



Workshop on “Review of Stability Data submitted for Market Authorization”

FOR

**OFFICERS OF CENTRAL DRUGS
STANDARD CONTROL ORGANIZATION**

ON

12th -14th February, 2014

- ✘ The workshop on “Review of Stability Data submitted for Market Authorization” was organized by Quality Assurance Division of CDSCO at Hotel Metropolitan, Bangla Sahib Road, New Delhi on 12th -14th February, 2014 to impart the knowledge on review of stability data to Officers of Central Drugs Standard Control Organization.
- ✘ Of the three days workshop, the first day of the workshop (i.e. 12th February, 2014) was organized for the vaccine manufacturers, Deputy Drugs Controller (India), Assistant Drugs Controller (India), and Inspectors of Biological Division, Quality Assurance Division, participants from Central Drugs Laboratory (CDL), Kasauli, participants from National Institute of Biologicals (NIB), Noida who are involved in review of Module III of CTD submission. Therefore all the vaccine manufacturers were invited as participants and selected manufacturer delivered presentation on Stability Study.
- ✘ On 13th & 14th February, 2014, participants were the Drugs Inspectors from New Drugs, Medical Devices, Biologicals, QA Division along with Deputy Drugs Controller (India) and Assistant Drugs Controller (India) of concerned division. Presentations on stability was made by Dr. Saranjit Singh, Professor & Head, Pharmaceutical Analysis, NIPER on both days along with case study, group discussion and evaluation.

Objective of the Workshop:

To strengthen the Regulatory system of India, it is required to improve the understanding and reviewing capacity of stability data of CDSCO and NCL reviewers because as per the requirements of Appendix IX of Schedule 'Y' stability study is to be performed to provide evidence on how the quality of a drug substance or formulation varies with time under the influence of various environmental factors such as temperature, humidity and light, and to establish shelf life for the formulation and recommended storage conditions.

AGENDA OF THE WORKSHOP: 12TH FEBRUARY, 2014

Time	Topic	Speaker
9:30 - 10:00	Registration	-
10:00 - 10:30	Inaugural session (Welcome address, Introduction of participants)	CDSCO
10:30 – 10:40	Introduction of the Workshop	CDSCO
10:40 – 11:00	Tea Break	
11:00 - 11:45	Stability Study Presentation	Mr. Vikas Dogar (Serum Institute of India Ltd)
11:45 – 11:55	Discussion on presentation	All Participants
11:55 - 12:40	Stability Study Presentation	Mr. Gopal Singh (Panacea Biotech Ltd)
12:40 – 12:50	Discussion on presentation	All Participants
12:50 – 13:50	Lunch Break	
13:50 – 14:35	Stability Study Presentation	Dr. Anandbabu/ Mr. Parag Nagarkar (Shantha Biotechnics Ltd.)
14.:35 -14:45	Discussion on presentation	All Participants
14:45 – 15:30	Stability Study Presentation	Mr. Suresh (Biological E. Limited)
15:30 – 15:40	Discussion on presentation	All Participants
15:40 – 16:00	Tea Break	
16:00 – 16:45	Stability Study Presentation	Mr D. Mahesh (Human Biologicals Limited)
16:45 – 16:55	Discussion on presentation	All Participants
16:55 – 17:30	Views of Public Sector Units on Stability Study and Open House Discussion	All Participants

AGENDA OF THE WORKSHOP: 13TH FEBRUARY, 2014

Time	Topic	Speaker
9:30 - 10:00	Registration	-
10:00 - 10:15	Inaugural session (Welcome address, Introduction of participants)	CDSCO
10:15 - 10:25	Introduction of the Workshop	CDSCO
10:25 – 10:45	Pre-assessment	CDSCO
10:45 – 11:00	Tea Break	
11:00 - 13:00	WHO STABILITY STUDIES GUIDELINES	Dr. Saranjit Singh (NIPER)
13:00 – 13:50	Lunch Break	
13:50 – 15:40	WHO Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
15:40 – 16:00	Tea Break	
16:00 – 17:00	WHO Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
17:00 – 18:00	Discussion on presentation	All Participants
9:30 - 10:00	Registration	-
10:00 - 10:15	Inaugural session (Welcome address, Introduction of participants)	CDSCO
10:15 - 10:25	Introduction of the Workshop	CDSCO
10:25 – 10:45	Pre-assessment	CDSCO
10:45 – 11:00	Tea Break	
11:00 - 13:00	WHO STABILITY STUDIES GUIDELINES	Dr. Saranjit Singh (NIPER)

