

**CM 23970 - LACTOSE(Mono)(Gamma Irradiated)
(Bacteriological Grade)**

INTENDED USE

Used in media fortissue culture and therefore production of vaccines of viral origin including foot and mouth disease, polio, dengue, coxsackie B3 and many other viruses. Other uses include growth of *lactobacilli*, spore growth of clostridia and in fermentation procedures for hormone production.

PRODUCT SUMMARY AND EXPLANATION

Lactose (Mono)Gamma Irradiated, an animaloriginpeptone, is the enzymatically hydrolyzed protein portion of milk whey. This supplement is a mixture of peptides,aminoacids, and carbohydrates, both simple and complex. LACTOSE (Mono) GammaIrradiated TBL to support thegrowthof many mammalian, bacterial, and insect cell types, and it has been used to produce both recombinant proteinsandanimal health vaccines. It is also used this supplement as an amino acid supplementfor mammalian cell culture media.

PRINCIPLE

Lactose (Mono)Gamma Irradiatedcontains high levels of essential amino acids. It is recommended for applications requiring a highlysoluble sourceofamino acids and peptides. It is especially useful in fermentations, laboratory media and in tissue culture or suitableforvaccine production.

INSTRUCTION FOR USE

LACTOSE(Mono)Gamma Irradiated TBL has been used as a nutritional source for lactobacilli. It is also useful for indole testing because of its hightryptophan content. Lactalbumin is frequently used in mammalian cell culture media as an amino acid supplement.

PHYSICAL PARAMETERS:

<i>S. No.</i>	<i>PRODUCT PARAMETERS</i>	<i>SPECIFICATION</i>	<i>RESULT</i>
1.	Appearance	white colour powder	Complies
2.	Solubility	10% w/v Boiling water gives clear solution	Complies
3.	Clarity	10% w/v aqueous solution is clear.	Complies

CHEMICAL PARAMETERS:

<i>S. No.</i>	<i>PRODUCT PARAMETERS</i>	<i>SPECIFICATION</i>	<i>RESULT</i>
1.	FTIR	Matches with the standard pattern	Complies
2.	Specific rotation	54.40° - 55.90°	Complies
3.	Acidity or alkalinity	Passes test	Complies
4.	Heavy metals (as Pb)	≤ 0.0005%	Complies
5.	Sulphated ash	≤ 0.100%	Complies
6.	Water (K.F.)	4.50% - 5.50%	Complies
7.	Assay (GC/HPLC)	98% - 102%	Complies



MICROBIAL PARAMETERS:

S. No.	PRODUCT PARAMETERS	SPECIFICATION	RESULT
1.	BACTERIAL ENDOTOXIN TEST		
	Typical Endotoxin level	≤5 EU/gm	Complies
2.	Sterility Testing	No Growth is observed after 14 Days for Bacteria 30 – 35 °C and for fungi at 20-25 °C	No Growth
3.	Irradiation Dose (kGy)	25kGy	Complies

INTERPRETATION:

Microbial culture response observed after an incubation at 35-37°C for 18 - 24 hours by preparing Phenol Red Broth Base (TM 255) using 0.5% of Lactose (Mono), Sterile (Y)

SL. No.	MICROORGANISM'S	STRAIN	ACID	GAS	RESULT
1	<i>Citrobacter freundii</i>	ATCC 8090	+	+	Complies
2	<i>Klebsiella aerogenes</i>	ATCC 13048(WDCM00175)	+	+	
3	<i>Escherichia coli</i>	ATCC 25922 (WDCM00013)	+	+	
4	<i>Klebsiella pneumoniae</i>	ATCC 13883	+	+	
	<i>subsp. pneumoniae</i>	(WDCM 00097)			
5	<i>Proteus hauseri</i>	ATCC 13315	-	-	
6	<i>Serratia marcescens</i>	ATCC 8100	-	-	
7	<i>Salmonella enterica</i>	ATCC 6539	-	-	
	<i>subsp. enterica Typhi</i>				
	<i>Salmonella enterica</i>				
8	<i>subsp. enterica</i>	ATCC 14028(WDCM 00031)	-	-	
	<i>Typhimurium</i>				
	<i>Shigella flexneri</i>				
9		ATCC 12022 (WDCM 00126)	-	-	
10	<i>Pseudomonas aeruginosa</i>	ATCC 27853 (WDCM 00025)	-	-	
11	<i>Staphylococcus aureus</i>	ATCC 25923 (WDCM 00034)	-	-	
	<i>subsp. aureus</i>				
12	<i>Bacillus subtilis subsp. Spizizenii</i>	ATCC 6633 (WDCM 00003)	-	-	
13	<i>Clostridium sporogenes</i>	ATCC 11437	-	-	
14	<i>Aspergillus brasiliensis</i>	ATCC 16404 (WDCM 00053) ATCC 10231	-	-	
15	<i>Candida albicans</i>	(WDCM 00054)	-	-	



PACKAGING

Standard packings 500gm, 5 kg & 50 kg. After packing tightly closed in a dry and well-ventilated place.

STORAGE

Store at room temperature in cool place, keep plastic bottle tightly closed in a dry and well-ventilated place. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

Product Deterioration: Do not use product if any contamination, discoloration or other sign of deterioration is found.

DISPOSAL

After use, contact a licensed professional waste disposal service to dispose of this material. Dispose of as unused product.



Quantity



Lot / Batch Number



Temperature Unit



Manufacturer



Best Before



Certification of
Good Manufacturing Practices

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

