

CERTIFICATE OF ANALYSIS
Cipla

BATCH No. : GB70187 A . R. No. : GI1700761 Qty. : 9,112 PACKS		AURITUSS INHALER 25/125 CFC FREE 120 MD Salmeterol And Fluticasone Propionate Inhaler 25/125 mcg/dose		MFG.DT. : 12/2016 EXP.DT. : 11/2018	
TEST		STANDARD		RESULT	
DESCRIPTION		A one piece filled metal container fitted with a valve with plastic stem and printed with product name, batch number and container number. On visual examination there should be no sign of physical damage such as dents, bulged containers bent valve stem and uneven crimping. A white homogeneous suspension or powder is obtained after opening the container.		Meets the requirement	
IDENTIFICATION By HPLC BY UV		The retention time of the principle peaks obtained in the chromatogram of the sample solution corresponds to that of the principle peaks of Salmeterol and Fluticasone Propionate in the chromatogram of the standard solution as obtained in the Assay. The light absorption spectrum of Sample solution in the range of 200 nm to 400 nm is concordant to that of Standard solution.		Meets the requirement	
RELATED SUBSTANCES BY HPLC salmeterol Impurity E (Ph.Eur impurity E) (%) salmeterol Impurity G (Ph.Eur impurity G) (%) fluticasone acid propionate (Ph.Eur impurity A) (%) Fluticasone acetate (Ph.Eur Imp. C) (%) S-methyl fluticasone propionate (Ph.Eur impurity D) (%) Single maximum Unknown Impurity (%) Total Impurities (%)		NMT 0.1 NMT 0.5 NMT 0.3 NMT 0.3 NMT 0.3 NMT 0.5 NMT 1.5		Meets the requirement Not Detected Not Detected Below Disregard Limit 0.1% Below Disregard Limit 0.1% Below Disregard Limit 0.1% Below Disregard Limit 0.1% Below Disregard Limit	
DATE OF RELEASE : 03.02.2017					
REMARK : COMPLIES WITH INHOUSE STANDARDS.					
QUALITY CONTROL : <i>(Signature)</i> Ranjit Puri (Section Head)		QUALITY ASSURANCE : <i>(Signature)</i> Santosh Jadhav QA Officer			
DATE : 03.02.2017		DATE : 03.02.2017			

1035-L-0018/F2

 Cipla Ltd., Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai - 400013,
 India Phone (91 22) 25756210 e-mail : savio@cipla.com WebSite www.cipla.com

 Mfg.Site: Cipla Ltd., Unit-II, Verna Industrial Estate, Verna, Salcette, Goa 403722, India
 Phone (91 832) 2889208 / 2889209 / 2889210, Fax (91 832) 2782479 / 2782805, e-mail :
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TEST		STANDARD		RESULT	
DEPOSITION OF THE EMITTED DOSE (AERODYNAMIC ASSESSMENT OF FINE PARTICLES) (BY HPLC) SALMETEROL (%) FLUTICASONE PROPIONATE (%)		NLT 25.0 NLT 25.0		Meets the requirement 57.9 57.3	
ASSAY (BY HPLC) SALMETEROL (%) FLUTICASONE PROPIONATE (%)		NLT 80.0 NLT 80.0		NMT 120.0 NMT 120.0 Meets the requirement 99.3 102.0	
UNIFORMITY OF DELIVERED DOSE		Complies with the test if 9 out of 10 results lie between 75.0 % and 125.0 % of the average value and all lie between 65.0 % and 135.0 %. If 2 or 3 values lie outside the range of 75.0 % to 125.0 %, repeat the test for 2 more containers. Not more than 3 of the 30 values lie outside the range 75.0 % to 125.0 % and no value lies outside the range 65.0 % to 135.0 %.		Meets the requirement	
NUMBER OF DELIVERIES PER CONTAINER (No.)		NLT 120		154	
AVERAGE WEIGHT OF METERED DOSE (mg)		NLT 65.0 NMT 85.0		75.8	
LEAK TEST (mg)		The average leakage rate of the 12 containers is not more than 525.0 mg per year and none of the containers leaks more than 750.0 mg per year. If one container leaks more than 750.0 mg per year, but not more than 1.1 g per year, determine the leakage rate of an additional 24 containers as directed herein. Not more than 2 of the 36 containers leak more than 750.0 mg per year, and none of the 36 containers leaks more than 1.1 g per year.		92.9	
DATE OF RELEASE : 03.02.2017					
REMARK : COMPLIES WITH INHOUSE STANDARDS.					
QUALITY CONTROL : <i>Patri</i> <i>Ranjit Patri (Section Head)</i> DATE : 03.02.2017		QUALITY ASSURANCE : <i>Sh</i> <i>Santosh Jodhar</i> <i>Officer</i> DATE : 03.02.2017			

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TEST		STANDARD		RESULT	
WATER CONTENT (ppm)		NMT 400.0		138.8	
PARTICLE SIZE (BY MICROSCOPY)		Particles below 2.5µm : Not less than 90.0% Particles between 2.5 µm and 10 µm : Not more than 10.0 %		Meets the requirement	
ALCOHOL CONTENT (% v/v)		NLT 2.80 NMT 3.70		3.12	
DATE OF RELEASE : 03.02.2017					
REMARK : COMPLIES WITH INHOUSE STANDARDS.					
QUALITY CONTROL : <i>Pati</i> Ranjit Pati (Section Head)		QUALITY ASSURANCE : <i>Sanjosh Jadhav</i> QA Officer 03.02.2017			
DATE : 03.02.2017		DATE :			

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TEST		STANDARD		RESULT	
AERODYNAMIC ASSESSMENT OF FINE PARTICLES (BY ANDERSON CASACDE IMPACTOR) SALMETEROL (mcg) FLUTICASONE PROPIONATE (mcg)		NLT 5.24 NLT 26.87 NMT 12.22 NMT 62.71		Meets the requirement 10.04 48.98	
NET WEIGHT (g)		NLT 9.0		12.5	
PRESSURE TEST (psi)		NLT 50 NMT 95		76	
DATE OF RELEASE : 03.02.2017					
REMARK : COMPLIES WITH INHOUSE STANDARDS.					
QUALITY CONTROL : <i>Ranjit Pahi</i> <i>Ranjit Pahi (Section Head)</i>		QUALITY ASSURANCE : <i>SL</i> <i>Suresh Jadhav</i> <i>QA officer</i> <i>03.02.2017</i>			
DATE : 03.02.2017		DATE :			

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TEST		STANDARD		RESULT	
PARTICULATE MATTER		The number of particles the longest axis of which is greater than 100 µm does not exceed 50.		Meets the requirement	
MICROBIOLOGICAL EXAMINATION OF NON STERILE PRODUCTS Microbial Enumeration tests Total Aerobic Microbial Count. (cfu/can) Total Combined Yeasts and Molds Count (cfu/can) Tests for Specified Microorganisms Staphylococcus aureus (per can) Pseudomonas aeruginosa (per can) Bile Tolerant Gram-Negative Bacteria (per can)		Not more than e2 Not more than e1 Should be Absent Should be Absent Should be Absent		Meets the requirement <10 <10 Absent Absent Absent	
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QUALITY CONTROL : <i>Pabi</i> Ranjit Pabi (Section Head)		QUALITY ASSURANCE : <i>SL</i> Santosh Jadhav QA Officer			
DATE : 03.02.2017		DATE : 03.02.2017			

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