Jahangirnagar University J. Biol. Sci. **4**(1): 85-89, 2015 (June)

- Short communication

Quality gradient of salbutamol sulphate preparations available in Bangladesh markets

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Key words: Quality gradient, Salbutamol, Antiasthmatics.

Quality of a drug product signifies the sum of all parameters that contribute to its potency, stability, safety, acceptability and effectiveness. It is mandatory for a manufactured and marketed drug product to comply with the regulatory affairs of the Directorate of Drug Administration of Bangladesh. For a marketed drug product, it is required to mention its strength, indications, side effects, precautions, storage conditions, shelf-life, batch number, dates of manufacture and expiration etc. on its labeling.

A drug product is considered as substandard when it does not comply with its pharmacopoeial specifications. Physical parameters contribute to the pharmacokinetic values of a pharmaceutical preparation. In a pharmaceutical preparation, a drug is required to be physically and chemically stable and that its organoleptic values remain unchanged till the declared expiry date under the stated storage conditions.

In Bangladesh about 5 million people suffer from asthma. In 1997, the pharma-market of respiratory products of Bangladesh was 977 million taka. Out of this, the bronchodilators and anti-asthmatic market was about 324 million taka that amounted about 2.3% of the total pharma-market (IMS, Quarter 1, 1998).

The present study was performed to understand the prevalent quality parameters of the local salbutamol products that were marketed in some rural and urban areas of Bangladesh.

Fifteen brands of salbutamol sulphate preparations available in Bangladesh local market were taken for quality assessment. The qualitative parameters as well as the quantitative strength of the preparations were analyzed. The quantity of the drug was measured using UV spectrophotometer following the method of BP (1988). From the study it was found that about 50% of the collected market preparations satisfied compendial specifications, while others did not.

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Both tablet and syrup forms of 15 salbutamol sulphate preparations manufactured by different local pharmaceutical companies were collected from the local market. For each brand, one hundred tablets and five bottles of syrup were purchased from approved retail pharmacies of Dhaka, Chittagong and Comilla. The samples were recorded as code number (Table 1 & 2). **S**tandard sample of Salbutamol Sulfate (99.9%) was collected from the Acme Laboratories (BD) Ltd., Dhaka, Bangladesh.

Table 1. Physical properties of the tablet samples

Code No	Average wt. (mg)	Thickness (cm)	Diameter (cm)	Hardness (Newton)	Weight variation (%)	Weight loss (%)	Disintegration time (min)
S01	167.68	0.40	0.88	45	+7.14 to -12.23	0.12	3:40
S02	200.98	0.25	0.89	58	+2,46 to -4.96	0.15	4:00
S03	201.01	0.29	0.81	43	+3.87 to -2.80	0.8	5:00
S04	157.77	0.36	0.74	18	+6.02 to -3.98	0.31	2:28
S05	102.19	0..26	0.65	53	+12.17 to -2.53	0.11	4:27
S 06	186.04	0.28	0.83	56.8	+11.5 to -5.34	0.0026	5:60
S07	176.45	0.27	0.83	43	+4.67 to -2.86	0.20	3:11
S08	108.91	0.35	0.66	33.7	+4.94 to -4.50	0.518	6:01
S 09	16S.59	0.29	0.84	29.4	+6,16 to -2.16	0.82	0:50
S 10	176.25	0.28	0.85	Broken	+2.86 to -4.00	Broken	Broken
S11	157.10	0.26	0.83	46	+0.89 to -4.64	0.25	5:13
S12	121.56	0.24	0.71	45.6	+2.33 to -3.75	0.19	5:50
S13	197.09	0.29	0.81	14	+3.47 to -1.66	0.26	4:00
S14	111.76	0.28	0.65	61.5	+0.03 to -5.95	0.27	6:00
S15	171.165	0.27	0.82	56	+6.91 to -5.64	0.64	4:43

The tablets were in strip and blister packing with imprints of manufacturing dates. But some of them had no manufacturing date on the strips or blisters, one had no expiry date and another had no batch number.

The coded tablets were destriped/deblistered carefully. The size, shape, colour, embossed marks were observed. Packaging and printing quality were also observed. Diameters and thickness of the samples were measured with slide-calipers (mm). Variations were determined statistically using the limits. Hardness of the tablet samples was also measured with the hardness tester ((Eureka, West Germany; in Newton). Weight variation tests of the samples were performed as per USP XXII (1990). Friability tests were conducted with the friabilator (Friability Tester, India). Disintegration tests (Disintegration Tester, Manesty) were performed as per USP XXII (1990). pH and density of syrup samples were recorded

against their code numbers. The drug contents of the preparations were analyzed by UV spectroscopic assay method (BP '88).

The physical and pharmaceutic parameters of the tablets have been given in Table 1. Tablet hardness affects disintegration and dissolution times of a drug product. As per the compendial specification, acceptable hardness for an oral tablet lies between 20 to 80 Newton. Two of the samples (S04 and S13) had hardness values below the compendial specification. One sample (S10) was found broken during depacking.

