



KERALA STATE DRUGS AND PHARMACEUTICALS LTD.

KALAVOOR PO, ALAPPUZHA, KERALA-688522

Specification of 20mm Grey Butyl Rubber stoppers Sterilized (Ready to use)

These are sterilized (ready to use) grey butyl non toxic rubber closures having the following specifications:

Sterilized By: Gamma Radiation

S.No	Test	Specification
1.	Description	The stopper is having four equi-distance lines and a small circle at the center at the top disc. Stoppers evenly and smoothly finished with uniform colour, free from flash and adhering rubber pieces.
2.	Colour	Grey
3.	Disc Diameter	18.60mm-19.10mm
4.	Plunger Diameter	13.00mm-13.20mm
5.	Total Height	8.20mm-8.80mm
6.	Disc Thickness	3.20mm-3.60mm
7.	Shore Hardness	40° A-50°A
8.	Fragmentation Test	Not more than 15 Fragments
9.	Self Sealability	None of the vials contains any trace of coloured solution.
10.	Appearance of solution	Sòlution A is not opalescent than opalescent standard OS3 and not more intensely coloured than reference solution BYS6.
11.	Acidity or alkalinity	To 20.0ml of the solution A add 0.1ml of bromothymol blue solution. Not more than 0.3ml of 0.01 M Sodium hydroxide or 0.8ml of 0.01M Hydrochloric acid is required to change the colour of the solution to blue or yellow respectively.
12.	pH	Not more than 0.3ml of 0.01 M Sodium Hydroxide or 0.8ml of 0.01M Hydrochloric acid.

Prepared by	Checked By	Checked by	Reviewed By	Approved By
Jr. Manager QA	Dy. Manager, Production	Production Head	QC Head	QA Head
Date: 05/10/18	Date: 05/10/18	Date: 5/10/18	Date: 5/10/18	Date: 5/10/18

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