

Annexure-I**Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL of year 2017**

S. NO.	PRODUCT	MANUFACTURER	BATCH NO.	MFG. DT.	EXP. DT.	SUB-STANDARD IN	TYPE/SOURCE OF SAMPLE	STATUS	REGULATORY ACTION/ CONCLUSION
1	Snake Venom Anti Serum IP	Vins BioProducts, Telangana	01AS15016	05/2015	04/2019	Potency Test	Field	NSQ	Under investigation
2	Snake Venom Anti Serum IP	Vins BioProducts, Telangana	01AS16028	06/2016	05/2020	Potency Test	Field	NSQ	Under investigation
3	Snake Venom Anti Serum IP	Bharat Serum & Vaccines Ltd., Ambernath	A05315062	05/2015	04/2019	Potency Test	DI	NSQ	Joint inspection carried out and no GMP violations found. Informed to Commissioner, Mumbai for necessary action.
4	Tetanus Vaccine Adsorbed IP	HBI, Hyderabad	TOX23B/15	04/15	03/2018	Physical Aspects	DI	NSQ	The investigation was carried out at manufacturing site & report has been forwarded to Drugs Controller Kerala as well as concerned officer for necessary action as per provisions of Drugs & Cosmetics Act & Rules thereunder.
5	Vi Polysaccharide Typhoid Vaccine IP	---	1050411	02/2015	09/2017	Identity Test	DI	NSQ	The investigation was carried out at manufacturing site & the manufacturer has denied the manufacturing of said batch. The report has been forwarded to Drugs Controller Andhra Pradesh & concerned officer for necessary action as per provisions of Drugs & Cosmetics Act & Rules thereunder.
6	Vi Polysaccharide Typhoid Vaccine IP	---	1050411	02/2016	09/2018	Identity Test	DI	NSQ	The investigation was carried out at manufacturing site & the manufacturer has denied the manufacturing of said batch. The report has been forwarded to Drugs Controller Andhra Pradesh & concerned officer for necessary action as per provisions of Drugs & Cosmetics Act & Rules thereunder.

7	Vi Polysaccharide Typhoid Vaccine IP	BioMed, Ghaziabad	TC010417	04/2017	03/2020	Vi Polysaccharide Content	DI	NSQ	The investigation was carried out at manufacturing site & report has been forwarded to Drugs Controller, Uttar Pradesh to recall the NSQ batches immediately and take necessary action under Rule 85 of Drugs & Cosmetics Rules, 1945. Also, directed all SLA/UT & CDSCO Zonal/Sub-Zonal offices for strict vigil on movement of batch
8	Vi Polysaccharide Typhoid Vaccine IP	BioMed, Ghaziabad	TC010915	09/2015	08/2018	Vi Polysaccharide Content	DI	NSQ	The investigation was carried out at manufacturing site & report has been forwarded to Drugs Controller, Uttar Pradesh to recall the NSQ batches immediately and take necessary action under Rule 85 of Drugs & Cosmetics Rules, 1945. Also, directed all SLA/UT & CDSCO Zonal/Sub-Zonal offices for strict vigil on movement of batch
9	DPT+HepB+Hib	B .E. Ltd, Hyderabad	2201035154A	02/2016	01/2018	Physical Parameters	DI	NSQ	Under investigation

Abbreviation: **NSQ**- Not of Standard Quality, **DI**: Drugs Inspector