Table 2. Physico chemical parameters of the salbutamol syrups

Code No	Colour	pH	Specific gravity
SR01	Lemon yellow	4.58	1.0472
SR02	Colourless	3.40	1.1142
SR03	Yellow	3.96	1.1137
SR04	Orange	5.68	1.0460
SRO5	Colourless	4.03	1.0985
SR06	Colourless	3.54	1.1175
SR07	Colourless	3.74	1.0966
5R08	Colourless	4.75	1.0073
SR09	Lemon yellow	3.38	1.0983
SR10	Pink	5.66	1.1028
SRI I	Pink	3.63	1.0100
SR12	Colourless	4.10	1.1254
SR13	Colourless	3.75	1.0392
5R14	Colourless	5.53	1.1123
SR15	Yellow	4.29	1.1053

Allowable weight variation for tablets having weights >130mg is ±10% and for 132 to 324mg is ±7.5% (BP '88 and USP '90). Three of the samples (S01, S05 and S06) did not comply with the specifications as the variations were +7.14% to -12.23%, +12.17% to -2.53% and +11.5% to -5.34% respectively. Samples S08, S09 and S15 exhibited the weight loss of 0.518%, 0.28% and 0.64% respectively in the friability tests and one of the tablet samples (S10) was found broken in the packing. All other tablet samples complied with the specification for disintegration time.

The results of the quantitative analysis of the tablets and syrups are presented in Table 3 & 4. Salbutamol sulphate content of two of the sampled syrup preparations (SR02 and SR09) were below the declared amount. In a study, Wall and Sunderland (1976) reported that decomposition of salbutamol sulfate was accelerated in presence of both glucose and sucrose in a concentration dependent manner. Samples SR02 and SR09 gave positive response to Fehling's test for sugars, while other 13 samples did not. So, decreased content of the drugs in the preparations SR02 and SR09 might be due to their accelerated decomposition because of the presence of such sugars in the preparations.

Table 3. Quantitative estimation of the Salbutamol sulfate syrups

Code No	Expiry date	Date of analysis	Quantity present (mg/ 5mL)*
SR01	Dec'99	Jan'98	1.704
SR02	Feb'99	Feb'98	0.062
SR03	Dec'99	Mar'98	1.051
SR04	Nov'99	Mar'98	1.016
SRO5	Oct'99	Dec'97	1.801
SR06	Sep'99	Nov'97	1.642
SR07	Mar'98	Feb'98	1.650
SR08	Feb'99	Feb'98	2.027
SR09	Sep'00	Mar'98	0.079
SR10	Nov'99	Mar'98	1.811
SR11	Mar'99	Dec'97	2.100
SR12	Mar'98	Nov'97	1.923
SR13	Nov'00	Feb'98	2.001
SR14	Oct'99	Dec'97	1.890
SR15	Feb'99	Dec'97	1.940

* Declared content of salbutamol sulphate of the samples were 2mg/5mL.

The quantitative analysis of tablets showed that out of 15 preparations S02, S04, S09, S10, S13 and S14 contained 3.018 mg , 3.366 mg, 3.086 mg, 3.319 mg, 3.031 mg and 1.701 mg of salbutamol sulphate, respectively that were below the compendial limit of acceptance (92% to 107%).

Table 4. Quantitative estimation of Salbutamol sulfate tablets

Code No	Expiry date	Date of analysis	Claimed amount (mg/tab.)	Active ingredient present (mg/tab.)
S01	Feb'00	Nov'97	4	3.801
S02	Mar'99	Jan'98	4	3.018
S03	Nov'00	Feb'98	4	3.892
S04	Oct'99	Dec'97	4	3.366
S05	Jul'00	Nov'97	4	4.230
S06	Apr'98	Dec'97	4	3.702
S07	Sep'98	Dec'97	4	3.966
S08	Jul'00	Jan'98	2	1.911
S09	Mar'99	Feb'98	4	3.086
S10	Nov'99	Feb'98	4	3.319
S11	Jun'00	Oct'97	2	1.944
S12	Aug'99	Oct'97	4	3.980
S13	Oct'99	Nov'97	4	3.031
S14	May'00	Nov'97	2	1.701
S15	Apr'00	Jan'98	4	4.101

Salbutamol sulphate is a very important drug for the treatment of acute and chronic asthmatic attack. This study revealed that a good number of salbutamol sulphate preparations available in the pharmaceutical market of Bangladesh are substandard. Moreover, formulation error in incorporation of sugars in Salbutamol sulphate liquid preparations was also detected in the study. Government regulatory authority should come forward and take necessary measures so that the manufacturers do not produce substandard medicines and that formulation errors do not exist in pharmaceutical dosage forms.

Acknowledgement: The authors wish to express thanks and appreciations to Acme Laboratories (BD) Ltd., Dhaka for the courteous supply of the standard salbutamol sulfate and for many other supports.

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