

UPUTSTVO ZA UPOTREBU (SRB)

Soyabean Casein Digest Medium Agar Plate

Podloga za kultivaciju širokog spektra mikroorganizama i za testiranje sterilnosti u farmaceutskim procedurama.

Sadržaj pakovanja:

Šifra artikla (pakovanja) REF	Opis	Šifra primarnog pakovanja:	Broj podloga
PRM290V20	Podloga izlivena u petri posudama od ø90	PRM290	20
PRM290V60			60
PRM290V240			240
PRM290M50	Podloga izlivena u petri posudama od ø50		40

Uputstva

Pod aseptičnim uslovima inokulisati ploču metodom površinskog zasejavanja i inkubirati je pod uslovima optimalnim za dati organizam.

Princip i interpretacija

Soyabean Casein Digest Agar je široko korišćena podloga, koja podržava rast različitih organizama čak i onih zahtevnih, kao što su *Neisseria* spp., *Listeria* spp., *Brucella* spp. itd. Njen jednostavan sastav bez inhibitora čini je pogodnom za detekciju antimikrobnih sredstava u hrani i drugim proizvodima. Soyabean Casein Digest Medium Agar (poznatiji kao Tryptone Soya Agar) je preporučen od strane različitih farmakopeja kao medijum u testiranju sterilnosti (1,2).

Tryptone Soya Agar je usklađen sa zahtevima USP (1) i koristi se u mikrobiološkim limit testovima i testovima efikasnosti antimikrobnih konzervanasa. Gunn i sar. (3) su koristili ovu podlogu za rast zahtevnih organizama. Kombinacija triptona i sojinog peptona čini ovu podlogu hranljivom tako što obezbeđuje aminokiseline i peptide dugog lanca za rast mikroorganizama. Natrijum hlorid održava osmotsku ravnotežu.

Kontrola kvaliteta

Podaci i rezultati kontrole kvaliteta dati su u sertifikatu analize za svaku seriju.

Skладиštenje i rok upotrebe

Čuvati između 15-25°C. Nakon prvog otvaranja čuvati na 2-8°C. Upotrebiti pre isteka datuma označenog na nalepnici.

Mere predostrožnosti


Ovaj proizvod ne sadrži hazardne supstance u koncentracijama koje su iznad propisanih limita određenih važećim zakonskim regulativama i zato nije klasifikovan kao opasan. Ipak, preporučeno je slediti smernice iz bezbednosnog lista za pravilnu upotrebu. Ovaj proizvod je namenjen isključivo za upotrebu u laboratorijskim uslovima, od strane profesionalno obučene osobe.


Proizvod ne upotrebljavati ukoliko je primarno pakovanje oštećeno ili proizvod ne odgovara navedenim karakteristikama.

Odlaganje otpada

Odlaganje otpada mora biti u skladu sa nacionalnim i lokalnim regulativama koje su na snazi. Svaka laboratorija je odgovorna za rukovanje i odlaganje otpada koji nastaje u toku rada.

Upotrebljeni simboli

	Evropski znak usaglašenosti		Držati uspravno
	In vitro dijagnostičko medicinsko sredstvo		Kataloški broj
	Ne izlagati direktno sunčevim zracima		Lot broj
	Konsultovati uputstvo za upotrebu		Rok upotrebe
	Ne koristiti više puta		Temperatura čuvanja
	Veličina pakovanja		Proizvođač
	Ovlašćeni predstavnik u Evropskoj uniji		

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Literatura

1. The United States Pharmacopoeia / National Formulary, 2016, USP 39, The United States Pharmacopoeial Convention Inc., Rockville, MD.
2. Indian Pharmacopoeia, 2014, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
3. Gunn B. A., Ohashi D K., Gaydos C. A., Holt E. S., 1977, J. Clin. Microbiol., 5(6) : 650.
4. Forbes B. A., Sahm A. S. and Weissfeld D. F., 1998, Bailey and Scotts Diagnostic Microbiology, 10th Ed., Mosby Inc. St. Louis, Mo.

Broj rešenja o registraciji: 515-02-02534-22-003

INSTRUCTION FOR USE

(EN)

Soyabean Casein Digest Medium Agar Plate

Soyabean Casein Digest Agar is used for cultivation of a wide variety of microorganisms and for sterility testing in pharmaceutical procedures.

Package contents:

Item code (packaging) REF	Description	Primary packaging code:	Number of products
PRM290V20	Substrate poured into petri dishes of ø90	PRM290	20
PRM290V60			60
PRM290V240			240
PRM290M40	Substrate poured into petri dishes of ø50		40

Directions

Surface spread the test inoculum aseptically on the plate and incubate under optimal conditions for the specific organisms.

Principle and interpretation

Soyabean Casein Digest Agar is a widely used medium, which supports the growth of wide variety of organisms even that of fastidious ones such as *Neisseria* spp., *Listeria* spp., and *Brucella* spp. etc. It has been frequently used in the health industry to produce antigens, toxins etc. Its simple and inhibitor-free composition makes it suitable for the detection of antimicrobial agents in the food and other products. Soyabean Casein Digest Agar (know Tryptone Soya Agar) is recommended by various pharmacopoeias as sterility testing medium (1, 2).

Tryptone Soya Agar conforms as per USP (1) and is used in microbial limit test and antimicrobial preservative - effective test. Gunn et al (3) used this medium for the growth of fastidious organisms. The combination of tryptone and soya peptone makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance.

Quality control

The data and results of quality control are given in the certificate of analysis for each lot.

Storage and shelf life

Storage between 15-25°C. After opening storage between 2-8°C. Use before expiry date on the label.














Warning and precautions


In vitro diagnostic use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques.

Symbols used on labels

	European Conformity mark		This side up
	is an in vitro diagnostic medical device (IVD)		Catalogue number
	Do not expose directly to sunlight		Batch code
	Consult instructions for use		Use-by date
	Do not re-use		Temperature limit
	Pack size		Manufacturer
	European Authorized Representative (Authorised Representative)		

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Reference

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