

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR 500 LTRS. VESSEL WITH VIBRO MIXER

Date	of Validation:
1.0	Objective of Validation: To validate the Performance of 500 lts Vessel with Vibro mixer with respect to the suspension/solution homogeneity of Metered Dose Inhaler of
	per container and to estimate water content.
2.0	Scope of Validation:
	Performance Validation of 500 lts. Vessel with Vibro mixer
3.0	Justification for selection of Item/Equipment/Process/Product/ System:
4.0	Site of study: Aerosol Department Location:
	Location:
	Location: Responsibility:
	Location: Responsibility: Representatives from:
	Location: Responsibility: Representatives from: Production :
	Location: Responsibility: Representatives from: Production : Engineering :
	Location: Responsibility: Representatives from: Production : Engineering : Safety :
4.0 5.0 6.0	Location: Responsibility: Representatives from: Production : Engineering : Safety : Quality Control :



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6.2 SOP, Make, Code number and Qualification details of Equipments:

Equipment	Make	Code No.	SOP No.	Qualification done On
Weighing				
balance				
Product				
circulation				
pump				
Product filler				
Homogenizer				
Manufacturing				
Vessel				

7.0	Contro	
/.0	Contro	15.

7.1 Calibration:

S.No.	Standard weights used	Actual Observation	
		At the Start	At the End
		Date:	Date:

7.2 Training:

S.No.	Name	Training Status	Checked By



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	Equipment	Limit of setting	Actual Setting			
			Machine N		Machine N	
	Product filler Air pressure (bar)		Line I	Line II	Line I	Line II
	Product circulation pump Air pressure (bar)					
	Manufacturing Vessel Vibrator Speed (%)					
	Temperature of suspension / solution					1
	Fill weight range of the suspension:					
.0	Validation Procedure:					
.1	Manufacture the batch as per the	Protocol and batch n	nanufacturing	record		
1	manufacture the batch as per the	1 Totocor and batch in	ilailaiac tai ilig	s record.		
.2	After 5 minutes of recirculation s content of active ingredient(s) pe			-	•	
.2	After 5 minutes of recirculation s content of active ingredient(s) pe hrs.			-	•	
	content of active ingredient(s) pe	r container & 1 contains s of recirculation sen e ingredient(s) per co	niner for wate	er content. Ini	tial sample gi	ven at
.3	content of active ingredient(s) pehrs. After 10, 15, 20, 25 & 30 minute	r container & 1 contains s of recirculation sen e ingredient(s) per co	d 3 container ontainer at -	er content. Init	tial sample givine to Q.C. wi	ven at th suspens
.3	content of active ingredient(s) pehrs. After 10, 15, 20, 25 & 30 minute for estimation of content of active	s of recirculation sen e ingredient(s) per co h ntainers, 2 containers e ingredient(s) per co contain	d 3 container ontainer at - rs. from each libratiner.	er content. Initials are served to the serve	tial sample givine to Q.C. with QC along with	th suspens suspension Q.C. with
2	content of active ingredient(s) pe hrs. After 10, 15, 20, 25 & 30 minute for estimation of content of active After every confor estimation of content of active At the middle of batch, ie. after _ suspension for estimation of content of co	s of recirculation sen e ingredient(s) per co h ntainers, 2 containers e ingredient(s) per co contain ent of active ingredie hrs.	d 3 container ontainer at - rs. from each libration ontainer. ers, 2 container. ers, 2 container ontainer.	er content. Initials of the series from each trainer & 1 contents of the series of the	tial sample given ine to Q.C. with QC along with a line is sent to the ntainer for was a footnet of a content	th suspension suspension Q.C. with
3 2 4	After every confor estimation of content of active. After every confor estimation of content of active. At the middle of batch, ie. after _ suspension for estimation of content of active. Last 3 containers from each line in the suspension for each line in the suspension	s of recirculation sen e ingredient(s) per co h ntainers, 2 containers e ingredient(s) per co contain ent of active ingredie hrs.	d 3 container ontainer at - rs. from each libration ontainer. ers, 2 container. ers, 2 container ontainer.	er content. Initials of the series from each trainer & 1 contents of the series of the	tial sample given ine to Q.C. with QC along with a line is sent to the ntainer for was a footnet of a content	th suspension suspension Q.C. with atter content
3 2 4	After 10, 15, 20, 25 & 30 minute for estimation of content of active. After every confor estimation of content of active. At the middle of batch, ie. after _ suspension for estimation of content of active. Middle sample given at Last 3 containers from each line ingredient(s) per container & 1 content of active.	s of recirculation sen e ingredient(s) per coh ntainers, 2 containers e ingredient(s) per co contain tent of active ingredie _hrs. is sent to Q.C. with sontainer for water con	d 3 container ontainer at - rs. from each libratiner. ers, 2 container. ers, 2 container. euspension for ontent. Last sa	er content. Initials of the series from each to the series from each stainer & 1 contents and the series from each stainer & 2 contents and the series from each stainer & 3 contents and the series from each	tial sample given ine to Q.C. with QC along with a line is sent to the ntainer for was a footnet of a content	th suspension suspension Q.C. with atter content
.3 .2 .4 .4	After 10, 15, 20, 25 & 30 minute for estimation of content of active. After every confor estimation of content of active. At the middle of batch, ie. after _ suspension for estimation of content of active. Middle sample given at Last 3 containers from each line ingredient(s) per container & 1 content of active.	s of recirculation sen e ingredient(s) per co h ntainers, 2 containers e ingredient(s) per co contain ent of active ingredie hrs. is sent to Q.C. with s ontainer for water co	d 3 container ontainer at - rs. from each libratiner. ers, 2 container ent(s) per container container.	er content. Initials of the series from each land to the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimated as a series from ea	tial sample given ine to Q.C. with QC along with a line is sent to the ntainer for was a footnet of a content	th suspension suspension Q.C. with atter content
.3	After 10, 15, 20, 25 & 30 minute for estimation of content of active. After every confor estimation of content of active. At the middle of batch, ie. after _ suspension for estimation of content of active. Middle sample given at Last 3 containers from each line ingredient(s) per container & 1 content of active. Acceptance Criteria: As per Finished Bulk Specification.	s of recirculation sen e ingredient(s) per co h ntainers, 2 containers e ingredient(s) per co contain tent of active ingredie hrs. is sent to Q.C. with s ontainer for water co	d 3 container ontainer at - rs. from each libratiner. ers, 2 container ent(s) per container to the container.	er content. Initials of the series from each land the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimation of the series from each stainer & 1 contents are stimated as a series from each	tial sample given ine to Q.C. with QC along with a line is sent to the ntainer for was a footnet of a content	th suspension suspension Q.C. with atter content



