER			
STP Ref. No.			
Sampling point		A.R. No.	
Date of analysis Start		Date of Completion	



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ANNEXURE X
TEMPLATE FOR MATERIAL SPECIFICATION (MISCELLANEOUS)

MATERIAL SPECIFICATION (MISCELLANEOUS)			
Specification No.		<Name of Material>	
Supersedes			
Status			
Effective Date			
Review Date			
Page No.		Material Code	



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ANNEXURE XI
TEMPLATE FOR STANDARD TEST PROCEDURE (MISCELLANEOUS)

STANDARD TEST PROCEDURES (MISCELLANEOUS)	
STP No.	<MATERIAL NAME>
Supersedes	
Status	
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ANNEXURE XII
TEMPLATE FOR ANALYTICAL RAW DATA SHEET (MISCELLANEOUS)
Header part for all pages:

Page X of Y

ANALYTICAL RAW DATA SHEET (MISCELLANEOUS)			
Name of Material / Product			
Batch No. / Lot No.		AR. No.	

For first page only:

Manufacturing Date		STP No.	
Expiry/Retest Date		Quantity Received	
Manufacturer		Date of sampling	
Supplier		Start Date of analysis	
G.R.N. No. / Date		Date of Completion	

Footer Part for all pages:

Prepared By	Checked By	Reviewed By	Approved By



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ANNEXURE XIII
TEMPLATE FOR ANALYTICAL RAW DATA SHEET (ADDITIONAL)

Header part of all pages:

Page 1 of 1

ANALYTICAL RAW DATA SHEET (ADDITIONAL)			
Name of Product/ Material			
Batch No./ Lot No.		A.R. No.	

For first page only:

Mfg. Date		STP No.	
Exp. Date/Retest date		Sample Quantity	
Start date of analysis		Date of completion	
Stage			

TESTS:

For footer part:

Analyzed By
Date:

Checked By
Date:



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ANNEXURE XIV
TEMPLATE FOR ANALYTICAL RAW DATA SHEET (REAGENT / INDICATOR)

Header part of all pages:

Page 1 of 1

ANALYTICAL RAW DATA SHEET (REAGENT / INDICATOR)			
Name of Reagent / Indicator			
Batch No.		Valid up to	
Reagent Batch no.		Preparation date	

For footer part:

Prepared By
Date:

Checked By
Date:



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ANNEXURE XV
TEMPLATE FOR THIN LAYER CHROMATOGRAPHY PLATE OBSERVATION SHEET

RESTRICTED CIRCULATION

THIN LAYER CHROMATOGRAPHY PLATE OBSERVATION SHEET			
Name of Product/ Material			
Batch No./ Lot No.		A. R. No.	
Test			
Date of analysis			

OBSERVATION

Performed by :	Checked by :
Date :	Date :



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STANDARD OPERATING PROCEDURE

Department:	SOP No.:
Title: Preparation, Approval, Distribution, Control, Revision and Destruction of Specifications, Standard Test Procedure and Analytical Raw Data Sheets	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE XVI
TEMPLATE FOR PACKING MATERIAL ANNEXURE

Header part for all pages

PACKING MATERIAL ANNEXURE			
Name of Material:		Specification No.:	
Effective Date:	Annexure Version No.:	Page No.:	

Middle (variable) part for respective materials

S.No.	Item Code	Test Parameters					

Footer part for all pages

Prepared By	Checked By	Reviewed By	Approved By