AGENDA OF THE WORKSHOP: 14TH FEBRUARY, 2014

Time	Topic	Speaker
10:00 - 10:40	ICH (Q1A to Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
10:40 – 11:00	Tea Break	
11:00 - 13:00	ICH (Q1A TO Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
13:00 – 13:50	Lunch Break	
13:50 – 15:40	ICH (Q1A to Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
15:40 – 16:00	Tea Break	
16:00 – 17:30	Case Studies and Discussion on presentation	All Participants
17:30 – 18:00	Post-assessment	CDSCO
10:00 - 10:40	ICH (Q1A to Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
10:40 – 11:00	Tea Break	
11:00 - 13:00	ICH (Q1A TO Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
13:00 – 13:50	Lunch Break	
13:50 – 15:40	ICH (Q1A to Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)
15:40 – 16:00	Tea Break	
16:00 – 17:30	Case Studies and Discussion on presentation	All Participants
17:30 – 18:00	Post-assessment	CDSCO
10:00 - 10:40	ICH (Q1A to Q1E) Stability Studies Guidelines	Dr. Saranjit Singh (NIPER)

List of Participants on 12 February, 2014

Sr. No.	Name of the Participant	Office Address	Designation
1.	Dr. Saranjit Singh	NIPER	Professor & Head, Pharmaceutical Analysis, NIPER
2.	Mr. S.P. Shani	CDSCO (EZ)	Deputy Drugs Controller (India)
3.	Dr. A. Ramkishan	CDSCO(QA)	Deputy Drugs Controller (India)
4.	Ms. Rubina Bose	CDSCO (HQ)	Assistant Drugs Controller (India)
5.	Dr. Inderjeet Singh Hura	CDSCO (HQ)	Assistant Drugs Controller (India)
6.	Mr. Jayant Gangakhedkar	CDSCO (HQ)	Assistant Drugs Controller (India)
7.	Mr. Sourabh Mittal	CDSCO (HQ)	Drugs Inspector
8.	Mr. Devendra Nath	CDSCO (HQ)	Drugs Inspector
9.	Mr. Rakesh Negi	CDSCO (HQ)	Drugs Inspector

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Sr. No.	Name of the Participant	Office Address	Designation
10	Mr. Amol Eknath Kandekar	CDSCO (HQ)	Drugs Inspector
11	Mr. Saurabh Garg	CDSCO (HQ)	Drugs Inspector
12	Mr. Rajesh Kumar Verma	CDSCO (HQ)	Drugs Inspector
13	Mr. Shashi Paul	CDSCO (HQ)	Drugs Inspector
14	Mr. Vinod Kumar	CDSCO (HQ)	Drugs Inspector
15	Mr. Ankur Bansal	CDSCO (HQ)	Drugs Inspector
17	Mr. Fahim Khan	CDSCO (HQ)	Drugs Inspector
18	Mr. Rahul Panwar	CDSCO (HQ)	Drugs Inspector
19	Mr. Yogesh Shelar	CDSCO (HQ)	Drugs Inspector

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Sr. No.	Name of the Participant	Office Address	Designation
20.	Ms. Shraddha Srivastava	CDSCO (HQ)	Drugs Inspector
21	Mr. Manish Singhal	CDSCO (HQ)	Drugs Inspector
22	Mr. Vinay Kumar Gupta	CDSCO (HQ)	Drugs Inspector
23	Dr. Sikha Yadav	NIB	Scientist Grade-II
24	Dr. Renu Jain	NIB	Scientist Grade-II
25	Smt. Gurminder Bindra	NIB	Scientist Grade-III
26	Mr. Sunil Kumar Goel	CDL	Technical Officer
27	Mr. Vivek Bansal	CDL	Technical Supervisor
28	Mr. Devinder Kumar	CDL	Technical Supervisor

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Sr. No.	Name of the Participant	Office Address	Designation
29	Mr. Devendra Barthwal	CDL	Technical Supervisor
30	Mr. Sachin Sood	CDL	Technical Supervisor
31	Mr D. Mahesh	Human Biologicals Limited	----
42	Mr. Vikas Dogar	Serum Institute of India Ltd	----
33	Mrs. Vidya A Sawakhande	Haffkine Biopharmaceutical Corporation Ltd.	----
34	Mrs. Sheron S. Borkar	Haffkine Biopharmaceutical Corporation Ltd.	Manager ,QA
35	Mr. Sanjay Maheshwari	Cadila Healthcare Limited	----
36	Mr. Prabhakar Rao	Chiron Behring Vaccine Ltd	----
37	Mr. Suresh	Biological E. Limited	----

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38	Mr. Madan Mohan	Biological E. Limited	----
39	Dr. Sunil Kumar	CRI, Kasauli	----
40	Dr. Yashwant Kumar	CRI, Kasauli	----
41	Mr. C.Palaniappan	Pasteur Institute	----
42	Dr. T. F. Hassan	BCG Vaccine laboratory, Guindy	----
43	Mr. Gopal Singh	Panacea Biotech Ltd	----
44	Dr. Shweta Gupta	Bharat Immunological & Biologicals Corporation Limited	----
45	Dr. Kankalpati Anil Kumar	Ranbaxy Laboratories Limited	----
46	Ajay Kumar	---	Manager, QA

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Sr. No.	Name of the Participant	Office Address	Designation
47	Sashnita. S	Biomed Pvt. Ltd	Quality Maneger
48	Sanjay Diwedi	Pancea Biotech Ltd	Assistant General Manager
49	Sanjay Kumar	Cadila Healthcare Ltd.	Sr. Supervisor

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4	Ms. Rubina Bose	CDSCO (HQ)	Assistant Drugs Controller (India)
5	Mr. Sanjeev Kumar	CDSCO (HQ)	Assistant Drugs Controller (India)
6	Mr. Jayant Gangakhedkar	CDSCO (HQ)	Assistant Drugs Controller (India)
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21	Mr. Sandeep Kumar	CDSCO (HQ)	Drugs Inspector
22	Mr. Jay Jyoti Roy	CDSCO (HQ)	Drugs Inspector
23	Ms. Sunitha Seerapu	CDSCO (HQ)	Drugs Inspector
24	Mr. Manoj Choudhary Jatav	CDSCO (HQ)	Drugs Inspector
25	Mr. Pratyush Kumar	CDSCO (HQ)	Drugs Inspector
26	Mr. Sri Babu	CDSCO (HQ)	Drugs Inspector
27	Mr. Sushanta Sarkar	CDSCO (HQ)	Drugs Inspector

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29	Mr. Balakumar Mahalingam	CDSCO (HQ)	Drugs Inspector
30	Dr. Bikash Roy	CDSCO (HQ)	Drugs Inspector
31	Mr. S. John Gerard	CDSCO (HQ)	Drugs Inspector
32	Mr. Haribabu J	CDSCO (HQ)	Drugs Inspector
33	Ms. Suniti Choudhary	CDSCO (HQ)	Drugs Inspector
34	Mr. Parthiban J	CDSCO (HQ)	Drugs Inspector
35	Mr. Manish Horo	CDSCO (HQ)	Drugs Inspector
36	Mr. Basant Kumar Yadav	CDSCO (HQ)	Drugs Inspector

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37	Dr. Vijai Singh Karwasara	CDSCO (HQ)	Drugs Inspector
38	Mr. Hemant Madhukar Patil	CDSCO (HQ)	Drugs Inspector
39	Mr. Arvind Singh Panwar	CDSCO (HQ)	Drugs Inspector
40	Mr. Bidya Sekhar Mishra	CDSCO (HQ)	Drugs Inspector
41	Ms. Sudarmathi S	CDSCO (HQ)	Drugs Inspector
42	Ms. A Anbuselvi	CDSCO (HQ)	Drugs Inspector
43	Mr. Dinesh Kumar	CDSCO (HQ)	Drugs Inspector
44	Ms. Kiran Singh	CDSCO (HQ)	Drugs Inspector



सत्यमेव जयते



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Venue: Hotel Metropolitan, Bangla Sahib Road, New Delhi 110001



ON FIRST DAY, MR. S.T. SHANI, DEPUTY DRUGS CONTROLLER (INDIA), CDSCO HIGHLIGHTED TO ALL THE PARTICIPANTS FOR THE NEED OF STABILITY AND ADDRESSED VARIOUS ISSUES PERTAINING TO THE STABILITY OF DRUGS



DR. A. Ramkishan, Deputy Drugs Controller (India), CDSCO addressed the importance of this workshop and highlighted the mandate, mission and vision of CDSCO, objective and expectation from this workshop.



PRE-ASSESSMENT OF THE PARTICIPANTS AT THE BEGINNING OF THE WORKSHOP





PRESENTATIONS ON STABILITY STUDIES BY DIFFERENT PHARMACEUTICAL MANUFACTURERS



Presentations on Stability studies by different vaccine manufacturers



FACILITATORS AND PARTICIPANTS TAKING KEEN INTEREST DURING THE PRESENTATIONS

 
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THE REVIEW OF STABILITY DATA WAS MADE MORE SIMPLER WITH THE ENLIGHTENMENT BY MR. S.P. SHANI, DEPUTY DRUGS CONTROLLER, INDIA.



WHO stability Guideline and various ICH guidelines were discussed by Mr. Saranjit Singh, Professor & Head, Pharmaceutical Analysis, NIPER

ON BOTH DAYS, DR. SARANJIT SINGH DISCUSSED VARIOUS STABILITY PROBLEMS, CASE STUDIES ON STABILITY OF DRUGS SUBSTANCES AND PRODUCTS WITH THE PARTICIPANTS IN REGULATORY PERSPECTIVE





GROUP DISCUSSION ON CASE STUDY



POST ASSESSMENT



Participants for workshop

Outcomes of workshop:

Detailed discussion on WHO and ICH stability study guidelines imparted knowledge to the participants on the stability requirements during regulatory submission of stability data and was useful for the participants to access the regulatory submission and to take appropriate decision.