

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL along with regulatory action of year 2017

S.No	Name of Vaccine	Manufacturer	Batch No.	Mfg Date	Exp Date	Sub-Standard in	Type/ Source of Sample	Status	REGULATORY ACTION/ CONCLUSION (Including recall status)
1	Bio Typh (Vi Polysaccharide Typhoid Vaccine) I.P.	Spurious	1050411	Feb-15 Feb-16	Sep-17 Sep-18	Identity Test	Drug Inspectors	Not of Standard Quality (Spurious)	Joint investigation conducted at manufacturing site of Bio Med, Ghaziabad on 25.10.2017 and it was concluded that NSQ batch was not manufactured by firm. Case filed before Hon'ble Court of District & Sessions Judge. The matter is under trial.
2	Tetanus Vaccine(adsorbed) I.P (AbhayTox)	M/s Human Biological Institute, (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli Post, Hyderabad-500032	Tox 23B/15	Apr-15	Mar-18	Physical aspect	Drug Inspectors	Not of Standard Quality	Joint investigation conducted at manufacturing site on 02.11.2017 and it was concluded that NSQ is due to improper storage condition of vials below recommended temperature. This office has sent communication to SLA as per procedures.

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL along with regulatory action of year 2018

S.No	Name of Vaccine	Manufacturer	Batch No.	Mfg Date	Exp Date	Sub-Standard in	Type/ Source of Sample	Status	REGULATORY ACTION/ CONCLUSION (Including recall status)
1	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) & Haemophilus influenzae Type-b Conjugate vaccine (Adsorbed)	M/s Biological E Ltd, Plot no. 1, SP Biotech Park, Phase II, Kolthur (Village), Shameerpet (mandal), Ranga Reddy (District), Telangana - 500078	220103715A	Feb-16	Jan-18	Physical aspect	Drugs Inspector	Not of Standard Quality	Joint investigation conducted at manufacturing site on 09.04.2018 & 10.04.2018. The investigation team noted certain observations which was communicated to the firm for response. The firm had submitted the compliance report for the noted observations. The concerned Drugs Inspector completed the procedures as per the Drugs & Cosmetics Act.
2	Peda Typh (Vi-Conjugate Typhoid Vaccine)	M/s Bio med., C-96, Bulandshar Road, Industrial Area, Ghaziabad-201009, U.P- 201009	TC010915	Sep-15	Aug-18	VI Polysaccharide content	Drug Inspectors	Not of Standard Quality	The sample was declared as Standard Quality under Form -2 of Drugs Rules.
3	Peda Typh (Typhoid Vi-Conjugate Vaccine)	M/s Bio med., C-96, Bulandshar Road, Industrial Area, Ghaziabad-201009, U.P- 201009	TC010417	Apr-17	Mar-20	VI Polysaccharide content	Drug Inspectors	Not of Standard Quality	The sample was declared as Standard Quality under Form -2 of Drugs Rules.
4	Tetanus Vaccine(adsorbed) I.P	Vials Received Without Label	--	--	--	Container Closer Integrity	Drug Inspectors	Not of Standard Quality	Case filed before Hon'ble Court. Judgement was passed wherein the accused were sentenced and fined.
5	Poliomyelitis Vaccine live oral I.P. Divalent (Bivalent/bOPV)	M/s Bio med., C-96, Bulandshar Road, Industrial Area, Ghaziabad-201009, U.P- 201009	B100318	Mar-18	Feb-20	Identity: Type-2 detected	Drug Inspectors	Not of Standard Quality	Joint investigation conducted at manufacturing site on 03.10.2018 to 06.10.2018 & 08.10.2018. The sample was also declared as Not Standard Quality in Form -2 under Drugs Rules. Case filed before Honble Court. The matter is under trial.
6	Poliomyelitis Vaccine live oral I.P. Divalent (Bivalent/bOPV)	M/s Bio med., C-96, Bulandshar Road, Industrial Area, Ghaziabad-201009, U.P- 201009	B100318	Mar-18	Feb-20	Identity Type-2 detected	Drug Inspectors	Not of Standard Quality	Joint investigation conducted at manufacturing site on 03.10.2018 to 06.10.2018 & 08.10.2018. The sample was also declared as Not Standard Quality in Form -2 under Drugs Rules. Case filed before Honble Court. The matter is under trial.

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL along with regulatory action of year 2019

S.No	Name of Vaccine	Manufacturer	Batch No.	Mfg Date	Exp Date	Sub-Standard in	Type/ Source of Sample	Status	REGULATORY ACTION/ CONCLUSION (Including recall status)
1	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) & Haemophilus influenzae Type-b Conjugate vaccine (Adsorbed)	M/s Biological E Ltd, Plot no. 1, SP Biotech Park, Phase II, Kolthur (Village), Shameerpet (mandal), Ranga Reddy (District), Telangana - 500078	220106717A	Oct-17	Mar-20	Physical aspect	Drug Inspectors	Not of Standard Quality	Joint investigation conducted at manufacturing site on 18.04.2019. The sample was declared as Standard Quality under Form -2 of Drugs Rules.
2	Tetanus Vaccine (Adsorbed) I.P.	M/s DANO Vaccines & Biologicals Pvt Ltd., Factory-575, Sivaredyguda, Ghatkesar-501301, (T.S.)	1641V	Nov-16	Oct-19	Physical aspect	Drug Inspectors	Not of Standard Quality	Administrative action recommended.

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL along with regulatory action of year 2022

S.No	Name of Vaccine	Manufacturer	Batch No.	Mfg Date	Exp Date	Sub-Standard in	Type/ Source of Sample	Status	REGULATORY ACTION/ CONCLUSION (Including recall status)
1	Covishield Vaccine	Spurious	4121MC040	07.07.2021	06.04.2022	Spurious	Drug Inspectors	Not of Standard Quality (Spurious)	The survey sample of corona virus vaccine purported to be manufactured by SIIPL was declared Spurious by CDL vide report no.: CDL/2022/3459 dated 16.06.2022. The police investigated the matter and filed criminal case bearing no. 3087/2021 dated 04.12.2021 before Hon'ble XXII Judicial Magistrate F.C. Aurangabad. The matter is under trial.
2	Covishield Vaccine	Spurious	4121MC019	14.06.2021	13.03.2022	Spurious	Drug Inspectors	Not of Standard Quality (Spurious)	The survey sample of corona virus vaccine purported to be manufactured by SIIPL was declared Spurious by CDL vide report no.: CDL/2022/3467 dated 16.06.2022.. The police has investigated the matter and filed separate criminal case bearing no. 3087/2021 dated 04.12.2021 before Hon'ble XXII Judicial Magistrate F.C. Aurangabad. The matter is under trial.
3	Unlabelled filled transparent fluid vial purported to be ChAdoX1 nCoV19 corona virus vaccine	Spurious	--	--	--	Identity, Assay, Biochemical test, Sterility Test, Physical aspect and Label review	Drug Inspectors	Not of Standard Quality (Spurious)	The sample was declared as NSQ (Spurious). Case filed before CJM Court & the matter is under trial.
4	ChAdoX1 nCoV19 corona virus vaccine (Covishield vaccine)	Spurious	4121MC034	01.07.2021	31.03.2022	Identity, Assay, Biochemical test, Sterility Test, Physical aspect and Label review	Drug Inspectors	Not of Standard Quality (Spurious)	The sample was declared as NSQ (Spurious). Case filed before CJM Court & the matter is under trial.
5	Novel Corona Virus - nCoV Vaccine (ZYCOV-D)	Spurious	I457BH110	29.09.2021	28.06.2022	Identity, Assay, Biochemical test, Sterility Test, Physical aspect and Label review	Drug Inspectors	Not of Standard Quality (Spurious)	The sample was declared as NSQ (Spurious). Case filed before CJM Court & the matter is under trial.

Detail of samples declared NOT OF STANDARD QUALITY (NSQ) by CDL along with regulatory action of year 2023

S.No	Name of Vaccine	Manufacturer	Batch No.	Mfg Date	Exp Date	Sub-Standard in	Type/ Source of Sample	Status	REGULATORY ACTION/ CONCLUSION (Including recall status)
1	Typhoid Polysaccharide Vaccine I.P. (TYPBAR)	M/s Bharat Biotech, Genome Valley Shameerpet, Hyderabad – 500 078 Telangana INDIA	54A22001A	Apr-22	Mar-25	O-acetyl Content	Drug Inspectors	Not of Standard Quality	Joint investigation conducted at manufacturing site on 19.07.2023 & 20.07.2023. The SLA suspended the product permission of Typhoid vaccine for 15 days.