

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL from 2013 to 2016

S. NO.	YEAR	PRODUCT	MANUFACTURER	BATCH NO.	MFG. DT.	EXP. DT.	SUB-STANDARD IN	TYPE/SOURCE OF SAMPLE	STATUS	REGULATORY ACTION/ CONCLUSION
1	2013	DTP+HepB+Hib	B .E. Ltd, Hyderabad	29072A13	-	12/14	Physical Aspects	Routine lot release	NSQ	Batch not released in market
2		DTP+HepB+Hib	B .E. Ltd, Hyderabad	29073A13	-	12/14	Physical Aspects	Routine lot release	NSQ	Batch not released in market
3		DTP+HepB+Hib	B. E. Ltd, Hyderabad	29074A13	-	12/14	Physical Aspects	Routine lot release	NSQ	Batch not released in market
4		DTP+HepB+Hib	B. E. Ltd, Hyderabad	29075A13	-	12/14	Physical Aspects	Routine lot release	NSQ	Batch not released in market
5		Snake Venom Antiserum	VINS, Hyderabad	01AS13027	11/11	10/13	Potency	Field	NSQ	Batch recalled
6		Tetanus Antitoxin	VINS ,Hyderabad	44AT11001	05/13	4/17	Potency	Routine lot release	NSQ	Batch not released in market
7	2014	Hepatitis-B	BBIL Hyderabad	51AD13050	08/13	07/16	Physical Aspect	Field	NSQ	Firm has initiated recall.
8		Snake Venom Antiserum	B. E. Ltd, Hyderabad	A1603914	07/14	06/16	Potency	Routine lot release	NSQ	Batch not released in market
9		TT	B. E. Ltd, Hyderabad	AM650	4/13	3/16	Physical Aspects	Field	NSQ	Batch recalled
10		DPT	HBI, Hyderabad	TAG05A/14	1/14	12/15	Physical Aspects	Field	NSQ	Batch recalled
11	2015	DTP+HepB+Hib	Shantha Biotech, Hyderabad	PLU007A15	4/15	3/17	Physical Aspects	Field	NSQ	Joint inspection carried out and no GMP violations found. No safety issues with the product, it was storage problem with this batch only.
12		TT	Bio Vaccines, Indore	15/TB/TT/A-01	07/15	06/17	Physical Aspects	Form 29	NSQ	This was experimental test batch not meant for commercial market.
13		TT	Bio Vaccines, Indore	15/TB/TT/A-02	07/15	06/17	Physical Aspects	Form 29	NSQ	This was experimental test batch not meant for commercial market.
14		TT	Bio Vaccines, Indore	15/TB/TT/A-03	07/15	06/17	Physical Aspects	Form 29	NSQ	This was experimental test batch not meant for commercial market.

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15	2016	DTP+HepB+Hib	Shantha Biotech, Hyderabad	PLU007A15	04/15	03/17	Physical Aspects	Field	NSQ	Joint inspection carried out and no GMP violations found. No safety issues with the product, it was storage problem.
16		DTP+HepB+Hib	B. E. Ltd, Hyderabad	220103515A	2/16	01/18	Physical Aspects	DI	NSQ	Process initiated

Abbreviation: NSQ- Not of Standard Quality