10.1

Machine No.:

PHARMA DEVILS

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Deviation:

11.0 Type of Validati 12.0 Frequency: 13.0 Risk Manageme	on: nt Studies:		
14.0 Results / Observa	tions:		
14.1 Machine No.: Frequency	Content of	Line:	Water Content (ppm)
Frequency	container (mg)	Container (mg)	-
After 5 min re-circulation	1. 2. 3.	1. 2. 3.	
After 10 min re-circulati	1. on 2. 3.	1. 2. 3.	
After 15 min re-circulati	1. on 2. 3.	1. 2. 3.	
After 20 min re-circulati	1. on 2. 3.	1. 2. 3.	
After 25 min re-circulati	1. on 2. 3.	1. 2. 3.	
After 30 min re-circulati	1. on 2. 3.	1. 2. 3.	

Line: _____



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Frequency	Content of	Content of	Water Content (ppm)
	container (mg)	Container (mg)	
	1.	1.	
Initial	2.	2.	
	3.	3.	
	1.		
After container Filling	2.	1.	
1 ming		2.	
After	1.	1.	
container Filling	2.	2.	
Middle	1.	1.	
container Filling	2.	2.	
After	1.	1.	
container Filling	2.	2.	
After	1.	1.	
container Filling	2.	2.	
	1.	1.	
Last	2.	2.	
	3.	3.	
Minimum			
Maximum			

15.0 Summary of Validation activity:

Content	Limits	Minimum	Maximum
/ containe	er		
(mg)			
/ containe	er		
(mg)			
Water Content (ppm)			
•			
6.0 Recommendations:			



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Date: Date: Date: view & Approval: pproved by Note uality Assurance Head ate: Date achments:	Team Appro	oval:		
view & Approval: pproved by Note uality Assurance Head ate: achments:	luction			Quality Assurance
pproved by Note uality Assurance Head ate: achments:	:	Date :	Date :	Date :
uality Assurance Head ate: Date achments:	Review & A _l	pproval:		
ate: Date achments:	Approved l	ру		Noted by
	Quality Ass Date:	surance Head		Unit Head Date:
obreviation:	Attachments			
obreviation:				
	Abbreviatio	n:		