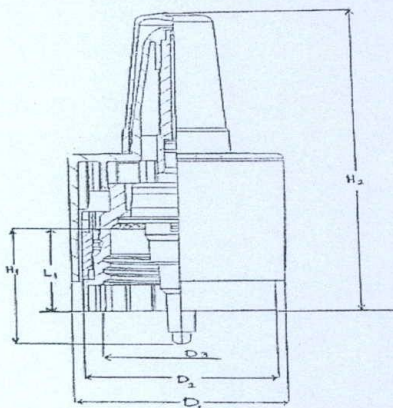


PACKAGING MATERIAL SPECIFICATIONS

Material

PUMP SPRAY, COUNTING, 91 µL, FOR NASOCALCIN SPRAYS



11211117

TESTS	SPECIFICATIONS	METHODS
*Appearance:	Well-formed and assembled plastic pumps with dust caps, free of visible defects.	Visual inspection performed according to In House method
*Color:	Body, white, dust cap, colorless as standard.	Visual inspection performed according to In House method
*Cleanliness:	Pump parts should be clean and free of contamination.	Visual inspection performed according to In House method
*Fitness and operation:	Pumps should fit bottles with pilferproof form and should operate normally.	Visual inspection performed according to In House method
*Fitness of dip-tube:	Dip-tube should fit center of the bottle without bending.	Visual inspection performed according to In House method
*Fitness of dust caps:	Dust caps should fit and removed easily.	Visual inspection performed according to In House method
*Weight of spray dose (AV/10):	Between 86 mg and 96 mg.	Test performed according to In House method
*Dimensions: (AV/10)	H ₁ : 40.0 ± 0.5 mm. H ₂ : 63.2 ± 0.4 mm. D ₁ : 27.9 ± 0.2 mm D ₂ : 25.0 ± 0.2 mm D ₃ : 17.5 ± 0.2 mm L ₁ : 17.2 ± 0.3 mm	Test performed according to In House method
*Microbiological quality:	TAMC: Not more than 10 ³ CFU/g. TYMC: Not more than 10 ² CFU/g.	Test performed according to USP <1111> Microbial examination of Non Sterile product

The tests marked with asterisk (*) are performed during stability test.

Shelf Life:

60 months

Packaging and storage:

600 pump sprays are packed into a plastic bag which packed into a carton box.

Sampling Procedures:

As per Working Instruction; WI-10-0-014

Sample Quantity

Number of Sample for In Process Tests: ---

Number of Sample for Packaging Materials Tests:

As per Working Instruction; WI-10-0-014

Prepared by: Quality Assurance Department

Approved by: Quality Assurance Manager

PACKAGING MATERIALS SPECIFICATIONS AND TEST NOTE



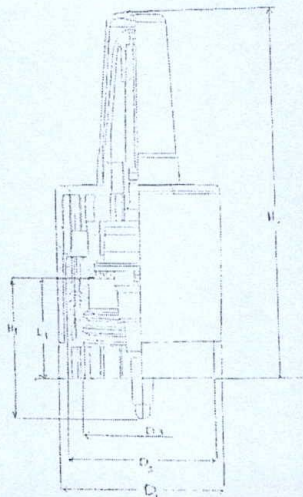
**PUMP SPRAY COUNTING, 91 µL, FOR NASOCALCIN SPRAYS
Pfeiffer 46222**

Material Code: 11211117

Ref : USP41, In House

<i>Manufacturer</i>	<i>No Of Sample Checked</i>	<i>QC No</i>	<i>Release Date</i>
<i>Quantity</i>	<i>No of Containers</i>	<i>Receiving Report No</i>	<i>Analyst</i>
<i>Batch No / Lot No</i>	<i>Exp Date / Shelf Life</i>	<i>Receiving Report Date</i>	<i>Chief Analyst</i>

<i>Tests</i>	<i>Specifications</i>	<i>Results</i>
Appearance:	Well-formed and assembled plastic pumps with dust caps, free of visible defects	-----
Cleanliness:	Pump parts should be clean and free of contamination	-----
Color:	Body, white, dust cap, colorless as standard	-----
Fitness and operation:	Pumps should fit bottles with pilferproof form and should operate normally	-----
Fitness of dip-tube:	Dip-tube should fit center of the bottle with out bending	-----
Fitness of dust caps:	Dust caps should fit and removed easily	-----
Dimensions (AV/10):	H1: Between 39.5 and 40.5 mm H2: Between 62.8 and 63.6 mm D1: Between 27.7 and 28.1 mm D2: Between 24.8 and 25.2 mm D3: Between 17.3 and 17.7 mm L1: Between 16.9 and 17.5 mm	----- ----- ----- ----- ----- -----
Microbiological quality:	TAMC: Not more than 1000 CFU/g TYMC: Not more than 100 CFU/g	----- -----
Weight of spray dose(AV/10):	Between 86 mg and 96 mg	-----



Remark

APPROVED BY:

REJECTED BY: