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SMS Central Lab	STANDARD OPERATING PROCEDURE	
Department: Analytical Services	Title: XRD Method Verification for Drug substance and Drug Product	

SOP No.	Supersedes	Effective Date	Next review on (or) before	Page No.
SMSCL-ASD078-01	SMSCL-ASD078-00	04/01/2024	04/01/2027	01 of 03

1.0 OBJECTIVE:

To lay down a procedure for "Method verification for Drug substance and Drug product of X-Ray Diffractometer'' with Auto-changer, Make: BRUKER AXS; Model: D8ADVANCE A25 and data generated through DIFFRAC.SUITE application.

2.0 SCOPE:

This SOP is applicable to "Method verification for Drug substance and Drug product of X-Ray Diffractometer'' and data generated through DIFFRAC.SUITE software used in Analytical Services Department of Central Laboratory Analytical Services, Building No.2, First Floor, Gagillapur, Hyderabad.

3.0 RESPONSIBILITY:

ASD - personnel shall follow the SOP & Group Leader or designee shall follow overall compliance of SOP.

DQA - Head (or) designee shall follow the compliance and approve the SOP.

4.0 PROCEDURE:

4.1.1 Establishment of specificity

To establish the specificity standard, placebo and sample shall be scanned in X-ray diffractometer by using the approved method.

Acceptance criteria:

Sample Diffractogram concordant with standard Diffractogram. And sample 2-Theta values should be ± 0.2° when compared with standard and There should be no

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interference at the Specified peak of interest when compared with standard and placebo.

Note:

1. For drug substance scan the standard and sample only
2. For drug product scan the standard, placebo and sample only

4.1.2 Establishment of method precision

Prepare individually six samples from homogeneous sample.

Perform individual scan on the six preparations by using approved method.

Acceptance criteria:

All six sample diffractograms should be concordant with the standard Diffractogram and 2-theta values should be with in ± 0.2°

4.2 Conclusion:

The results obtained shall be compiled and a verification summary report is prepared to conclude the suitability of the analytical method for its intended use.

5.0 DOCUMENTATION

5.1 Formats:

Nil

5.2 Change history Format-SMSCL-DQA001-F03*

*Current version to be followed.

6.0 REFERENCE ANNEXURE:

NA

7.0 REFERENCES:

a) BRUKER user Manual

b) USP<941>: Characterization of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD).

8.0 ABBREVIATIONS/APPENDIX

XRD	: X-Ray Diffractometer
ASD	: Analytical Services Department
SOP	: Standard Operating Procedure
e.g.	: Example
NA	: Not Applicable
AMD	: Analytical maintenance Department
PMMA	: Poly methyl methacralate
USP	: united States of pharmacopeia

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SMS Central Lab	CHANGE HISTORY		
Document No.	**SMSCL-ASD078-01**	**Page No.**	**01 of 01**
Department	**Analytical Services**		
Type of Document	**SOP**		
Title	**XRD Method Verification for Drug substance and Drug Product**		

Current Version	Superseded Version	Change Particulars	
		S.No.	Specific changes made in version
SMSCL-ASD078-00	Nil	01	New SOP (Effective Dt:04/01/2021)
SMSCL-ASD078-01	SMSCL-ASD078-00	01	Periodical Revision of SOP (Ref.CCF.No.: SMSCL/CC/ASD/24/001) i) Make & Model removed from title. ii) Responsibilities modified in section No.:3.0.

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Signature			
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